



ASSOCIATION FOR MOLECULAR PATHOLOGY

Education. Innovation & Improved Patient Care. Advocacy.

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**Report to the Intersociety Pathology Council
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Submitted by Mary Steele Williams, MNA, MT(ASCP)SM, CAE, Executive Director

Leadership: AMP's current President is Dr. Charles Hill and its President-Elect is Dr. Federico Monzon. Mary Williams is the Executive Director. AMP is governed by a Board of Directors and its Executive Committee.

Collaborations: AMP is a constituent member of the Federation of American Societies for Experimental Biology (FASEB); its offices are located on FASEB's Beaumont Campus. AMP is also a member of the Association of Pathology Chairs (APC) Pathology Roundtable and a cooperating society of the American Board of Pathology. AMP values collaborations and seeks to advance its mission in collaboration with other professional societies and groups. During 2015, AMP worked widely, including with most or all members of the IPC, particularly ASCP and CAP. Our most important collaborations in the past year have been in advocacy and clinical practice guidelines (see below) and we thank our fellow professional societies for working with AMP and utilizing our expertise for the benefit of all.

Membership: AMP's current membership is ~2,300.

Annual Meeting: The AMP 2015 Annual Meeting was held November 5-7 in Austin, TX and had an attendance of ~2,060 scientific registrants. AMP held four events prior to the Annual Meeting program: a Reference Materials Forum with ~110 registrants; a Molecular Pathology Outreach Course (co-sponsored by CAP and the Texas Society of Pathologists) with an attendance of 106; a workshop for science educators in the local area; and an International evening that focused on Opportunities and Challenges for Global Molecular Pathology. A highlight of the 21st annual meeting was a session on CLIA modernization of laboratory developed procedures. The session, "Modernization of CLIA Regulations for Laboratory Developed Testing Procedures, an Update from Washington, featured Congressman Michael Burgess, MD (R-TX), a member of the House Energy & Commerce Committee, who is a long-time supporter of modernizing and strengthening the existing CLIA program.

This year, AMP will hold its 22nd annual meeting November 10-12 in Charlotte, NC. The Molecular Pathology Outreach Course, a Workshop for K-12 and undergraduate Science Educators, and the Reference Materials Forum will be held prior to the Annual Meeting Program.

Awards: Dr. Brian Druker was the keynote speaker at the 2015 Annual Meeting and the recipient of the AMP Award for Excellence in Molecular Diagnostics. The AMP Jeffrey A. Kant Leadership Award, which honors a member who has contributed significant leadership to benefit the mission and goals of the society, was presented to Dr. Barbara Zehnauer. The AMP Meritorious Service Award, which recognizes significant service given by a member to the Society, was presented to Dr. Roger Klein. AMP also provides Young Investigator Awards and Technologist Awards based on abstract submissions and poster presentations at the annual meeting. In addition, several awards to support travel to the annual meeting are provided, one of which is sponsored by the Intersociety Council for Pathology Information (ICPI).

Publications: AMP's official journal, *The Journal of Molecular Diagnostics (JMD)*, is now in its 18th year. It is co-owned with the American Society for Investigative Pathology (ASIP), is managed by ASIP, and is published

bimonthly by Elsevier. *JMD*'s Editor-in-Chief is Dr. Barbara Zehnbaauer. Currently the leading molecular pathology journal, *JMD*'s impact factor rose in 2014 to 4.851 (now ranked 8 of 75 pathology journals) and, for the first time, *JMD* has surpassed *The American Journal of Pathology* in ranking.

In 2015, AMP published multiple manuscripts and special articles; the first four listed below were published in *JMD* and are available for free download.

- *The Evolving Role of the Laboratory Professional in the Age of Genome Sequencing: A Vision of the Association for Molecular Pathology.* [http://jmd.amjpathol.org/article/S1525-1578\(15\)00071-9/pdf](http://jmd.amjpathol.org/article/S1525-1578(15)00071-9/pdf)
- *Do Circulating Tumor Cells, Exosomes and Circulating Nucleic Acids Have Clinical Utility for Molecular Pathologists?: A Report of the Association for Molecular Pathology.* [http://jmd.amjpathol.org/article/S1525-1578\(15\)00047-1/pdf](http://jmd.amjpathol.org/article/S1525-1578(15)00047-1/pdf)
- *Reporting Incidental Findings in Genomic Scale Clinical Sequencing: A Clinical Laboratory Perspective: A Report of the Association for Molecular Pathology.* [http://jmd.amjpathol.org/article/S1525-1578\(14\)00245-1/pdf](http://jmd.amjpathol.org/article/S1525-1578(14)00245-1/pdf)
- *Next-Generation Sequencing for Infectious Disease Diagnosis and Management: A Report of the Association for Molecular Pathology.* [http://jmd.amjpathol.org/article/S1525-1578\(15\)00172-5/pdf](http://jmd.amjpathol.org/article/S1525-1578(15)00172-5/pdf)
- In January 2015, AMP released a white paper titled *A Molecular Diagnostic Perfect Storm: The Convergence of Regulatory & Reimbursement Forces that Threaten Patient Access to Innovations in Genomic Medicine* detailing these challenges and utilizes it to support advocacy initiatives. This paper is the result of a collaboration between members from the Clinical Practice, Economic Affairs, and Professional Relations Committees. https://amp.org/publications_resources/position_statements_letters/documents/PerfectStorm-FINAL-CD.pdf
- The American College of Medical Genetics and Genomics (ACMG) with representatives from AMP and CAP published *Standards and Guidelines for the Interpretation of Sequence Variants: A Joint Consensus Recommendation of ACMG and AMP.* <http://www.nature.com/gim/journal/v17/n5/full/gim201530a.html>

The *JMD* CME program, which for 2015 participants may earn up to 36 credit hours in category 1 credit towards the AMA Physician's Recognition Award, is growing.

Clinical Practice: AMP's Clinical Practice Committee (CPC), chaired by Dr. Marina Nikiforova in 2015, continues to work on a variety of clinical practice issues. The CPC is comprised of representatives from each of AMP's scientific subdivisions: infectious diseases, hematopathology, solid tumors, genetics, and informatics. Its purpose is to address the challenges of clinical laboratories and, therefore, improve the patient care services we provide. Separate working groups plan, organize and coordinate efforts such as practice guidelines, sample exchanges, reporting surveys, validation and quality control measures, and help advocate for policies that will advance the practice of high quality clinical molecular pathology services. Topics currently being addressed include but are not limited to advanced sequencing for both inherited and somatic mutations, variant interpretation and reporting, hematological malignancies, establishment of clinical utility for molecular procedures in inherited conditions and cancer, and emerging clinical microbiology applications of MALDI-TOF mass spectrometry.

AMP representatives and liaisons have been appointed to collaborate on numerous additional clinical practice related projects with CAP, ACMG, American Society of Cytopathology, Papanicolau Society of Cytology, CDC, NIST's Genome In A Bottle Consortium Steering Committee, Joint Commission, American Medical Informatics Association, and the Association for Pathology Informatics.

Practice Guidelines: AMP is continuing to collaborate with other organizations to improve patient care. The following projects are underway:

- *Evaluation of Molecular Markers for Colorectal Cancer.* In collaboration with College of American Pathologists (CAP), American Society of Clinical Pathology (ASCP), Association for Molecular Pathology (AMP), and American Society of Clinical Oncology (ASCO).
- *Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors – Revision.* Update and extension of the April 2013 guideline developed jointly by the College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP). *J. Mol Diagn.* 2013;15:415-453.
- Multiple AMP-led working groups with liaison representation from CAP, ACMG, ASCO, American Medical Informatics Association, and the Association for Pathology Informatics are addressing various aspects of advanced sequencing clinical implementation, validation, bioinformatics, interpretation, and reporting.

Economic Affairs: This committee, co-chaired in 2015 by Dr. Aaron Bossler with Dr. Samuel Caughron as Vice Chair (chaired by Dr. Caughron in 2016), is actively engaged in reimbursement, coding, and economic policy issues. Coverage and reimbursement for molecular pathology tests continues to be one of AMP's primary advocacy initiative. CMS, which runs Medicare, has taken a heavy-handed approach in denying coverage or reducing payment for many medically necessary molecular pathology tests. This has created a challenging environment for clinical practice and for innovators to translate new genomic discoveries into clinical applications. AMP continues to work with the broader professional community to address policy challenges and opportunities; and, to engage and inform payers aiming to achieve rightful reimbursements for services that are vital to patient care. AMP and CAP typically collaborate to respond to CMS local jurisdiction draft local coverage determinations (LCDs).

Protecting Access to Medicare Act (PAMA): The long overdue proposed rule was released on September 25, 2015. AMP's comments express concern about a number of issues in the proposed rule including the narrowly-defined advanced diagnostic laboratory tests (ADLTs); the data collection and reporting timeline; the gapfill process; the local coverage determination (LCD) process; and consolidation of the Medicare Administrative Contractors (MACs). Additionally, AMP's comments voiced support for a new CPT code set approved by AMA CPT editorial panel to fulfill the PAMA codification requirements and made suggestions to CMS on ways to maximize the expertise of the Advisory Panel on Clinical Diagnostic Laboratory Tests as well as suggestions to the gapfill process that would increase its transparency. AMP's comments to CMS on the proposed rule are available online:

http://amp.org/publications_resources/position_statements_letters/documents/AMPCommentstoCMSonPAMA-CMS-1621-P-FINAL.pdf

Molecular Pathology CPT Codes: AMP is pleased that in its final CLFS determinations, CMS adopted most of our proposed crosswalk recommendations for the Tier 1 Molecular Pathology CPT codes for CY2016. However, AMP supported crosswalks for the 2016 genomic sequencing procedure (GSP) CPT codes and is concerned that the 2016 GSP CPT codes will undergo gapfill to determine pricing. The 2015 gapfill process for GSP CPT codes resulted in low or non-existent prices for these codes and the lack of transparency involved in the gapfill process has left it unclear how each contractor determined prices and what data was utilized. To mitigate these concerns, AMP supports increased transparency in the gapfill process proposed by CMS in the Medicare Clinical Diagnostic Laboratory Tests Payment System proposed rule.

Gene Sequencing Procedures (GSPs): AMP released its micro-cost and health economic models for gene sequencing procedures in March 2015 with over 450 downloads thus far. AMP offers these models at no charge, hoping that they are broadly used by laboratories to assist in accurately calculating the cost of their NGS services and, therefore, effectively communicate value and cost to payers. AMP is currently conducting a survey. It is important that all who download the models complete this survey so we can determine use of the models and outcomes. The models and supporting materials are available here:

<http://amp.org/committees/economics/NGSPricingProject.cfm>. A publication is in press in *JMD*.

Medicare Administrative Contractors: AMP continues to advocate with CMS regarding actions taken by Medicare Administrative Contractors (MACs). During 2015, AMP provided responses to various MACs for over 20 draft local coverage determinations (LCDs), many of which were problematic as the policies deny or narrow coverage for many molecular pathology procedures. Monitoring these policies was a major focus of the committee in 2015 and will continue to be a focus in 2016. AMP collaborated with the College of American Pathologists (CAP) to draft these letters and we are thankful to the AMP members who volunteered their time and subject matter expertise.

Palmetto MoIDX Program: The MAC Palmetto designed the MoIDX program, which is a coverage and payment program for the molecular CPT codes and includes McKesson-owned Z-Code Identifiers. Each laboratory in Palmetto's jurisdiction that would like to obtain coverage for a molecular test must meet the requirements of the MoIDX program. The list of problems with the program is long. The laboratory must obtain a Z-code to uniquely discriminate its test; and, if the test is an LDP, the laboratory must also submit a detailed dossier so that Palmetto GBA can apply an assessment of the assay validation data (analytical validity) as a major component of its determination of clinical utility, and thus Medicare coverage and pricing. A multi-society coalition, which includes AMP, is working to address these multiple problems because they not only result in non-coverage/denial issues for the Palmetto jurisdiction, but they become national coverage determinations and strongly influence the decisions of the private payers. Most recently, AMP responded to a new policy by Palmetto entitled "Analytical Performance Specifications for Comprehensive Genomic Profiling." AMP expressed numerous serious concerns including circumvention of the local coverage determination (LCD) process, strict testing limitations, and a prohibition against PhD scientists, which is in direct violation of the Social Security Act and CMS' regulations in both CLIA and the PFS.

Membership Affairs: The AMP Membership Affairs Committee (MAC) provides recommendations to the Board and assistance to other committees regarding matters of membership and professional development. The committee plays an important role in helping AMP respond to the needs of its members and in facilitating the development of leaders in the field of molecular pathology.

The MAC has, over the past year, revised the membership structure to include a dedicated category for technologists as well as early career members, continued to recruit newly certified MGPs and others emerging in the field, planned and hosted the first-time attendees / new members luncheon at the Annual Meeting, and developed and launched a "Pathway to Service in AMP" initiative.

International Affairs: The International Affairs Working Group was formally established as the International Affairs Committee (IAC) chaired by Dr. Lei Po (Chris) Wong (Hong Kong). The IAC helps nurture molecular pathology outside of North America. The German Society of Pathology became the fourth AMP International Affiliate. AMP co-sponsored molecular pathology conferences in India, Brazil, and Korea. In 2016, AMP will co-sponsor molecular pathology conferences in India and Korea; additional international conferences will be considered. AMP is also organizing its first global conference to be held outside of the United States in 2017. Four individuals were selected to receive International Membership Grant awards, and one individual received the first International Trainee Travel Award to attend the AMP 2015 Annual Meeting.

Professional Relations: AMP's Professional Relations Committee addresses regulatory and legislative issues that impact molecular pathology. AMP strives to make recommendations, advocate for and affect policy designed to preserve patient access to appropriate testing and mitigate burgeoning negative impact on healthcare. An important feature of AMP's advocacy efforts is interaction and coordination with other relevant professional associations.

Laboratory Developed Procedures (LDPs): A major advocacy issue of 2015 has been regulatory oversight of laboratory developed testing procedures (LDPs), also known as laboratory developed tests (LDTs). AMP provided both oral and written comments to FDA on "Draft Guidance for Industry, Food and Drug Administration Staff,

and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs),” expressing that medical device regulations are poorly suited for, and inapplicable to, the oversight of LDPs. AMP submitted numerous comments to and engaged actively with both the House Energy and Commerce Committee and Senate Committee on Health, Education, Labor and Pensions (HELP) regarding regulation of LDPs, including comments to the House Energy and Commerce Committee on Draft Legislation on the Regulation of In Vitro Clinical Tests. AMP does not support this legislation and maintains that Laboratory Developed Procedures (LDPs) are professional services and thus are very distinct from distributed tests.

The Senate Health, Education, Labor, and Pensions (HELP) Committee is in the process of drafting legislation that would provide avenues for enhanced support for medical innovation and patient access to new medicines and technologies. In an effort to support the Senate HELP Committee’s review of laboratory test regulation, the Committee developed a proposal to modernize the CLIA regulations and maintain oversight of LDPs under those regulations. The proposal incorporates the perspectives, feedback, and requests from multiple stakeholders and consists of a tiered, risk-based structure that avoids duplication of activities within and between federal agencies.

Regulatory Oversight of Next Generation Sequencing (NGS) Diagnostic Tests: In 2015, FDA held three workshops on NGS, most recently convening two back-to-back workshops on November 12 and 13, each focusing on two different aspects of Next Generation Sequencing In Vitro Diagnostic Tests. The workshop on November 12 discussed a standards-based approach to analytical performance evaluation of NGS in vitro diagnostic tests and the topic of the November 13 workshop was the use of databases for establishing the clinical relevance of human genetic variants. The purpose of the workshops was to hear from the stakeholder community about the current approaches and optimal design of both analytical performance standards and the use of databases for NGS in a clinical setting. AMP provided oral comments at both workshops and also submitted written comments. In 2016, AMP continues to engage with FDA on this issue and will be providing oral and written comments to their upcoming workshop on NGS-based oncology panels.

White Papers: The Professional Relations, Economic Affairs, and Clinical Practice Committees joined forces to draft the white paper titled *A Molecular Diagnostic Perfect Storm: The Convergence of Regulatory & Reimbursement Forces that Threaten Patient Access to Innovations in Genomic Medicine* detailing these challenges and utilizes it to support advocacy initiatives. The paper details the many regulatory and reimbursement forces adversely affecting molecular diagnostic testing. AMP uses this paper to support advocacy initiatives. It is online at http://www.amp.org/publications_resources/position_statements_letters/PerfectStorm.cfm.

The Professional Relations Committee also released its updated position statement on Direct Access Genetic Testing, concluding that clinically meaningful tests could benefit patients and consumers and should be made available directly to the public, but only if certain conditions are met. Conversely, AMP opposes direct access to genetic tests that are performed for the purpose of selling additional health-related products or services and do not provide clinically meaningful or actionable information. For recreational or novelty genetic testing, such as ancestry testing, AMP maintains a neutral position as these reports typically do not include health information.

Training & Education (T&E): AMP’s education initiatives continue to grow. The T&E Committee addresses needs in molecular pathology, presents webinars, workshops, courses, and identifies AMP member expertise for educational collaborations.

Curriculum Frameworks: A task force of the T&E Committee published an AMP Report in *JMD* (March 2016), “*A Suggested Molecular Pathology Curriculum for Residents*” (Aisner, *et al.*), which provides recommendations for a molecular pathology curriculum for pathology residents. It is available for free online at *JMD* at [http://jmd.amjpathol.org/article/S1525-1578\(15\)00264-0/pdf](http://jmd.amjpathol.org/article/S1525-1578(15)00264-0/pdf). Other task forces are developing frameworks for molecular pathology curricula for different trainees, including molecular genetic pathology fellows and primary care residents.

Education Programs: The committee presented nine webinars in 2015, including a new “Informatics 101” series, with nearly 1500 total attendees. The Molecular Pathology Outreach Course was offered at the annual meeting with nearly 100 participants. An online version is being produced as the “Molecular Diagnostic Toolkit and Applications” in early 2016. The biennial live MGP Review Course was held April 30 – May 3 in Bethesda, MD with 58 participants. The online self-study Molecular Genetic Pathology Review Course is now offered through the end of 2016. The committee also developed a “Science Educator Workshop” for high school science teachers and undergraduate college faculty at the annual meeting. Entitled, “Teaching Precision Medicine, Genomics, and Molecular Diagnostics in Your Classroom,” the workshop’s main goals were to update teachers/instructors on relevant, timely topics in the clinical molecular diagnostics laboratory, and provide an awareness of the molecular pathology profession through sharing academic and personal life experiences as a means of workforce development.

CME/PACE: The ASCP is AMP’s joint provider for CME/CMLE credits for courses and the annual meeting. AMP offers ASCLS PACE credit for the webinar program.

Collaborative Education: In 2015, AMP planned sessions and identified AMP speakers for the ASCP, CAP, USCAP, and the Society for Laboratory Automation and Screening (SLAS) annual meetings, Cambridge Healthtech Institute (CHI) Conferences, and a regional meeting in Troy, MI (Beaumont Symposium on Molecular Medicine). AMP also collaborates with ASCO and CAP on an online monthly Molecular Oncology Tumor Board discussion board series.

AMP hosts the Molecular Genetic Pathology (MGP) Fellowship Program Directors, and has volunteer representatives to the ASCP RISE Committee, ASCP Task Force on Certification in Molecular Diagnostics, APC Fellowship Directors Ad Hoc Committee, AACC Lab Tests Online, and the NHGRI’s Inter-Society Coordinating Committee for Practitioner Education in Genomics.