



**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. Federico Monzon and its President-Elect is Dr. Kojo Elenitoba-Johnson. 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 2016, 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 2016 Annual Meeting was held November 10-12 in Charlotte, NC 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) with an attendance of 80; a workshop for science educators and students in the local area with an attendance of 65; and an International Showcase evening that focused on Quality Assurance and Standardization of Molecular Testing Around the World. A highlight of the 22nd annual meeting was a session entitled "Secrets of the Human Genome: The 35-year Journey of Genomic Medicine" delivered by Eric S. Lander, PhD of the Broad Institute of Harvard and Massachusetts Institute of Technology.

This year, AMP will hold its 23rd annual meeting November 16-18 in Salt Lake City, UT. The Molecular Pathology Outreach Course, a workshop for high school and undergraduate science educators and students, and the Reference Materials Forum will be held prior to the Annual Meeting Program.

**Awards:** Dr. Eric Lander was the keynote speaker at the 2016 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. Timothy J. O'Leary. The AMP Meritorious Service Award, which recognizes significant service given by a member to the Society, was presented to Dr. Neal I. Lindeman. 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, including the Technologist Travel Award, the International Trainee Travel Award, and an additional trainee travel award sponsored by the Intersociety Council for Pathology Information (ICPI).

**Publications:** AMP's official journal, *The Journal of Molecular Diagnostics (JMD)*, is now in its 19<sup>th</sup> 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, the *JMD* impact factor has continued to rise in 2016 and for the first time has gone over 5, increasing from 4.851 to 5.201.

The Professional Relations, Economic Affairs and Clinical Practice Committees joined forces to form the Framework for the Evidence Needed to Demonstrate (FEND) Clinical Utility Task Force, which was formed two years ago to develop clinical utility definitions that appropriately recognize the full contribution and value of molecular diagnostic testing to improve patient care. In August, The Task Force, chaired by Dr. Elaine Lyon, published a report in *The Journal of Molecular Diagnostics* titled *The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer* [http://jmd.amjpathol.org/article/S1525-1578\(16\)30088-5/pdf](http://jmd.amjpathol.org/article/S1525-1578(16)30088-5/pdf). The report emphasizes that a clinical test result's utility depends on the context in which it is used to classify a patient's disease or disorder and/or guide management and recommends a fundamental shift to achieve the proactive, patient-centered approach necessary for modern healthcare.

AMP convened and led a working group with liaison representation from ASCO, CAP, and ACMG that developed consensus guideline recommendations for both clinical laboratory professionals and oncologists that assess the status of next-generation sequencing (NGS)-based cancer tests and establish standardized classification, annotation, interpretation, and reporting conventions for somatic sequence variants. The resulting manuscript *Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists* was published in the January 2017 issue of *The Journal of Molecular Diagnostics* [http://jmd.amjpathol.org/article/S1525-1578\(16\)30223-9/pdf](http://jmd.amjpathol.org/article/S1525-1578(16)30223-9/pdf). These new recommendations resulted from the successful ACMG, AMP, and CAP efforts on germline variant interpretation and were additionally informed by the diverse perspectives expressed at the ASCO, AMP, and CAP Genomic Roundtable stakeholder discussions.

AMP additionally convened and led a working group with liaison representation from CAP that produced consensus recommendations to help clinical laboratory professionals achieve high quality sequencing results and deliver better cancer patient care. The manuscript, *Guidelines for Validation of Next Generation Sequencing (NGS)-based Oncology Panels: A Joint Consensus Recommendation of the Association for Molecular Pathology and College of American Pathologists*, will be released online ahead of publication in *The Journal of Molecular Diagnostics* in March 2017. This report addresses NGS test development, optimization and familiarization, and best practices for establishing test performance characteristics. The recommendations emphasize the critical role of the molecular laboratory director in establishing and utilizing an error-based approach for patient risk management. A companion manuscript containing best practices recommendation for validation of the NGS bioinformatics pipeline will be submitted shortly for publication.

*Evaluation of Molecular Markers for Colorectal Cancer: Guideline from the College of American Pathologists, American Society of Clinical Pathology, Association for Molecular Pathology, and American Society of Clinical Oncology* was released simultaneously online ahead of print in all four societies' journals in February 2017 [http://jmd.amjpathol.org/article/S1525-1578\(16\)30224-0/pdf](http://jmd.amjpathol.org/article/S1525-1578(16)30224-0/pdf). AMP extends our sincere appreciation to all of the subject matter experts, patient advocates, and professional organizations for their tireless work to make this guideline a reality. This guideline and the others highlighted above are indicative of the impressive accomplishments that can be realized when professional societies work collaboratively to improve patient care. We look forward to continuing to work productively with our professional organization partners in 2017.

In 2016, AMP published the following additional manuscripts and special articles in *JMD* available for free download:

- *A Suggested Molecular Pathology Curriculum for Residents: A Report of the Association for Molecular Pathology*. [http://jmd.amjpathol.org/article/S1525-1578\(15\)00264-0/pdf](http://jmd.amjpathol.org/article/S1525-1578(15)00264-0/pdf)

- *Genomic Sequencing Procedure Microcosting Analysis and Health Economic Cost-Impact Analysis: A Report of the Association for Molecular Pathology.* [http://jmd.amjpathol.org/article/S1525-1578\(16\)00053-2/pdf](http://jmd.amjpathol.org/article/S1525-1578(16)00053-2/pdf)
- *Emerging and Future Applications of Matrix-Assisted Laser Desorption Ionization Time-of-Flight (MALDI-TOF) Mass Spectrometry in the Clinical Microbiology Laboratory: A Report of the Association for Molecular Pathology.* [http://jmd.amjpathol.org/article/S1525-1578\(16\)30144-1/pdf](http://jmd.amjpathol.org/article/S1525-1578(16)30144-1/pdf)

The JMD CME program, which for 2016 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 2016, continues to work on a variety of clinical practice issues. Dr. Antonia Sepulveda is the incoming 2017 CPC Chair. 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, and emerging clinical microbiology applications.

AMP representatives and liaisons have been appointed to collaborate on numerous additional clinical practice related projects with CAP, ACMG, American Society of Cytopathology, Papanicolaou 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:

- *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.
- *Specimen Collection and Molecular Testing Prioritization for Pulmonary Neoplasms.* Guideline being developed by the College of American Pathologists (CAP) in collaboration with the American College of Chest Physicians (ACCP), American Society of Cytopathology (ASC), American Thoracic Society (ATS), Association for Molecular Pathology (AMP), Papanicolaou Society of Cytopathology (PSC), and Pulmonary Pathology Society (PPS).
- Multiple AMP-led working groups with liaison representation from multiple other professional societies are addressing various aspects of advanced sequencing clinical implementation, validation, bioinformatics, pharmacogenomics, hematopathology, and infectious diseases.

**Economic Affairs:** This committee, chaired in 2016 and 2017 by Dr. Samuel Caughron, 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 increasingly either denied coverage or reduced payment for many medically necessary molecular pathology tests through the activities of its Medicare Administrative Contractors (MACs). The increasing restrictions create 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 and policymakers 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):**

CMS released the final rule in June of 2016. In the final rule, CMS delayed the effective date for the implementation of PAMA price setting for lab tests by one year, until January 1, 2018. Under PAMA, laboratories are required to report HCPCS laboratory codes, associated private payer rates, and volume data if they have more than \$12,500 in Medicare revenues from laboratory services on the Clinical Laboratory Fee Schedule (CLFS) and receive more than 50% of their Medicare revenues from laboratory and physician services during a collection period. The first round of data reporting begun in 2017 and initial reports are due to CMS by March 31, 2017. Details on registration and reporting procedures continue to emerge from CMS. EAC continues to notify and educate membership on the details of this new and vast rule.

**Molecular Pathology CPT Codes:** in 2016, AMP provided written and oral comments to CMS on the Calendar Year 2017 Clinical Lab Fee Schedule (CY2017 CLFS) and 2016 Gapfill Determinations. AMP recommended crosswalk recommendations for the new 2017 CLFS molecular pathology procedures, genomic sequencing procedures (GSPs), and microbiology procedures. AMP is pleased that in its final CLFS determinations, CMS abandoned gapfill for the genomic sequencing procedures (GSPs) and instead recommended crosswalk for price determination of the new GSP codes in 2017.

For the 2016 gapfill final determinations, AMP submitted comments to CMS and remains concerned that the final determinations are undervalued. Since CMS began utilizing the gapfill process to price services on the CLFS, AMP has expressed concerns about the lack of transparency. It remains difficult to constructively respond to gapfill values, as the lack of transparency leaves no discernible rationale for how MACs determine preliminary gapfill pricing. AMP hopes that implementation of PAMA will ultimately improve the pricing process for molecular tests. However, initial price undervaluation remains a significant concern and threatens patient access to care if laboratories stop being able to provide critical procedures.

**Gene Sequencing Procedures (GSPs):** On March 4, 2016, *The Journal of Molecular Diagnostics* published the results of the 2015 Genomic Sequencing Procedure (GSP) Cost and Value Model Project in a manuscript titled "Genomic Sequencing Procedure Microcosting Analysis and Health Economic Cost-Impact Analysis: A Report of the Association for Molecular Pathology." In 2014, AMP, with the help of Boston Healthcare Associates, gathered more than a dozen protocols to analyze cost information about laboratory validation, pre-analytics, sequencing, bioinformatics, and interpretation. A major objective of the project was to provide laboratories with tools to accurately estimate the cost of performing GSP services. *The Journal of Molecular Diagnostics* published report includes aggregated cost and personnel time data from nine laboratories performing 13 GSPs. In addition, payer cost-impact models for three clinical scenarios were generated with assistance from key opinion leaders: impact of using a targeted gene panel in optimizing care for patients with advanced non-small-cell lung cancer, use of a targeted multi-gene panel in the diagnosis and management of patients with sensorineural hearing loss, and exome sequencing in the diagnosis and management of children with neurodevelopmental disorders of unknown genetic etiology. Each model demonstrated economic value by either reducing health care costs or identifying appropriate care pathways. The paper is available for download to members and non-members here: [http://jmd.amjpathol.org/article/S1525-1578\(16\)00053-2/fulltext](http://jmd.amjpathol.org/article/S1525-1578(16)00053-2/fulltext)

**Genomic Medicine Payer Summit:** AMP continues to advocate with CMS regarding actions taken by Medicare Administrative Contractors (MACs). In 2016, EAC undertook a significant initiative to bring together molecular pathology experts and payers to discuss how traditional routes for establishing coverage apply to molecular procedures. The in-person meeting, held on May 11, 2016 in Chicago, IL, aimed to identify opportunities for working together to ensure patient access to appropriate procedures. The one-day gathering focused on discussion topics such as ideas for improvement of the current coding structure to better assist laboratories and payers, establishment of proper processes to ensure coverage policy that allows patients to receive appropriate testing, and determination of payment rates for molecular procedures and ways the laboratory community can assist. EAC found tremendous value in the meeting and hosted three subsequent virtual meetings with both private and Medicare payers. The conversations are an important opportunity for dialogue on critical issues and

an ability for payers to provide input and feedback to AMP's efforts at improving the economic landscape for molecular testing. EAC plans to build upon this engagement with payers in 2017.

**Medicare Administrative Contractors' (MACs) Local Coverage Determinations (LCDs):**

During 2016, AMP provided responses to various MACs for over 15 draft local coverage determinations (LCDs). Many of the coverage policies released contained substantial problems, either denying or narrowing coverage for important molecular pathology procedures. Currently, AMP is in the process of drafting comments to several additional draft local coverage determinations (LCDs) which will be submitted to the MACs in late March. Monitoring these policies was a major focus of the committee in 2016 and will continue to be a focus in 2017. 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:** In 2016, the MoIDx Program announced expansion to WPS (MAC Jurisdictions 5 and 8), which includes the states of Iowa, Kansas, Missouri, Nebraska, Indiana, and Michigan. AMP is extremely concerned about the rapid expansion of the MoIDx Program. With WPS' recent adoption of the program, 6 MAC jurisdictions, including 23 states, American Samoa, Guam, and the North Mariana Islands operate under the program; this represents half of the MAC jurisdictions. The continued expansion of MoIDx creates a number of issues for laboratories and the AMP members who provide molecular diagnostic testing. In September, AMP EAC leaders met with representatives from the pricing and coverage groups at CMS to again discuss AMP's concerns.

**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.

In 2016, the MAC hosted AMP's first ever regional learning and networking event in conjunction with the American Association for Clinical Chemistry Annual Meeting in Philadelphia. This event served to pilot a new style of AMP events that we hope will allow us to bring AMP educational programming to smaller regional audiences.

**International Affairs:** The International Affairs Committee (IAC) is chaired by Dr. Rami Mahfouz (Lebanon). The IAC helps nurture molecular pathology outside of North America. AMP co-sponsored molecular pathology conferences in India, Italy, and Korea. In 2017, AMP will co-sponsor molecular pathology conferences in India and Korea; additional international conferences will be considered. AMP is also launching its inaugural Global Congress on Molecular Pathology in Berlin, Germany, April 3-5. Individuals from India, Malaysia, and Nepal received 2016 International Membership Grants, and trainees from India, Iraq, and Nepal received an International Trainee Travel Award, enabling them to attend the AMP 2016 Annual Meeting in Charlotte, NC.

**Professional Relations:** AMP's Professional Relations Committee is chaired by Dr. Roger Klein and 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 2016 continued to be regulatory oversight of laboratory developed testing procedures (LDPs), also known as laboratory developed tests (LDTs). In late 2016, FDA stated that it would not finalize their guidance on LDP oversight. AMP is pleased that FDA decided not to finalize the guidance and believe this decision is in the best interest of patients, healthcare providers, and the entire field of molecular pathology.

On September 20, 2016, AMP participated in two events designed to help educate lawmakers and congressional staff about LDPs and the vital role they play in precision medicine and patient care. AMP co-hosted a briefing

with the American College of Medical Genetics and Genomics (ACMG) and Infectious Diseases Society of America (IDSA). Dr. Karen Kaul, AMP past-president, was a witness at the U.S. Senate Committee on Health, Education, Labor & Pensions (HELP) Hearing titled “Laboratory Testing in the Era of Precision Medicine,” where she testified to the HELP committee about how LDPs are currently designed, validated, regulated, and used in a variety of clinical settings, specifically explaining the potential harms and benefits of additional LDP regulation that could be enormously disruptive to health care and likely have profound adverse consequences for patients across the country.

AMP remains actively engaged with legislators on Capitol Hill on this issue and 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.

**Regulatory Oversight of Next Generation Sequencing (NGS) Diagnostic Tests:** Since early 2015, FDA has been seeking feedback on how best to regulate next generation sequencing (NGS) diagnostic tests either by holding public workshops or by releasing discussion papers. This year, FDA began releasing draft guidances on NGS, the first of which is directed towards NGS-based *in vitro* diagnostics (IVDs) for inherited conditions. As a result, AMP has been very engaged on this issue, providing feedback to FDA on NGS-based diagnostic tests for a number of clinical uses including, inherited conditions, oncology, and infectious diseases.

In February, FDA held a workshop and released a white paper on NGS-based oncology panels. The workshop consisted of a number of panel discussions that focused on the challenges of conducting next generation sequencing oncology procedures including analytical, pre-analytical, and clinical claims challenges. AMP members comprised a large proportion of the panel guests and AMP provided written comments to FDA on this topic stressing that validation of the performance characteristics of NGS instruments and reagents, and assays themselves, must inherently rely on a method-based approach that is reflective of the nature and types of variants likely to be seen in clinical practice.

In June, FDA released a draft guidance for infectious disease NGS-based diagnostic devices. AMP collaborated with the Association Society for Microbiology (ASM), Association of Public Health Laboratories (APHL), Infectious Disease Society of America (IDSA), and the Pan-American Society for Clinical Virology (PASCV) to develop comprehensive comments to FDA on this issue. The societies asked FDA to focus the guidance on agnostic testing, as it particularly vital to infectious disease detection. The comments urge FDA to be flexible with regards to the review of ID NGS-based tests, express concern over the proposed requirement to use the FDA-ARGOS database, and state the critical role of the laboratory and health care professional to ensuring proper test performance, and clear and timely communication of results.

In July, to support the President’s Precision Medicine Initiative, FDA released two draft guidances on NGS. The first draft guidance provides recommendations for designing, developing and validating NGS-based tests for rare hereditary diseases, and addresses the potential for using FDA-recognized standards to demonstrate analytical validity, which is how well a test predicts the presence or absence of a particular genomic change. The second draft guidance describes an approach wherein test developers may rely on clinical evidence from FDA-recognized public genome databases to support clinical claims for their tests and provide assurance of accurate clinical interpretation of genomic test results – an easier path for marketing clearance or approval. AMP provided both written and oral comments on these drafts. In the comments, AMP addressed specific questions asked by FDA and stressed that FDA to focus its attention on helping to ensure the performance characteristics of NGS instruments, reagents, and related software. AMP 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.

FDA has stated its intention to continue to release guidances related to next generation sequencing in 2017 and AMP plans to remain engaged on this issue.

**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 8 webinars in 2016, including a new "Emerging Fronts in Molecular Pathology" series. The Molecular Pathology Outreach Course was offered at the annual meeting with nearly 100 participants. An online, on-demand version is available as the "Molecular Diagnostic Toolkit and Applications" course in AMP's new learning platform, AMP Online. The biennial live Molecular Genetic Pathology (MGP) Review Course is being held on June 1-4 in Bethesda, MD. The online self-study MGP Review Course was 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 offered ASCLS PACE credit for the 2016 webinar program.

**Collaborative Education:** In 2016, AMP planned sessions and identified AMP speakers for the ASCP, CAP, USCAP annual meetings, Cambridge Healthtech Institute (CHI) Conferences, and a regional meeting in Troy, MI (Beaumont Symposium on Molecular Medicine). AMP presented a collaborative webinar with PASCV on the Zika virus. AMP also collaborates with ASCO and CAP on an online monthly Molecular Oncology Tumor Board discussion board series, as well as with Association of Community Cancer Centers (ACCC) on a Virtual Molecular Tumor 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.