AMP 2016 Committee and Subdivision Annual Reports

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Solid Tumors Subdivision Chair	Laura J. Tafe, MD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

AMP Awards Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Federico A. Monzon, MD
Member	Ken Bahk, PhD
Member	Marc Ladanyi, MD
Member	Tadd S. Lazarus, MD
Member	Barbara A. Zehnbauer, PhD

PURPOSE SUMMARY:

The Awards Committee consists of 5 members (4 appointed) who oversee the nomination and selection of the recipient of the Award for Excellence in Molecular Diagnostics, the Jeffrey A. Kant Leadership Award, and, if determined applicable, the recipient(s) of the Meritorious Service Award(s). The Committee evaluates the current awards, addresses the need for new awards, and conducts the formal nomination process for potential award recipients.

The President-Elect serves as the Chair of the Awards Committee. The remaining 4 committee members are appointed by the Board and serve rotating two-year terms. The annual selection of 2 incoming committee members is conducted by the committee and the candidates' names are brought forward for Board approval and appointment.

Timeline for AMP Awards

The Awards Committee coordinated the timing of the AMP recognition awards as follows:

November through February: Nominations from the Board, Committees, and Membership
March: Review and selection by Awards Committee
April through May: Notification of recipients
May through September: Assess need for new recognition awards

Award Recipients

- 2016 Jeffrey A. Kant Leadership Award: Timothy J. O'Leary, MD, PhD
- 2016 Meritorious Service Award: Neal I. Lindeman, MD
- 2018 Award for Excellence in Molecular Diagnostics: To be announced

FASEB Excellence in Science Award Committee

As a constituent society of the Federation of American Societies for Experimental Biology (FASEB), AMP has representation on the FASEB Excellence in Science Award Committee, which is "given in recognition of outstanding achievement by women in biological science. Recipients are women whose career achievements have contributed significantly to further our understanding of a particular discipline by excellence in research." Shuji Ogino, MD, PhD, served as AMP's representative.

AMP Clinical Practice Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Marina N. Nikiforova, MD
Genetics Subdivision Representative	Birgit Funke, PhD
Genetics Subdivision Representative	Monica J. Basehore, PhD
Hematopathology Subdivision Representative	Jennifer Crow, MD
Hematopathology Subdivision Representative	David S. Viswanatha, PhD
Infectious Diseases Subdivision Representative	Linda Cook, PhD
Infectious Diseases Subdivision Representative	Benjamin Pinsky, MD, PhD
Informatics Subdivision Representative	Somak Roy, PhD
Informatics Subdivision Representative	Mark J. Routbort, MD, PhD
Solid Tumors Subdivision Representative	Lawrence Jennings, MD, PhD
Solid Tumors Subdivision Representative	Meera R. Hameed, MD
Junior Member	Arivarasan Karunamurthy, MD
Junior Member	Ryan J. Schmidt, MD, PhD

PURPOSE SUMMARY:

The Clinical Practice Committee (CPC) is comprised of AMP members with expertise in one or more of the molecular specialties: infectious diseases, hematopathology, solid tumors, genetics and informatics. Its purpose is to address the challenges of clinical laboratories and; thereby, improve the service we provide. Separate working groups plan, organize and coordinate efforts such as practice guidelines, sample exchanges, reporting surveys, validation and quality control measures, and advocate for policies that will advance the practice of high quality clinical molecular pathology services.

Publications

- **September 2016:** *The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer: A Report of the Association for Molecular Pathology.* Loren Joseph, Milena Cankovic, Samuel Caughron, Pranil Chandra, Rajyasree Emmadi, Jill Hagenkord, Stephanie Hallam, Key Jewell, Roger Klein, Victoria Pratt, Paul Rothberg, Robyn Temple-Smolkin and Elaine Lyon, *The Journal of Molecular Diagnostics*. (http://dx.doi.org/10.1016/j.jmoldx.2016.05.007)

- **November 2016:** *Emerging and Future Applications of MALDI-TOF Mass Spectrometry in the Clinical Microbiology Laboratory: A Report of the Association for Molecular Pathology.* Led by Christopher Doern and Susan Butler-Wu as a joint project of the Infectious Diseases Subdivision Leadership and the Clinical Practice Committee. (http://dx.doi.org/10.1016/j.jmoldx.2016.07.007)

Clinical Practice Guidelines, Working Groups, and Task Forces

- *Interpretation of Sequence Variants in Somatic Conditions (Cancer).* AMP-led workgroup chaired by Marilyn Li with Eric Duncavage (Co-chair, AMP), Marina Nikiforova (Advisor), Cindy Vnencak-Jones, Somak Roy, Shashikant Kulkarni (ACMG), Daynna Wolf (ACMG), Neal Lindeman (CAP), Michael Datto (CAP), Lia Tsimberidou (ASCO) and Anas Younes (ASCO). Manuscript in press, *The Journal of Molecular Diagnostics*.

- *Development of Analytical Validation Standards for Next-generation Sequencing (NGS) Detection of Somatic Variants*. AMP-led workgroup chaired by Larry Jennings with Marina Nikiforova (Advisor),

Christopher Corless, Suzanne Kamel-Reid, Ira Lubin, Maria Arcila, John Pfeifer and Karl Voelkerding (CAP). Manuscript submitted to *The Journal of Molecular Diagnostics.*

- *Evaluation of Molecular Markers for Colorectal Cancer.* Joint collaboration of College of American Pathologists (CAP), American Society of Clinical Pathology (ASCP), Association for Molecular Pathology (AMP), and American Society of Clinical Oncology (ASCO). Manuscript in press for joint publication to *The Journal of Molecular Diagnostics*, *The Journal of Clinical Pathology*, *The Journal of Clinical Oncology*, and *Archives of Pathology and Laboratory Medicine*.

	AMP	**ASCP**	**CAP**	**ASCO**
Co-Chair	Antonia Sepulveda, MD, PhD	Wayne W. Grody, MD, PhD	Stanley R. Hamilton, MD	Carmen Allegra, MD
Expert Panelists	Federico A. Monzon, MD	Veena Singh, MD	Daniel Sargent, PhD	Scott Kopetz, MD, PhD
	Noralane M. Lindor, MD	Allison Cushman-Vokoun, MD, PhD	Bruce Minsky, MD	Christopher Lieu, MD
	William Funkhouser, MD, PhD	Kevin Halling, MD, PhD	Jan Nowak, MD, PhD	

- **In development:** *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*. For more information: http://www.amp.org/committees/clinical_practice/LungBiomarkerGuideline.cfm

	CAP	**IASLC**	**AMP**
Co-Chair	Philip T. Cagle, MD	Yasushi Yatabe, MD, PhD	Neal I. Lindeman, MD
Expert Panelists	Keith Kerr, MD	Erik Thunnissen, MD, PhD	Dara L. Aisner, MD, PhD
	Mary Beth Beasley, MD	Marc Ladanyi, MD	David Kwiatkowski, MD, PhD
	Eric Bernicker, MD	Ming S. Tsao, MD	Lynette Sholl, MD
	Sanja Dacic, MD, PhD	Benjamin Solomon, MBBS, PhD	Maria E. Arcila, MD

- **In development**: *Developing Standards for NGS Bioinformatics Pipeline Validation: single nucleotide variants (SNVs), small indels (<=21bp) and multi-nucleotide variants (MNVs).* AMP-led workgroup chaired by Somak Roy with Eric Klee, Nefize Sertac-Kip, Alexis Carter, Christopher Coldren, Annette Meredith, Arivarasan Karunamurthy (Junior Member, CPC), Karl Voelkerding (CAP) and Chen Wang (AMIA).

- **In development**: *AMP Guidelines for Laboratory Detection and Interpretation of Intragenic (Exonic Level) Deletions/Duplications.* Chaired by Madhuri Hegde with Elaine Lyon, Carolyn Sue Richards and Birgit Funke.

- **In development**: *Utility of Myeloid Mutations in Diagnosis and Prognosis of MDS, non-CML MPN, and MDS/MPN.* Chaired by Jennifer Crow with Annette Kim, Rachel Sargent, Rebecca McClure and Mark Ewalt.

- **In development**: ***V**ariant **I**nterpretation **T**est **A**cross **L**abs (VITAL).* Chaired by Elaine Lyon with Madhuri Hegde, Julie Gastier-Foster, Carolyn Sue Richards and Sherri Bale. Project supported by an unrestricted educational grant from QIAGEN, Inc.

- **In development***: Standardization of clinically relevant pharmacogenetics alleles.* Chaired by Vicky Pratt with Lisa Kalman, Andria del Tredici, Stuart Scott, Karen Weck, Houda Hachad and Yuan Ji.

- **In development:** *Appropriate Collection and Handling of Thoracic Specimens for Laboratory Testing*. College of American Pathologists (CAP) in collaboration with the American College of Chest Physicians (CHEST), Association for Molecular Pathology (AMP), American Society for Cytopathology (ASC), American Thoracic Society (ATS), Pulmonary Pathology Society (PPS), Papanicolaou Society of Cytopathology (PSC), Society of Interventional Radiology (SIR), and Society for Thoracic Radiology (STR). AMP Expert Panelist and Steering Committee member Jan Nowak; AMP Expert Panelist Dara Aisner.

Liaisons/Representation to Other Organizations

- CAP Molecular Oncology Committee, Paul Rothberg
- CAP Cancer Biomarker Reporting Committee, Deborah Dillon
- ACMG Interpretation of Sequence Variants, Julie Gastier-Foster and Elaine Lyon
- NIST Genome in a Bottle Steering Committee, Monica Basehore
- American Society of Cytopathology / Papanicolau Society of Cytology Task Force on The Use of Molecular Testing on Cytologic Specimens, Anna Berry
- CDC Laboratory Community of Practice Work Group, Alexis Carter
- ACMG Incidental Findings in Inherited Diseases Update Workgroup, Carolyn Sue Richards
- CAP/AMP/ASCO Roundtable, Marina Nikiforova
- ACMG ClinGen Somatic Cancer Clinical Domain Workgroup, Marilyn Li
- CAP/ASCP /ASCO HER2 Testing in Gastroesophageal Adenocarcinoma Guideline project, Advisory Panelist, William Sukov
- CAP NGS Project Team, Birgit Funke
- ASCO-CAP Liquid Biopsies White paper project, Tina Lockwood
- CAP NGS Test Validation/Metrics manuscripts Working group, Marina Nikiforova

Additional Accomplishments

- AMP launched and hosted the Open Public Comment Period with CAP and IASLC for the *Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors – Revision* update in July 2016.
- AMP hosted a Reference Materials Forum prior to the 2016 Annual Meeting on Tuesday, Nov 8, 2016 with representatives from CDC, NIST, and NCI.
- Multiple CPC members participated and provided input to the AMP response to the FDA draft LDT guidance document.
- Multiple CPC and Scientific Subdivision members hosting or presenting in AMP Webinar events.
- CPC members actively brainstormed and documented a list of several important project ideas to be undertaken by the CPC in the future.

Congratulations on a job well done!

Requests from the CPC:

- We encourage all AMP members to alert the Board or appropriate committees when laboratory guidelines or recommendations are opened for public comment.
- We encourage AMP members to actively contribute to calls for information from the CPC.

Suggestions from AMP members for new CPC initiatives are always welcome! Visit http://amp.org/committees/clinical_practice/ for more details.

AMP Economic Affairs Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Samuel K. Caughron, MD
Vice Chair, New Codes	Aaron D. Bosslier, MD, PhD
Vice Chair, Coverage	Richard D. Press, MD, PhD
Member	Dara L. Aisner, MD, PhD
Member	Pranil Chandra, DO
Member	Andrea Ferreira-Gonzalez, PhD
Member	Jill Hagenkord, MD
Member	Lloyd Hutchinson, PhD
Member (*Ex Officio* – PRC Chair)	Roger D. Klein, MD, JD
Member	Elaine Lyon, PhD
Member	Linda M. Sabatini, PhD
Member	Michele Schoonmaker, PhD
Member	Ester Stein, MBA
Member	Katherine Tynan, PhD
Junior Member	Anthony Sireci, MD
Committee Advisor	Jan A. Nowak, MD, PhD

PURPOSE SUMMARY:

The Economic Affairs Committee (EAC) addresses, advises, and educates the AMP Board of Directors, membership, payers, legislators, and the public on economic issues of importance to the field of molecular pathology; prepares documents of importance to the Centers for Medicare & Medicaid Services (CMS); and develops and advocates for sound economic policies that promote the provision of high quality molecular pathology services. The Committee's scope encompasses short and long-term issues associated with the coding for molecular procedures, utilization of and coverage for molecular pathology, the determination of test pricing, and the potential economic impact of public policy decisions on molecular pathology practice. The Committee interacts with the American Medical Association and other interested organizations in order to achieve common goals.

2016 ACTIVITIES:

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 worked with the broader professional community to address policy challenges and opportunities, and engaged and informed payers aiming to achieve rightful reimbursements for appropriate patient care services.

Genomic Medicine Payer Summit

This year 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. An EAC subcommittee, led by **Dr. Sam Caughron**, planned and participated in an in-person meeting, held on May 11, 2016 in Chicago, IL, which 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 has 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.

Genomic Sequencing Procedure (GSP) Reimbursement

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. This project was overseen by a special committee, chaired by **Dr. Linda Sabatini.** 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.

Awarding and Administration of Medicare Administrative Contractor (MAC) Contracts

AMP submitted comments on February 19, 2106 to a request for information from CMS regarding awarding and administration of Medicare Administrative Contractor (MAC) contracts. AMP provided a number of recommendations to CMS to improve how MACs serve as primary operational contacts between the Medicare fee-for-service program and providers across the country. AMP stated that transparency and stakeholder engagement are critical to ensuring that MACs are successful in their endeavors to appropriately and fairly make coverage assessments. AMP provided specific recommendations regarding MACs meeting their responsibilities, including that CMS should exercise its authority to oversee the work of the MACs in a timely and transparent manner; MACs should be assessed on their transparency and public engagement as a measurement of their level and quality of service; CMS should assess the MAC's adherence to the gapfill process as a measurement of quality of service; and that MACs should be evaluated based on the relationships with health care providers within their jurisdictions.

Protecting Access to Medicare Act (PAMA)

The long overdue Protecting Access to Medicare Act (PAMA) proposed rule was released on September 25, 2015 and AMP provided written comment to CMS on this proposed rule in late 2015. 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 will begin in 2017 with initial reports due to CMS by March 31, 2017. Details on registration and reporting procedures have begun to emerge from CMS. EAC continues to notify and educate membership on the details of this new and vast rule.

Established by PAMA, the Advisory Panel on Clinical Diagnostic Tests (The Panel) is to advise on various issues under PAMA including payment rates for new tests, including whether to use crosswalking or gapfilling processes for initial price determination; application of market rates for established tests; and evaluation and designation of tests as "advanced laboratory diagnostic tests" as defined by the Act. Several AMP members were selected for the Panel, with **Dr. Vicky Pratt** serving as AMP's representative to the Panel. CMS convened the first meeting of the Panel on August 26, 2015 and continued to hold various Panel meetings throughout 2016.

Clinical Lab Fee Schedule (CLFS) and Gapfill Determinations
During the summer, AMP provided written and oral comments to CMS on the Calendar Year 2017 Clinical Lab Fee Schedule (CY2017 CLFS) and 2016 Gapfill Determinations. **Dr. Aaron Bossler** represented AMP at the annual CLFS meeting at CMS on July 18, 2018. He presented crosswalk recommendations for the new 2017 CLFS molecular pathology procedures, genomic sequencing procedures (GSPs), and microbiology procedures.

In September, CMS released the CY2017 CLFS Preliminary Determinations and the 2016 Final Gapfill Payment Determinations. For most of the new 2017 molecular CPT codes, including microbiology procedures and Genomic Sequencing Procedures (GSP's), CMS recommended use of crosswalk to existing codes to determine initial pricing. Many of the preliminary CMS recommendations included changes recommended by AMP. AMP appreciates that the preliminary CMS determination abandons gapfill for the GSPs and instead recommends crosswalk for price determination of the new GSP codes in 2017. AMP is in the process of developing comments to CMS on these values.

For the 2016 gapfill final determinations, AMP had submitted comments to CMS on the preliminary determinations in August 2016. 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. In late September, CMS released final gapfill determinations and AMP is in the process of responding to those values.

Educational Initiatives
In an effort to keep the membership informed of economic issues facing molecular diagnostics and to increase the knowledge base of the often complicated issues, the EAC held various webinars throughout the year. The first EAC-led webinar of the year provided an overview of the molecular coding, coverage, and reimbursement processes with a focus on Centers for Medicare and Medicaid Services' (CMS) methods used by the MACs to make coverage assessments. Later in the year, upon the release of the PAMA final rule, EAC held another webinar to inform membership on details contained within the final rule. EAC members also assisted with the webinar series based on the EAC, PRC, and CPC joint manuscript titled "The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer."

Medicare Administrative Contractors' (MACs) Local Coverage Determinations (LCDs)
AMP continues to advocate with CMS regarding coverage policy actions taken by Medicare Administrative Contractors (MACs). During 2016, AMP provided responses to various MACs for over 15 draft 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 November. Monitoring emerging policies continued to be a major focus of the committee and was led by **Dr. Richard Press.** AMP and the College of American Pathologists (CAP) collaborated to draft joint responses. The EAC is very thankful to the AMP members who volunteered their time and subject matter expertise to assist in responding to the diverse coverage policy issues.

In 2016, the MolDx 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 MolDx 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 MolDx 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.

CPT Codes

The EAC CPT Work Group, led by **Dr. Aaron Bossler**, advises on the AMP position on new CPT code proposals submitted to the Pathology Coding Caucus (PCC) and the Molecular Pathology Advisory Group (MPAG). Throughout the year, the Work Group also submits new CPT code change proposals to AMA. In 2016, AMP submitted eight CPT code change proposals.

Outside Organization Representation

- **Dr. Jan Nowak** serves on the CPT Editorial Panel
- **Drs. Victoria Pratt, Jan Nowak, Aaron Bossler have been appointed to the new AMA Proprietary Laboratory Analyses Technical Advisory Group (PLA-TAG)**
- **Dr. Aaron Bossler** serves on the PCC, with **Dr. Sam Caughron** serving as Alternate.
- The AMA Molecular Pathology Advisory Group (MPAG) includes AMP members **Drs**. **Aaron Bossler, Roger Klein, Elaine Lyon**, and **Victoria Pratt**.

AMP Finance Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Andrea Ferreira-Gonzalez, PhD
President	Charles E. Hill, MD, PhD
Past President	Janina A. Longtine, MD
President-Elect	Federico A. Monzon, MD
Member	Mary C. Lowery-Nordberg, PhD
Member	Timothy T. Stenzel, MD, PhD
Member	Gail H. Vance, MD

The Finance Committee oversees AMP's financial affairs, including reviewing quarterly revenue & expense reports and recommending to the Board for approval an annual operating budget and the investment policy for the Association's assets.

AMP International Affairs Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair and Hong Kong Affiliate Liaison (East Asia)	Lei Po (Chris) Wong, PhD
Member (Africa)	Adewunmi Oluseye Adeoye, MD
Member (South Asia)	Sheik Mohammad Khorshed Alam, PhD, MD
Member and Professional Relations Liaison	David E. Barton, PhD
Member (East Asia)	Yoon-La Choi, MD PhD
Member (Latin America)	Renata A. Coudry, MD, PhD
Member and India Affiliate Liaison (South Asia)	Bibhu R. Das, PhD
Member (Australia)	Andrew P. Fellowes, PhD
Member and Korea Affiliate Liaison (East Asia)	Jin-Yeong Han, MD, PhD
Member (Middle East) and Training & Education Liaison	Rami Mahfouz, MD
Member (Middle East)	Imran Mirza, MD
Member (Southeast Asia)	Lynette Lin Ean Oon, MD
Member (Latin America)	Roberta Sitnik, PhD
Member (Africa)	Denis Francis York, PhD
Germany Affiliate Liaison	Joerg Maas
Assn of Indian Pathologists in North America Liaison	Priti Lal, MD
Advisor	Helen Fernandes, PhD
Advisor	Patrik Vitazka, MD, PhD

PURPOSE SUMMARY:

The International Affairs Committee (IAC):

- Enhances AMP as an international organization
- Promotes AMP's vision and mission internationally
- Facilitates international presence and participation in AMP groups and programs
- Expands excellence in education and advocacy on behalf of patients, clinicians, and lab professionals to an international audience
- Enables the interaction of scientists and molecular pathologists in the various parts of the world

2016 ACTIVITIES:

- Conceptualized the inaugural 2017 Global Congress on Molecular Pathology, April 3-5, 2017 in Berlin, Germany
- AMP 2016 Annual Meeting Events
  - International Showcase Evening, "Quality Assurance and Standardization of Molecular Testing Around the World"
  - Going Global with AMP luncheon
- Selected International Trainee Travel Awardees from Nepal, India, and Iraq
- Awarded International Membership Grants to scientists from Nepal, India and Malaysia.
- Recommendation for the 2017 IAC Chair (Rami Mahfouz, MD, MPH)
- Exploratory discussion with the Global Genomic Medicine Collaborative (G2MC) for inclusion of molecular laboratory professionals.
- Planned to relaunch the international Sample Exchange Program for members using the AMP Sample Exchange Community in the CHAMP platform.
- AMP speakers supported at international (non-U.S.) conferences:

- Ted E. Schutzbank, PhD for the Molecular Pathology Association of India (MPAI) 5th Annual Conference, Chandigarh, India. Organizing Committee AMP Member: Bibhu R. Das, PhD
- Elaine Lyon, PhD at the 2016 Annual Meeting of Korean Society of Genetic & Molecular Diagnosis, Seoul, Korea. Organizing Committee AMP Member: Jin-Yeong Han, MD, PhD
- Charles E. Hill, MD, PhD at the 3rd Joint Meeting of Pathology and Laboratory Medicine, XXIII Congress of the Italian Society of Pathology and Translational Medicine II Congress of the Italian Society of Clinical Pathology and Laboratory Medicine in Collaboration with the American Society for Investigative Pathology (ASIP) in Montesilvano, Italy. Organizing Committee AMP Member: Francesco Curcio, MD.

AMP Membership Affairs Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Nirali M. Patel, MD
Member	Betsy A. Bove, PhD
Member	Yi Ding, MD, PhD
Member	Midhat S. Farooqi, MD, PhD
Member	Matthew Hiemenz, MD
Member	Giovanni Insuasti-Beltran, MD
Member	Cynthia L. Jackson, PhD
Member	Ruth Ann Luna, PhD
Member	Ron M. Przygodzki, MD
Member	Wanda Reygaert, PhD
Member	Yaolin Zhou, MD
International Affairs Liaison	Lei Po (Chris) Wong, PhD

PURPOSE SUMMARY:

The AMP Membership Affairs Committee (MAC) provides recommendations to 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.

Responsibilities

- Assesses and makes recommendations that will enhance the professional development of AMP members and the benefits of AMP membership
- Provides regular and timely notification to members about opportunities for special projects within or outside of standing committees and subdivisions
- Facilitates leadership development for AMP through various initiatives such as the *ad hoc* and junior member volunteer process
- Receives requests from Chairs or Board for *ad hoc* members to work on projects and manages the volunteer application process
- Surveys member volunteers annually regarding their volunteer service experiences
- Surveys the membership periodically regarding how well their membership in AMP is meeting their needs and how well AMP is serving the needs of the profession
- Conducts a member recruitment and retention program

2016 ACTIVITIES:

- Planned and hosted the first ever **AMP Regional Learning and Networking Event**, held immediately prior to the AACC Meeting in Philadelphia
- Formed a Membership Recruitment/Strategic Plan Task Force to address the membership growth and retention goals of the strategic plan
- Designed and prepared targeted new member recruitment pieces (webpages, free webinar offerings, etc.) to attract people to AMP and AMP-hosted events at the USCAP Meeting in Seattle and the AACC Meeting in Philadelphia.
- Planned and hosted the First-Time Attendees/New Member Luncheon and Early Career Luncheon at the Annual Meeting
- Selected the winners of the Technologist Travel Awards
- Solicited and vetted volunteers for the Career Consults at AMP CENTRAL Program
- Designed and hosted the 2016 Career Consults at AMP CENTRAL Program
- Spearheaded research into new targets for AMP Membership growth

AMP Nominating Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Janina A. Longtine, MD
Genetics Subdivision Representative	Hanna Rennert, PhD
Genetics Subdivision Representative	D. Brian Dawson, PhD
Hematopathology Subdivision Representative	Timothy C. Greiner, MD
Hematopathology Subdivision Representative	Dan Jones, MD, PhD
Infectious Diseases Subdivision Representative	Susan M. Novak-Weekley, PhD
Infectious Diseases Subdivision Representative	Janice M. Matthews-Greer, PhD
Informatics Subdivision Representative	Annette Leon Meredith, PhD
Informatics Subdivision Representative	Jorge Lemos Sepulveda, MD, PhD
Solid Tumors Subdivision Representative	George J. Netto, MD
Solid Tumors Subdivision Representative	Loren Joseph, MD

PURPOSE SUMMARY:

The AMP Nominating Committee is composed of the Past President (Chair) and two representatives from each subdivision. The chair and subdivision representatives are responsible for recruiting qualified AMP members to run for elected offices. A ballot is compiled and made available for voting by all current Regular AMP members. Voting for elected offices takes place during the month of May each year.

2016 ACTIVITIES:

The Nominating Committee nominated Officers and Committee Representatives for the 2016 annual elections.

AMP Professional Relations Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Roger D. Klein, MD, JD
Member	Stephen P. Day, PhD
Member	Rajyasree Emmadi, MD
Member	Robert F. Klees, PhD
Member	Jordan Laser, MD
Member	Elaine Lyon, PhD
Member	Roberta Madej, PhD
Member	Shelby Melton, MD
Member	Timothy J. O'Leary, MD, PhD
Member	Victoria M. Pratt, PhD
Member	Daniel E. Sabath, MD, PhD
Junior Member	Eric Q. Konnick, MD
International Affairs Committee Liaison	David E. Barton, PhD
AMP Representative to FASEB Science Policy Committee	Gregory J. Tsongalis, PhD (2014-2016)
(Ex Officio)	Betsy A. Bove, PhD (2016-2018)

PURPOSE SUMMARY:

The AMP Professional Relations Committee (PRC) is the primary liaison between AMP and other organizations for public policy issues other than reimbursement, which is the purview of the Economic Affairs Committee. Major responsibilities of the Committee include:

1. Communicating and coordinating activities with the appropriate government offices, coalitions, trade associations, and patient and professional organizations to inform policy discussions that have an impact on the practice of molecular pathology;
2. Developing AMP positions on emerging issues affecting molecular pathology;
3. Interacting with a wide variety of entities, including other professional associations, Congress and U.S. Federal Agencies such as FDA, CDC, DHHS;
4. Advocating for policy changes in legislation and regulation that will advance the practice of molecular pathology.

The committee membership includes individuals employed in a variety of medical, scientific, institutional and commercial capacities.

2016 ACTIVITIES:

The PRC continues to monitor the activities of, and in some cases work with, federal agencies and panels such as FDA and CMS as well as policy committees such as IOM. After extensive discussion, the committee drafts AMP's policy positions and comments to federal agencies and members of Congress. AMP's government relations consultants, Jennifer Leib, Megan Anderson Brooks, and Lindsey Trischler of CRD Associates, keep the Committee informed of all policy and legislative activity, assist in drafting policy positions, provide advice regarding advocacy strategies, and guide AMP's presence on Capitol Hill. Jennifer Leib, Megan Anderson Brooks, AMP Senior Policy Analyst Tara Burke, AMP Executive Director Mary Williams, and when possible, Committee or other AMP members meet with congressional staff to educate them about issues relevant to molecular pathology, to offer AMP's expertise, and to advocate for AMP members' interests. (Note: As a 501c3 tax-exempt organization, AMP is prohibited from participating in any partisan activities and may not have a Political Action Committee (PAC). In addition, its direct and grassroots lobbying activities are limited per IRC 501h.)

Oversight of Laboratory Developed Testing Procedures (LDPs)
A major advocacy issue of 2016 continues to be regulatory oversight of laboratory developed testing procedures (LDPs), also known as laboratory developed tests (LDTs). In late 2014, the FDA issued a "Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and an accompanying "Draft Guidance for Industry, Food and Drug Administration Staff, and Clinical Laboratories: FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)." Since then, AMP continues to advocate that FDA medical device regulations are poorly suited for, and inapplicable to, the oversight of LDPs. In 2015, a working group of the Committee developed a proposal to modernize the CLIA regulations and maintain oversight of LDPs under those regulations. The proposal consists of a tiered, risk-based structure that avoids duplication of activities within and between federal agencies. Among the current proposals that have been circulated in Washington, AMP believes its proposal currently has the greatest consensus among the professional societies because it incorporates the perspectives, feedback, and requests from multiple stakeholders.

In December 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 a careful and thorough examination of the LDPs mentioned in FDA's report, AMP concluded that FDA oversight would likely prevent few of the potential patient harms postulated by the Agency. 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.

In 2016, 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. FDA has stated their intent to release the final draft guidance in 2016 and legislative alternative regulations are also under consideration.

Regulatory Oversight of Next Generation Sequencing 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 releasing discussion papers. This year, FDA begun 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 including, **Drs. Dara Aisner, John Pfeifer, Robert Klees,** and **Madhuri Hedge**. **Dr. Roger Klein** presented public comment on behalf of AMP. Additionally, 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. Subsequently, in September, FDA held a workshop to discuss both drafts. AMP provided both written and oral comments on these drafts, with **Dr. Madhuri Hegde** presenting AMP oral comments. 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.

Examining the Return of Genetic Test Results and Interpretations

In March, FDA held a workshop with the purpose of providing input to assist the Agency in understanding patient and provider perspectives on receiving potentially medically relevant genetic test results. The topics focused on better defining the specific information patients and providers prefer to receive, 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. Panel discussions were divided among different clinical scenarios such as well patient/predictive tests, acute disease tests, and chronic disease tests. **Dr. Eric Konnick** presented public comments on behalf of AMP. Both AMP's written and oral comments to FDA on this workshop expressed deep concern about the scope of the workshop. FDA framed the workshop as part of its contribution to the Precision Medicine Initiative, but the workshop's discussions did not focus on returning research results, but rather clinical test results, and AMP concluded that comments submitted will be used by the agency in regards to clinical testing, which may have very significant consequences for patient access to diagnostics. Most importantly, AMP stated in its comments that the activities that occur in the practice of laboratory medicine and pathology, including the performance and interpretation of findings from numerous laboratory procedures, are professional medical services that fall clearly within the scope of practice of medicine and are beyond the purview of the FDA.

Capitol Hill

Throughout 2016, AMP met with numerous offices on Capitol Hill regarding restrictions on the oversight and regulation of LDPs. Specifically, AMP met with staff for Senators Alexander, Murray, Moran, Tester, Cassidy, Cochran, Baldwin, Feinstein and Merkley. AMP also met with staff working for Representatives Harris, Burgess, Honda, Aderholt, Rooney, and DeLauro.

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). At the briefing, **Dr. Janina Longtine** represented AMP, presenting examples of how LDPs are vital in oncology clinical practice. **Drs. Sherri Bale** and **Angela Caliendo** also gave impactful presentations on the value of LDPs. Further, **Dr. Karen Kaul** 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.

Publications

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." 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.

Collaborations

AMP continues to participate in a variety of policy discussions with other professional societies, laboratory groups, as well as coalition groups such as the Personalized Medicine Coalition (AMP representatives **Drs. Shelby Melton** and **Roger Klein**), IOM Roundtable on Translating Genomic-Based Research for Health (AMP representative **Dr. Vicky Pratt**), Federation of American Societies for Experimental Biology (FASEB) (AMP representatives **Drs. Greg Tsongalis** (2014-2016) and **Betsy Bove** (2016-2018), and the Cancer Leadership Council.

AMP Program Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Victoria M. Pratt, PhD
Chair-Elect	Daniel Sabath, MD, PhD
Genetics Representative	Josh Deignan, PhD
Genetics Representative	William Edward Highsmith, Jr, PhD
Hematopathlogy Representative	Rebecca McClure, MD
Hematopathlogy Representative	Bryan L. Betz, PhD
Infectious Diseases Representative	Alexandra Valsamakis, MD, PhD
Infectious Diseases Representative	Amy L. Leber, PhD
Informatics Representative	Eric William Klee, PhD
Informatics Representative	Christopher D. Coldren, PhD
Solid Tumors Representative	Jennifer Laudadio, MD
Solid Tumors Representative	Alexander Craig MacKinnon, Jr, MD, PhD
Technical Topics Representative	Amanda LeBlanc, MS
Technical Topics Representative	Cindy A. Meadows, MB(ASCP)

PURPOSE SUMMARY:

The Program Committee is responsible for overall planning and organization of the AMP Annual Meeting, including sessions and abstracts/posters. In addition, the Committee selects the winners of the Technologist Poster Awards.

2016 ACTIVITIES:

Programming the 2016 Annual Meeting, “Big World. Molecular Medicine. One Community.” from November 10-12, 2016 at the Charlotte Convention Center in Charlotte, NC.

AMP Publication and Communication Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Jane Gibson, PhD
JMD Editor-in-Chief	Barbara A. Zehnbauer, PhD
Test Directory Editor	Alexis Carter, MD
Web Editor	Mary C. Lowery-Nordberg, PhD
Electronic Media Advisor	Dahui Qin, MD, PhD
Electronic Media Advisor	Mohamadou Sene, BS, MB(ASCP)
Advisor	Shalini Verma, MD
Member	Shaochun Bai, PhD
JMD Managing Editor	Emily Essex

PURPOSE SUMMARY:

The Publication and Communication Committee is comprised of appointed volunteers from the AMP membership. The task of the Committee is to review and monitor all AMP "publications," whether print or electronic. The Committee is also responsible for the implementation of periodic updates to the various committee and subdivision homepages(s) on the AMP website. The committee communicates via monthly conference calls.

2016 ACTIVITIES:

- Solicited submissions for the AMP/CAP TODAY Case Report Program
- Reviewed and ultimately submitted a record 10 case reports for ultimate publication in CAP TODAY
- Assisted the Test Directory Editor and Associate Editors on the successful launch of the newly redesigned AMP Test Directory
- Proposed and produced a new Publications Policy for AMP that addresses the evolving needs of AMP committees and working groups
- Continued to review and monitor the AMP website, providing input as needed

AMP Strategic Opportunities Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Federico A. Monzon, MD
Member	Steven I. Gutman, MD
Member	Ester Stein, MBA
Member	Karl V. Voelkerding, MD
Board Member	Andrea Ferreira-Gonzalez, PhD
Board Member	Roger D. Klein, MD, JD

PURPOSE SUMMARY:

The Strategic Opportunities Committee assesses the opportunities and challenges in the molecular pathology profession and other environments external to the organization that affect AMP interests.

2016 ACTIVITIES:

The Strategic Opportunities Committee carries out the activities listed below and provides relevant reports and recommendations to the Board of Directors:

- Assessing trends and activities in the broad environment external to AMP, *i.e.,* "Horizon Scanning"
- Identifying and assessing external threats that could prevent AMP from attaining its goals
- Identifying and assessing external opportunities that can help AMP attain its goals
- Identifying organizations for potential relationships that can help AMP attain its goals

AMP Training & Education Committee Annual Report, 2016

COMMITTEE MEMBERS:

Chair	Annette S. Kim, MD, PhD
Genetics Subdivision Representative	Allison Cushman-Vokoun, MD, PhD
Genetics Subdivision Representative	Avni Santani, PhD
Hematopathology Subdivision Representative	Cecilia Ching Sze Yeung, MD
Hematopathology Subdivision Representative	Jennifer Dunlap, MD
Infectious Diseases Subdivision Representative	Colleen Kraft, MD
Infectious Diseases Subdivision Representative	Kevin Alby, PhD
Informatics Subdivision Representative	N. Sertac Kip, MD, PhD
Informatics Subdivision Representative	Jeremy P. Segal, MD, PhD
Solid Tumors Subdivision Representative	Eric J. Duncavage, MD
Solid Tumors Subdivision Representative	Anthony N. Snow, MD
Junior Member	Juan C. Gomez-Gelvez, MD
Junior Member	Jason N. Rosenbaum, MD
Medical Technologist Member	Tessara Baldi, BS
Membership Affairs Committee Liaison	Matthew Hiemenz, MD
International Affairs Committee Liaison	Rami Mahfouz, MD

PURPOSE SUMMARY:

The Training and Education (T&E) Committee is comprised of representatives from each of AMP's subdivisions: genetics, hematopathology, infectious diseases, informatics and solid tumors. It oversees important issues such as education and certification in molecular pathology and mentoring of trainees, as well as developing educational programs for different audiences.

Educational Programs

- ***Molecular Pathology Outreach Course (MPOC 2016):*** The T&E committee organized an annual outreach course held just prior to annual meeting which was geared to individuals with little experience in molecular diagnostics. This year the course was entitled "*AMPlicons: A Practical Molecular Toolkit and Case Studies.*" The course included an overview of applications of molecular pathology, followed by case studies presented by T&E members.

- ***Molecular Genetic Pathology (MGP) Online Review Course:*** An online, self-study course (a recorded version of the 2015 live course) is available through December 31, 2016 at: http://www.amp.org/mgp2015/self-study.cfm

- ***Science Educator Workshop:*** The Science Educator Workshop: Teaching Precision Medicine, Genomics, and Molecular Diagnostics in Your Classroom was held on November 9, 2016. This all-day workshop event targeted high school and college science teachers and their students who live and/or work in the vicinity of Charlotte, NC. The workshop included presentations on hot topics in precision medicine and molecular diagnostics, a panel on the career paths into the field of clinical diagnostics, and several hands-on, small group activities and teaching resources that educators could bring back to their classrooms.

- ***Early Bird Sessions at the Annual Meeting - Case Studies presented by Trainees or Technologists:*** The T&E committee hosts an opportunity for fellows, residents, postdocs, graduate students, or technologists who attended the AMP 2016 Annual Meeting to present an interesting and/or challenging case study during an Early Bird Session. Trainee/technologist presenters in 2016 were:

Case Studies in Genetics	Case Study: Compound Melanocytic Nevus and Rhadomyosarcoma in Setting of HRAS Mutation	Paul Lee, MD, PhD	Washington University at St. Louis, St. Louis, MO
	Case Study: Research Whole Exome Sequencing Identifies a Genetic Diagnosis of Neuronal Ceroid Lipofuscinosis Type 6 after a Panel Test Miss	Nicole Boczek, PhD	Mayo Clinic, Rochester, MN
	Case Study**:** A Hematopoietic Chimera Case Identified by Chromosomal Microarray	Yang Cao, PhD	Mayo Clinic, Rochester, MN
	Case Study: Maternally Inherited 133 kb Deletion of 14q32 Causing a Paternal UPD14 Phenotype (Kagami-Ogata Syndrome)	Hou-Sung Jung, PhD	Dartmouth-Hitchcock Medical Center, Lebanon, NH
Case Studies in Solid Tumors	Case Study: ALK Expression in a Non-small Cell Lung Cancer Not Associated with ALK Rearrangement by FISH or by Targeted NGS-based Fusion Assay	Patrick Mann, MD	University of Colorado Hospital, Aurora, CO
	Case Study: ALK-rearranged Adenocarcinoma with Transformation to High Grade Neuroendocrine Carcinoma at a Metastatic Site Showing Retained ALK Rearrangement	Jill Miller, MD	University of Vermont Medical Center, Burlington, VT
	Case Study: Next-Generation Sequencing Panels Aid in the Diagnosis of Rare Collision Tumors	Jonas Heymann, MD	New York-Presbyterian Hospital-Columbia University Medical Center, New York, NY
	Identification of a Silent EGFR Mutation Leading to Allele Dropout in EGFR p.L858R Genotyping	Helio A. Costa, PhD	Stanford University, Stanford, CA
Case Studies in Infectious Diseases	Case Study: Culture Negative Endocarditis Due to Tropheryma whipplei	Catherine Stefaniuk, DO	Case Western Reserve University, University Hospitals - Cleveland Medical Center, Cleveland, OH
	Case Study: Histopathologic Findings and the Diagnosis of CNS Tropheryma whipplei on Paraffin-embedded Tissue	Andrew Bryan, MD, PhD	University of Washington, Seattle, WA

Case Studies in Hemato-pathology	Case Study: 5q Microdeletion Identified via Microarray Analysis Allows for Targeted Therapy in B-Lymphoblastic Leukemia	Kendall Brewer, MD	Medical University of South Carolina, Charleston, SC
	Case Study: The Use of Next-Generation Sequencing (NGS) to Identify a Case of Clonal Cytopenias of Undetermined Significance (CCUS)	Meghan Riley, MD	Washington University at St. Louis, St. Louis, MO
	Case Study: Donor-derived Clonal Hematopoiesis in an Acute Myeloid Leukemia (AML) Patient with History of Sex-mismatched Peripheral Blood Stem Cell Transplantation	Alissa Minkovsky, MD, PhD	Brigham and Women's Hospital, Boston, MA
	Case Study: A Case of Undiagnosed Diamond Blackfan Anemia	Tripti Kumar, DO	Beaumont Health System, Royal Oak, MI

- ***Webcasts:***

Date	Title	Speakers/T&E Moderators
January 26	**Emerging Fronts in Molecular Pathology:** Clonal Hematopoiesis of Indeterminate Potential	Benjamin L. Ebert, MD, PhD (Cecilia Yeung, MD)
April 27	**Emerging Fronts in Molecular Pathology:** Building Synthetic Immunity to Cancer Using Chimeric Antigen Receptors	Michael C. Milone, MD, PhD (Kevin Alby, PhD)
April 29	**Zika Virus: Diagnostic Testing and Front-Line Management.** *An Educational Event Collaboration Between the Association for Molecular Pathology and the Pan American Society for Clinical Virology*	Benjamin Pinsky, MD, PhD, and Cecilia Perret, MD (Kevin Alby, PhD)
May 9	**Emerging Fronts in Molecular Pathology:** Targetable Genetic Bases for Immune Evasion in Lymphomas	Margaret A. Shipp, MD (Jennifer Dunlap, MD)
May 27	**Emerging Fronts in Molecular Pathology:** Bacterial and Fungal Typing by Sequence-based Methods	Lynn Bry, MD, PhD (Colleen Kraft, MD)
June 9	**Emerging Fronts in Molecular Pathology:** Promise and Pitfalls of Circulating Tumor DNA	Christine Lockwood, PhD (Cecilia Yeung, MD)
June 30	**The Who, What and When of the PAMA Final Rule**	Erika Miller, JD (Tara Burke, PhD)
Sept 28	**The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer:** *Part 1 - An Overview of AMP's Framework for the Evidence Needed to Demonstrate Clinical Utility*	Loren Joseph, MD and Elaine Lyon, PhD (Roger Klein, MD, JD)
Oct 5	**The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer:** *Part 2 –Clinical Utility for Oncology Cases*	Pranil Chandra, DO and Rajyasree Emmadi, MD (Loren Joseph, MD)
Oct 11	**The Spectrum of Clinical Utilities in Molecular Pathology Testing Procedures for Inherited Conditions and Cancer:** *Part 3 - Clinical Utility for Inherited Conditions*	Vicky Pratt, MD and Stephanie Hallam, PhD (Elaine Lyon, PhD)

Education Initiatives

- ***Continuing Education credits (PACE, CME, and CMLE):*** AMP continues to apply for PACE credits (AMP Webinars), as well as CME credits via a joint providership with ASCP. Accredited activities include the MGP Review Course (live and online), the MPOC, and the 2016 Annual Meeting. Continuing Medical Laboratory Education (CMLE) is provided for non-physicians via a joint providership with ASCP.

- ***AMP Online:*** The T&E Committee and staff spent significant time to design and develop educational materials for populating the new online learning platform connected at www.amp.org/education. Selected online educational offerings are complimentary for AMP members. Current content includes the Online MGP Review Course, the Molecular Diagnostic Toolkit and Practical Applications, and webinar bundles on NGS 101 and Informatics 101.

- ***Target Audience Groups (TAGs):*** The T&E committee established TAGs within the T&E committee dedicated to the development of new educational materials to extend the positive influence and educational mission of AMP to meet the needs of molecular professionals and non-molecular audiences. The following TAGS were created: Trainees, Technologists, Oncologists, Primary Care Physicians, and the lay (non-medical) public. Early accomplishments include the piloting of "How-to" videos and case studies for technologists as well as the development of a syllabus for the training of laboratory management. In addition, ideas for clinician "pocket cards" for common testing algorithms in molecular testing were vetted as well as educational "road shows" to reach primary care and lay audiences.

Trainee Activities (Residents, Fellows, and Students)

- ***AMP 2016 Annual Meeting***
  - Annual Trainee Luncheon and Book Drawing: The T&E junior members organized table discussion topics between junior and senior faculty members at the 2016 Trainee Luncheon. Topics included finding a job, securing a fellowship, career development, and research. Donated textbooks from AMP member authors were given away at the Trainee Luncheon.
  - Poster Walks: T&E Members led small groups to various posters of interest for discussion.

- ***United States and Canada Academy of Pathology (USCAP)***
  - AMP hosted a trainee Meet 'n Greet breakfast reception at USCAP 2016. Supported by the Jeffrey A. Kant – AMP Education Fund. Complimentary AMP Associated Memberships were provided to four trainees new to AMP.

Technologist Activities

- Technologist luncheon at the Annual Meeting
- Future planning of the development and coordination of resources for technologists

Awards

- Young Investigator Awards – 53 poster candidates
- Technologist Poster Awards – 24 poster candidates
- International Trainee Travel Award (Supported by the Jeffrey A. Kant – AMP Education Fund) – Three recipients (from India, Nepal and Iraq).

Membership Educational Needs Survey

The AMP Strategic Plan mandates that the educational needs of the membership are to be assessed annually. The committee launched the online survey in September. A roundtable discussion regarding its results will be held during a specialty luncheon at the 2016 Annual Meeting. T&E Chair Annette Kim is leading the effort and

facilitating the panel and audience discussions. The input and feedback will help guide the T&E Committee in planning for future educational projects and offerings to meet the needs of our membership.

Molecular Genetic Pathology Fellowship Program Directors (MGP PD) Working Group

The MGP Program Directors (MGP PD) Council consists of David Wu (Chair), Dolores Lopez-Terrada (Chair-Elect), and Marie DeFrances (Past-Chair). Shuko Harada is the incoming Chair-Elect. The MGP PD Council facilitates the discussions of the MGP Program Directors Working Group and responds to the ABP and ACGME on matters related to MGP Fellowship programs.

Curriculum Development Task Forces

- ***Molecular Pathology Residency Training:*** Chaired by Charles Hill, the Task Force developed a suggested molecular pathology curriculum for residents. The guidelines were published in *JMD* in February 2016 (A Suggested Molecular Pathology Curriculum for Residents: A Report of the Association for Molecular Pathology). Other authors are: Dara Aisner, Anna Berry, Brian Dawson, Randy Hayden, and Loren Joseph.

- ***Genomics Education for Primary Care Residents:*** This Task Force is led by Laura Tafe, with members Devon Chabot-Richards, and Maria Arcila. Their task is to develop a modified basic genomics curriculum for primary care residents*, i.e.*, internal medicine, family practice, pediatrics to be submitted to a primary care-type journal.

- ***MGP Fellow Training and Curriculum in Genomics Task Force:*** Chaired by Anna Berry, the Task Force, established in August 2012, is in the final stages of outlining a suggested molecular pathology and genomics curriculum for fellows. Upon completion, the manuscript will be submitted to *JMD*. Other members are: Alanna Church, Linda Jeng, Roger Klein, Mahesh Mansukhani, Federico Monzon, John Pfeifer, Hanna Rennert, Iris Schrijver, Laura Tafe, Vivianna Van Deerlin and David Wu.

Co-Sponsorships, Companion Meetings, and/or Collaborations

- ***United States and Canadian Academy of Pathology (USCAP) 2016***
  The AMP 2016 Companion Society Symposium, "*Implementing Molecular Testing to Make Treatment Decisions",* was co-moderated by Eric Duncavage and James R. Cook:
  - *New Insights into Molecular Monitoring in Cancer**,** Eric J. Duncavage, MD*
  - *Molecular Monitoring in AML Can Inform Prognosis, Jeffrey M. Klco, MD, PhD*
  - *Clinical Application of NGS for MRD Monitoring in Lymphoid Neoplasms, David Wu, MD, PhD*
  - *Cell-free Tumor DNA for Cancer Monitoring, Christina Lockwood, PhD*
  - *Summary Overview, James Cook, MD, PhD*

  An AMP-USCAP co-sponsored Special Course, "Molecular Diagnostic and Genomic Applications in Cancer: A Primer for the Pathologist", was co-directed by George Netto, MD, and Karen Kaul, MD, PhD.

- ***Regional/Local Conferences***
  - ***Beaumont Symposium*** – September 16-17 in Troy, MI.
    Organizer: Bobby Boyanton. AMP faculty included: John Gibson, Sabine Hellwig, Jimmy Lin and Mark Micale.

- ***American Society for Clinical Pathology (ASCP)***
  - ***ASCP 2016 AMP Workshop: September 14-16 in Las Vegas, NV:*** Cecilia Yeung presented a Molecular Diagnostic Primer for Technologists.

- ***College of American Pathologists (CAP)***
  - ***CAP 2016 Course Presentations:*** **September 25-28 in Las Vegas, NV**
    Sequence Gazing: Variant Calling and Interpretation for Next-Generation Sequencing, presented by Eric Duncavage & Ian Hagemann

- ***ASCO-CAP-AMP Molecular Oncology Tumor Boards***
  The Molecular Oncology Tumor Boards are a series of monthly user-driven discussions designed to help cancer care providers with the interpretation and understanding of tumor molecular profiling tests and studies: http://university.asco.org/motb. AMP collaborates with the American Society for Clinical Oncology (ASCO) and the College of American Pathologists (CAP).
  - AMP Liaisons: Christopher Watt and Maria Arcila.

- ***ACCC-AMP Virtual Molecular Tumor Boards***
  AMP is collaborating with the **Association of Community Cancer Centers** (ACCC) to develop a series of 12 virtual tumor boards available for on-demand viewing at: http://accc-cancer.org/resources/virtual-tumor-boards.asp.
  - AMP Liaisons: Annette Kim and Eric Duncavage (Eric Duncavage was invited to speak at the ACCC National Conference on October 20 in St. Louis, MO).

- ***Cambridge Health Institute (CHI) Conferences***
  - **Molecular Medicine Tri-Conference,** March 6-11, 2016, San Francisco
    - **Short Courses:**
      - ***Assay Selection, Validation, and Compliance for NGS Testing :*** Eric Duncavage, Colin Pritchard and Avni Sananti
      - ***Clinical Informatics: Returning Results from Big Data:*** Eric Klee, Nilesh Dharajiya and N. Sertac Kip
    - **Keynote Session**
      - ***Why an Accurate Diagnosis is Fundamental to Health Care:*** Elaine Lyon, PhD, Loren Joseph, MD and Linda Sabatini, PhD
        - The Diagnostic Dilemma in Inherited and *de novo* Disease
        - DNA Intelligence in the War on Cancer: The Utility of Molecular Genetic Analysis
        - An Accurate Diagnosis Impacts the Economics of Health
  - **Biomarkers & Diagnostics World Congress** May 17-19, 2016, Philadelphia, PA
    - **Symposium**
      - **NGS as a Clinical Test Symposium:** Elaine Lyon, Avni Santani, Kojo Elenitoba-Johnson and Jennifer Morrisette
  - **Next Generation Dx Summit,** August 18-20, 2016, Washington, DC
    - **Plenary Keynote Panel**
      - ***Disruptive Innovation in Laboratory Medicine: Game Changing Technologies and Approaches:*** Ted Schutzbank (moderator) and Rebecca McClure and other panelists (industry)

Newly Appointed Positions:

- Second Technologist Member (2-year term)

AMP Subdivision Leadership Annual Report, 2016

SUBDIVISION LEADERSHIP

	Genetics	Hematopathology	Infectious Diseases	Informatics	Solid Tumors
Chair	Siby Sebastian	Todd Kelley	Michael Lewinski	Alexis Carter	Laura Tafe
Clinical Practice Committee	Birgit Funke	Jennifer Crow	Linda Cook	Somak Roy	Larry Jennings
	Monica Basehore	David Viswanatha	Benjamin Pinsky	Mark Routbort	Meera Hameed
Nominating Committee	Hanna Rennert	Timothy Greiner	Susan Novak-Weekley	Annette Meredith	George Netto
	Brian Dawson	Dan Jones	Janice Matthews-Greer	Jorge Sepulveda	Loren Joseph
Program Committee	Joshua Deignan	Rebecca McClure	Alexandra Valsamakis	Eric Klee	Jennifer Laudadio
	William Edward Highsmith	Bryan Betz	Amy Leber	Christopher Coldren	Alexander McKinnon, Jr
Training & Education Committee	Allison Cushman-Vokoun	Cecilia Yeung	Colleen Kraft	Nefize Sertac-Kip	Eric Duncavage
	Avni Santani	Jennifer Dunlap	Kevin Alby	Jeremy Segal	Anthony Snow

PURPOSE SUMMARY:

The Subdivision Leadership consists of a Chair and Representatives to the Clinical Practice, Nominating, Program, and Training & Education Committees. Subdivision Chairs are responsible for the successful operation and development of the subdivision that they lead. Each Subdivision Leadership group meets quarterly and function as a body of discipline-specific subject matter experts; as such, they support one another as their representatives to committees see that initiatives and projects are designed that will address issues of importance to their discipline. They carry out their subdivision leadership responsibilities by:

- Identifying and ascertaining the needs of the subdivision membership and of the discipline itself
- Discovering, vetting, and recommending projects to the Clinical Practice Committee, Training & Education Committee, or other relevant committee
- Providing input and suggestions regarding content for the Annual Meeting and other educational events
- Assisting to identify and recommend future AMP volunteers and leaders

2016 ACTIVITIES

Genetics - Addressed contemporary genetics topics as they relate to the clinical molecular diagnostics laboratory, including next-generation sequencing and whole genome and exome sequencing and non-invasive prenatal testing.

Hematopathology - Addressed topics in molecular hematopathology, including advances in translational research, next-generation sequencing and immunology.

Infectious Diseases

- Addressed infectious disease topics relevant to the clinical molecular diagnostics laboratory, including next-generation sequencing and emerging molecular infectious disease testing platforms.
- Developed and hosted ID Town Hall at the AMP 2016 Annual Meeting to engage AMP ID Subdivision members regarding challenges and opportunities for the infectious diseases community and how AMP might best address them.

Informatics - Addressed topics related to clinical applications and development of validation guidelines for next-generation sequencing bioinformatics pipelines for somatic variants and other clinical practice guidelines.

Solid Tumors - Addressed topics related to clinical applications and development of next-generation sequencing validation guidelines for somatic variants and other evidence-based clinical practice guidelines projects.

Requests from the Subdivision Leadership

- We encourage all AMP members to alert their Subdivision Chair or Representatives for current or emerging specific needs that AMP should consider and address.
- We encourage AMP members to actively contribute to requests for information from their respective Subdivision Leadership.