AMP 2019 Committee and Subdivision Annual Reports

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Solid Tumors Subdivision Chair	Roger D. Klein, MD, JD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

AMP Awards Committee Annual Report, 2019

COMMITTEE MEMBERS:

Chair	Karen E. Weck, MD
Member	Helen Fernandes, PhD
Member	David R. Hillyard, MD
Member	Thomas W. Prior, PhD
Member	Vivianna Van Deerlin, MD, 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, if any

Selected Award Recipients

- 2019 Jeffrey A. Kant Leadership Award: Karl V. Voelkerding, MD
- 2019 Meritorious Service Award: Rami Mahfouz, MD, MPH
- A special Distinguished Service Award: Mary Steele Williams
- 2021 Award for Excellence in Molecular Diagnostics: To be announced in Spring 2021

AMP Clinical Practice Committee Annual Report, 2019

COMMITTEE MEMBERS:

Chair	Daniel Jones, MD, PhD
Genetics Subdivision Representative	Jianling Ji, MD
Genetics Subdivision Representative	Pinar Bayrak-Toydemir, MD, PhD
Hematopathology Subdivision Representative	Noah A. Brown, MD
Hematopathology Subdivision Representative	Marian Harris, MD, PhD
Infectious Diseases Subdivision Representative	Kenneth L. Muldrew, MD
Infectious Diseases Subdivision Representative	Daniel N. Cohen, MD, PhD
Informatics Subdivision Representative	Justin Zook, PhD
Informatics Subdivision Representative	Annette L. Meredith, PhD
Solid Tumors Subdivision Representative	Pranil Chandra, DO
Solid Tumors Subdivision Representative	Jonathan Earle, MD
Junior Member	Megan Wachsmann, MD
Junior Member	Celeste Eno, 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, therefore, improve the service we provide. The AMP Clinical Practice Guidelines Program is comprised of multiple AMP-led working groups that 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. The majority of these projects include representation from other professional organizations and groups. AMP's External Representatives Program additionally fosters collaboration by providing AMP subject matter experts to clinical practice projects led by other professional organizations and groups.

Publications

- **September 2019:** *Recommendations for Clinical CYP2C9 Genotyping Allele Selection: A Joint Recommendation of the Association for Molecular Pathology and College of American Pathologists.* Led by Victoria Pratt with Andria del Tredici, Houda Hachad, Yuan Ji, Lisa Kalman, Stuart Scott, Larisa Cavallari, Ann Moyer, Michelle Whirl-Carrillo and Karen Weck, *The Journal of Molecular Diagnostics*. (https://doi.org/10.1016/j.jmoldx.2019.04.003)

Additional Accomplishments

- AMP hosted a Reference Materials Forum prior to the 2019 Annual Meeting on Tuesday, November 5, 2019 with representatives from CDC, NIST, and NCI.
- Multiple CPC and Scientific Subdivision members hosting or presenting in AMP Webinar events.
- Multiple AMP working groups presenting at the 2019 AMP Annual Meeting.
- AMP Subdivisions hosting Open Forums for their Subdivision members on Saturday, November 9, 2019.
- CPC members actively brainstormed and launched three new projects in 2019. Several additional project ideas are awaiting to be launched in the near future.
- Multiple early career AMP members working on CPC working groups as Junior members.

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 or email cpcprojects@amp.org.

AMP Clinical Practice Guidelines Program

Working Group / Task Force	Members
Recommendations for Clinical Warfarin Sensitivity Genotyping Allele Selection	Victoria Pratt (Chair), Larisa Cavallari, Lisa Kalman, Andria Del Tredici, Houda Hachad, Yuan Ji, Stuart Scott, Karen Weck, Ann Moyer (CAP representative), and Michelle Whirl-Carrillo (CPIC representative) and Reynold Ly
Recommendations for Laboratory Detection and Interpretation of Intragenic (Exonic Level) Deletions/Duplications	Madhuri Hegde (Chair), Elaine Lyon, Carolyn Sue Richards and Birgit Funke
Variant Interpretation Test Across Labs (VITAL) Inherited Conditions	Elaine Lyon, (Chair), Madhuri Hegde, Julie Gastier-Foster, Carolyn Sue Richards, Sherri Bale and Glenn Palomaki; unrestricted educational grant support from QIAGEN, Inc.
Guidance for Non-standard or Emerging Applications: Liquid Biopsy	Christina Lockwood (Chair), Laetitia Borsu, Christopher Gocke, Milena Cankovic, Kandelaria Rumilla, Meera Hameed, Jason Merker (CAP representative), Geoffrey Oxnard (ASCO representative), Jonathan Earle, Jean Lopategui and Jacquelyn Reuther
Guidance/Standards for NGS Germline Variant Confirmation	Kristy Crooks (Chair), Avni Santani, Diana Mandelker, Steve Lincoln, Kelly Hagman (NSGC representative) and Ryan Schmidt
NGS Utility for Assessment of T/B-cell Clonality	David Viswanatha (Chair), Keyur Patel, Maria Arcila, Timothy Greiner, Joseph Khoury (CAP representative), David Wu, Devon Chabot-Richards (SH representative) and Habibe Kurt
New Frontiers in Infectious Diseases Multiplex Testing	Michael Lewinski (Chair), Susan Butler-Wu, Kevin Alby, Jennifer Dien Bard, Alex Greninger, Esther Babady (PASCV representative), Duane Newton (ASM representative), Kimberly Hanson (IDSA representative) and Samia Naccache
Guidance/Standards for Tumor Mutational Burden Testing by Molecular Methods	Larissa Furtado (Chair), Jeffrey Gregg, Benjamin Kipp, Jonathan Nowak, Susan Hsiao, Antonia Sepulveda, Ahmet Zehir, Jeremy Segal, Lauren Ritterhouse, Mark Boguski, Carlo Bifulco (SITC representative), Neal Lindeman (CAP representative), Solange Peters (ASCO representative) and Daniel Dolderer
Implementation of AMP/ASCO/CAP Reporting and Interpretation of Somatic Sequence Variants Recommendations in Clinical Practice (VITAL Somatic)	Marilyn Li (Chair), Somak Roy, Cindy Vnencak-Jones, Catherine Cottrell, Matthew Ferber, Kai Wang and Scott Turner
Guidance/Standards for the Use of In Silico Approaches for Validation of NGS Bioinformatics Pipelines	Eric Duncavage & Justin Zook (Co-chairs), Mark Routbort, Joshua Coleman, Annette Meredith, Carlos Jose Suarez, Sabah Kadri, Somak Roy (CAP representative), Monica de Baca (API representative) and Chad Vanderbilt
Molecular MRD Monitoring in Acute Myeloid Leukemia	Keyur Patel (Chair), Noah Brown, Dan Jones, Marian Harris, Rashmi Goswami, Duane Hassane, Todd Druley, Brian Parkin, Annette Kim, Christopher Watt (CAP representative), Aaron Shaver (ASH representative), David Wu (SH representative) and Harrison Tsai

AMP External Representatives Program

AMP Representative	Collaborating Organization(s)	Workgroup / Committee
Daniel Farkas	College of American Pathologists	Molecular Oncology Committee
Scott Turner	American College of Medical Genetics and Genomics, ClinGen, College of American Pathologists	Interpretation of Sequence Variants Update Workgroup
Monica Basehore	National Institute of Standards and Technology	Genome in a Bottle Steering Committee
Carolyn Sue Richards	American College of Medical Genetics and Genomics	Incidental Findings in Inherited Diseases Update Workgroup
Lauren Ritterhouse Ahmet Zehir	College of American Pathologists, American Society of Clinical Oncology	PD-L1 Testing in Lung Cancer Workgroup
Federico Monzon	American Society of Clinical Oncology	CancerLinQ Oncology Leadership Council
Marilyn Li	American College of Medical Genetics and Genomics, ClinGen	Somatic Cancer Clinical Domain Workgroup
Maria Bettinotti	Foundation for the National Institutes of Health	Biomarkers Consortium Steering Committee for Inflammation and Immunity
Ming Rong	Foundation for the National Institutes of Health	Biomarkers Consortium Steering Committee for Metabolic Diseases
Snehal Patel	Foundation for the National Institutes of Health	Biomarkers Consortium Steering Committee for Cancer
Christina Lockwood	Foundation for the National Institutes of Health	Biomarkers Consortium Identification and Validation of ctDNA Reference Materials Working Group
Sinchita Roy-Chowdhuri	American Society of Cytopathology	Organizational liaison
Benjamin Pinsky	American Society for Microbiology	Next Generation Sequencing Coalition
Pranil Chandra	College of American Pathologists	Personalized Healthcare Committee Incidental Findings in the Context of Tumor Genomic Evaluations Project Workgroup
Nikoletta Sidiropoulos Jane Gibson	College of American Pathologists	Cytopathology Committee/Personalized Healthcare Committee Pre-analytics for Precision Medicine Cytology Preparations for Molecular Testing Project Team
Ryan Schmidt	College of American Pathologists	Genomic Medicine Resource Committee
Avni Santani	Clinical Laboratory Standards Institute	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine, 2nd Edition (MM09) Working Group

AMP Representative	Collaborating Organization(s)	Workgroup / Committee
Winand N.M. Dinjens	World Health Organization	International Collaboration for Cancer Classification and Research (IC3R) Meeting
Frederick Nolte	Test Renaming for Understanding and Utilization (TRUU-Lab) coalition	Steering Committee
Peter Canoll Dolores Lopez-Terrada Meera Hameed	College of American Pathologists, American Association of Neuropathologists, American Society of Clinical Oncology, Society for Neuro-Oncology	Diagnostic Testing for Diffuse Gliomas Workgroup
Antonia Sepulveda	College of American Pathologists, American Society of Clinical Oncology	Checkpoint Inhibitor Testing in Body Sites Other Than Lung
Jan Nowak Dara Aisner	College of American Pathologists, American College of Chest Physicians, American Society for Cytopathology, American Thoracic Society, Pulmonary Pathology Society, Papanicolaou Society of Cytopathology, Society of Interventional Radiology, Society for Thoracic Radiology	Appropriate Collection and Handling of Thoracic Specimens for Laboratory Testing Workgroup
Mary Lowery-Nordberg Jennifer Yoest	American Association of Clinical Chemistry	Lab Tests Online Editorial Board
Eric Duncavage	Association of Community Cancer Centers	Advisory Committee

AMP Economic Affairs Committee Annual Report, 2019

COMMITTEE MEMBERS:

Chair	Samuel K. Caughron, MD
Vice Chair, New Codes & Pricing	Anthony N. Sireci, MD, MS
Vice Chair, Coverage	Pranil Chandra, DO
Member	Jennifer Dien Bard, PhD
Member	Rajyasree Emmadi, MD
Member	Andrea Ferreira-Gonzalez, PhD
Member	Tanner Hagelstrom, PhD, MBA
Member	Mathew Hiemenz, MD
Member	Susan Hsaio, MD, PhD
Member	Lloyd Hutchinson, PhD
Member	Loren Joseph, MD
Member (*Ex Officio* – PRC Chair)	Jordan Laser, MD
Member	Elaine Lyon, PhD
Member	Federico Monzon, MD
Member	Jay L. Patel, MD
Member (*Ex Officio* – President)	Victoria Pratt, PhD
Member	Richard Press, MD, PhD
Member	Aparna Rajadhyaksha, MD
Member	Oana C. Rosca, MD
Member	Katherine Tynan, PhD
Member (*Ex Officio*-President-Elect)	Karen Weck, MD
Junior Member	Salvatore Priore, MD, PhD
Committee Advisor	Aaron D. Bossler, MD, PhD
Committee Advisor	Jan A. Nowak, MD, PhD

PURPOSE SUMMARY:

The Economic Affairs Committee (EAC) addresses, advises, and educates the AMP Board of Directors, membership, payors, 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 availability to patients 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.

2019 ACTIVITIES:

CMS, who has oversight of Medicare, has increasingly either denied coverage or reduced payment for many medically necessary molecular pathology tests. 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 engage and inform payors who aim to achieve rightful reimbursements for appropriate patient care services.

Molecular Pathology Economics Summit

On September 20, over 70 participants from pharmaceutical companies, diagnostic manufacturers, clinical laboratories, patient groups, as well as trade and professional associations attended AMP's inaugural Economics Summit in Washington, DC. The Economic Affairs Committee undertook this initiative recognizing that multiple

stakeholders from different industries are affected by the economic challenges plaguing clinical molecular diagnostics. Each industry and stakeholder is uniquely impacted, but there is common alignment around an interest in improving the overall economics for diagnostic testing.

During the Summit, a series of roundtable discussions were held, each focused on a specific stakeholder perspective including clinical laboratories, pharmaceutical companies, in vitro diagnostic manufacturers, and patient advocacy groups. Interactive candid discussions explored the unique challenges confronting each of these stakeholder groups. The group's guided discussions identified barriers to appropriate reimbursement for molecular pathology procedures; the impact of these barriers on various stakeholders and patient access to care; potential solutions and/or novel approaches to overcoming barriers, with the goal of identifying shared policy agendas for the participating stakeholders.

The committee will release a summary of the meeting, work to address identified barriers and solutions with attendees in 2019, and has plans to make this an annual event moving forward.

National Coverage Determination for NGS for Advanced Cancer for Medicare Beneficiaries
In late November 2017, CMS released a proposed National Coverage Determination (NCD) for next generation sequencing (NGS) for advanced cancer. The proposed policy had the potential to restrict laboratories' ability to obtain Medicare coverage for NGS-based tests for oncology. CMS received over 315 comments, with the majority of the comments expressing concern and seeking clarification from CMS on the proposed policy. Last year, CMS released the final NCD for Next-Generation Sequencing (NGS) for Medicare Beneficiaries with Advanced Cancer (referred to here as the NGS NCD) and was an improvement over the proposed policy.

AMP remained cautious about the implementation of this policy and watched it closely. Late last year, when CMS published implementation guidance to the MACs, stakeholders discovered that CMS includes germline testing within the scope of the NGS NCD. The implication of this interpretation is both germline and somatic tumor NGS-based testing will become non-covered for Medicare beneficiaries with early-stage cancer. In response to this, AMP spearheaded a stakeholder sign-on letter with 62 other organizations to urge CMS to revise its current interpretation of the NCD by limiting it to somatic tumor testing and to communicate this change to the MACs. This sign-on letter is significant in that it showed the diversity of stakeholders, which included providers, patient advocates, diagnostic test manufacturers, academic medical centers and laboratories, are all concerned about the downstream effects of the agency's NGS NCD interpretation on patient care.

In response to stakeholder concern, on March 26th, the CMS Coverage and Analysis Group (CAG) announced their plans to reopen the NCD. At the end of April 2019, CMS opened a formal reconsideration of "the evidence available for tests of germline mutations to identify those with hereditary cancer who may benefit from targeted treatments based on the results of the test" included in the NGS NCD. AMP submitted comments to CMS that stressed that the NCD should never have included NGS-based germline testing and requested that CMS exclude NGS-based germline testing for early stage cancer from the scope of the NCD. AMP recommended that CMS instead delegate the authority to develop coverage policies for NGS-based germline testing for early stage cancers to the local Medicare Administrative Contractors (MACs) if CMS determines it is unable to exclude germline testing from the NCD's scope. AMP also pointed out that this course of action would allow for MACs to reinstate the coverage for germline testing for patients that was in place before the NCD's effective date. Beyond AMP's request for the delegation of coverage decisions, AMP provided extensive evidence and guidelines that support the medical benefit of testing procedures that analyze germline mutations.

Following the release of the tracking sheet (announcing the reopening of the NCD), CMS has 6 months to issue a Proposed Decision Memo and then 90 days to issue the Final Decision. Following the release of the Proposed Decision Memo, there will be a 30-day comment period and AMP plans to comment. Additionally, AMP continues to meet with staff for the Senate Finance Committee and the House Ways and Means Committee, the two committees with jurisdiction over Medicare, to discuss our concerns with the NGS NCD. AMP will remain

highly engaged on this issue to ensure that CMS' policy does not hinder patient access to clinically-appropriate testing for cancer patients.

Protecting Access to Medicare Act (PAMA)
Under the Protecting Access to Medicare Act of 2014 (PAMA), laboratories that perform clinical diagnostic laboratory tests are required to report the amounts they are paid by private insurers for the laboratory tests to the Centers for Medicare and Medicaid Services (CMS). CMS then sets the Medicare payment rates for laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS) based on the weighted median of the private payor data. During the CY 2019 Physician Fee Schedule rulemaking process, CMS revised the definition of "Applicable Laboratory" to now include outreach hospital laboratories. AMP held a webinar in December 2018 to educate members about the updated PAMA requirements and to help members determine if their laboratory is an "applicable laboratory."

The next round of collecting private payor data began on January 1, 2019 and will need to be reported to CMS starting on January 1, 2020. Data must be reported by March 31, 2020. CMS will post preliminary CY2021 Medicare CLFS rates (based on the weighted median private payor rates) in late 2020 and those rates will be effective on January 1, 2021.

AMP remains very concerned about the effects of PAMA. In 2019, the Laboratory Access for Beneficiaries (LAB) Act was introduced in Congress. The LAB Act is bipartisan legislation that addresses some of AMP's and other stakeholders' concerns with PAMA. It delays the next round of data reporting by one year and delays the timing for payment reductions under PAMA. These delays are important so that applicable laboratories have time to understand the reporting requirements, make preparations to accurately collect their data, and ensure those data are accurately reported to CMS.

AMP wrote a letter of support for the LAB act applauding its introduction. AMP believes that the bill is an important first step to addressing concerns with implementing parts of the Protecting Access to Medicare Act (PAMA). However, AMP continues to have concerns about additional elements of PAMA implementation beyond those that are addressed in this bill, including and most notably concerns regarding the integrity of data submitted by laboratories to establish market-based pricing for codes on the Clinical Laboratory Fee Schedule (CLFS). In addition to supporting the LAB Act, AMP looks forward to working with the Agency and Congress to ensure that clinical laboratories maintain the ability to provide potentially life-saving services to patients.

Professional Reimbursement
In late 2018, members from both EAC and the Professional Relations Committee (PRC) decided to address anew two significant deficiencies in reimbursement for professional services. The first being that only physicians (MD/DO) are reimbursed for clinical interpretation of molecular results, even though a substantial amount of interpretation work is done by PhDs. This was a major policy focus for AMP 2011-2012, until the new molecular pathology CPT codes were placed on the CLFS. The second issue is that the current coding structure does not align well with the professional services of interpreting these results and preparing a test report. This joint EAC and PRC working group worked diligently in 2019 to understand the coding landscape for professional services and continues to gather data on PhDs and MDs performing interpretations of molecular procedures. Both objectives of this working group will be a focus for EAC and PRC in 2019.

National Correct Coding Initiative (NCCI) Manual
Late last year, the National Correct Coding Initiative (NCCI) contractors and the Centers for Medicare and Medicaid Services (CMS) released revisions to the Pathology/Laboratory Services section of the NCCI Policy Manual for Medicare Services, and corresponding updates to the Policy Manual for Medicaid Services, that took effect on January 1, 2019. AMP remains very concerned about the effect these revisions will have on our members and the negative impact to patient access to medically appropriate molecular testing. AMP requested that the updates be withdrawn and that any future manual updates be developed in consultation with the relevant stakeholders. Additionally, AMP signed on to a letter with eight other organizations. This letter

expressed concern at the process by which these updates were promulgated, requested the NCCI contractors/CMS withdraw these updates and work with the stakeholders moving forward. In addition to these comment letters, AMP and the aligned stakeholders met with CMS on this issue. AMP continues to work with stakeholders and CMS on this issue.

Clinical Lab Fee Schedule for Calendar Year 2019
During the summer, AMP provided written and oral comments to CMS on the Calendar Year 2020 Clinical Lab Fee Schedule (CY2020 CLFS). **Dr. Anthony Sireci** represented AMP at the annual CLFS meeting at CMS on June 24, 2019. He presented crosswalk recommendations for the new and reconsidered CY2020 CLFS molecular pathology, genomic sequencing, and microbiology procedures.

Additionally, the Advisory Panel on Clinical Diagnostic Tests (The Advisory Panel) reviewed stakeholder recommendations present to CMS in June and voted on the best approach to pricing new and reconsidered codes. The Panel was established by PAMA and advises CMS on various issues under PAMA including payment rates for new tests, including whether to use the crosswalk or gapfill methodology for initial price determination. Several AMP members are members of The Panel, with **Drs**. **Aaron Bossler, Elaine Lyon,** and **Pranil Chandra** nominated by AMP to serve.

In late September, CMS released the CY2020 CLFS Preliminary Determinations for the new and reconsidered services. While some of the preliminary CMS determinations align with AMP and other laboratory organizations' recommendations, some of the preliminary recommendations provided by CMS differ vastly from both the Advisory Panel recommendations and stakeholder input and, in many cases, do not represent the best options for crosswalks. AMP provided detailed comments to CMS on the preliminary determinations at the end of October. Pricing determinations will be finalized later this year.

Educational Initiatives
Healthcare economics is a complex ecosystem comprised of players in the provider space (doctors, patients, professional societies), healthcare leaders, government agencies and payors in the private sector. Navigating this space can be very difficult but is vital for molecular professionals, particularly laboratory directors, to understand. In 2017, a workgroup formed within the EAC, led by **Drs. Dara Aisner and Anthony Sireci**, to develop a manuscript that builds off of previous efforts by the EAC to educate others on molecular diagnostic coding, coverage, and reimbursement process, procedures, and policies. This manuscript is currently undergoing peer review at the *Journal of Molecular Diagnostics*.

Medicare Administrative Contractors' (MACs) Local Coverage Determinations (LCDs)
AMP continues to advocate with CMS regarding coverage policy actions taken by Medicare Administrative Contractors (MACs). Thus far in 2019, AMP has provided responses to various MACs for approximately 7 draft local coverage determinations (LCDs). Currently, AMP is in the process of drafting comments to additional draft 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. Pranil Chandra.** 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.

Capitol Hill and Agency Activity
Throughout 2019, AMP met with numerous offices on Capitol Hill regarding concerns about Medicare coverage and pricing, including majority and minority staff of Senate Finance and House Ways and Means Committees. Additionally, AMP met with CMS representatives from both the pricing and coverage groups about concerns regarding the national coverage determination on NGS, pricing process for PLA codes, NCCI edits, and gapfill pricing transparency.

CPT Codes

The EAC New Codes and Pricing Subcommittee, led by **Dr. Anthony Sireci**, advises and reviews new CPT code applications submitted to the Pathology Coding Caucus (PCC) and the Molecular Pathology Advisory Group (MPAG). Throughout the year, the Subcommittee also submits new CPT code change proposals to AMA. In 2019, AMP submitted six CPT code change applications. The subcommittee also provided input to CMS' National Correct Coding Initiative (NCCI) to help ensure national correct coding methodologies of procedure to procedure (PTP) and medically unlikely edits (MUEs) for molecular procedures.

Outside Organization Involvement

- **Dr. Jan Nowak** serves on the CPT Editorial Panel
- **Drs. Victoria Pratt, Jan Nowak, Aaron Bossler** serve on the AMA Proprietary Laboratory Analyses Technical Advisory Group (PLA-TAG)
- **Dr. Aaron Bossler** serves on the PCC, with **Dr. Anthony Sireci** serving as the technical advisor.
- The AMA Molecular Pathology Advisory Group (MPAG) includes AMP members **Drs**. **Anthony Sireci, Roger Klein, Elaine Lyon**, and **Victoria Pratt**.

AMP Finance Committee Annual Report, 2019

COMMITTEE MEMBERS:

Chair	Daniel E. Sabath, MD, PhD
President	Victoria M. Pratt, PhD
President-Elect	Karen Weck, MD
Past President	Kojo S. J. Elenitoba-Johnson, MD
Member	Sharathkumar Bhagavathi, MD
Member	Steven A. Schichman, MD, PhD
Member	Xiao-Ming Yin, MD, PhD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

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, 2019

COMMITTEE MEMBERS:

Chair and Membership Affairs Liaison (Middle East)	Rami Mahfouz, MD
Member (Africa)	Adewunmi Oluseye Adeoye, MD
Member and Professional Relations Liaison (Europe)	David E. Barton, PhD
Member (East Asia)	Benedict Yan, MBBS
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 Kyung Lee, MD, PhD
Member (Southeast Asia)	Lynette Lin Ean Oon, MD
Member and Training & Educ Liaison (Latin America)	Roberta Sitnik, PhD
Member and Hong Kong Affiliate Liaison (East Asia)	Lei Po (Chris) Wong, PhD
Member (Africa)	Denis Francis York, PhD
German Affiliate Coordinator	Silke Lassmann, PhD
Italy Affiliate Coordinator	Massimiliano (Max) M. Corsi Romanelli, MD, PhD
Advisor	Helen Fernandes, PhD
Advisor	Jin-Yeong Han, 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

2019 ACTIVITIES:

- Vetted and approved a new International Affiliate member: Middle East Molecular Biology Sources
- AMP Global Congress was held on May 16-18, 2019 in Hong Kong
- AMP 2019 Annual Meeting Events:
  - Certification in Molecular Pathology Outside the USA luncheon
- Selected International Trainee Travel Awardees from India and Canada.
- Awarded International Membership Grants to scientists from India and Tanzania.
- Supported AMP speakers at international (non-U.S.) conferences:
  - Margaret L. Gulley, MD at the Molecular Pathology Association of India 7th Annual Meeting, Mumbai, India. Organizing Committee AMP Member: Bibhu R. Das, PhD
  - Mark D. Ewalt, MD at the 2019 Annual Meeting of Korean Society for Genetic Diagnostics, Seoul, Korea. Organizing Committee AMP Member: Jin Kyung Lee, MD, PhD.
  - Andrea Ferreira-Gonzalez, PhD and Victoria Pratt, PhD at the Brazilian Society of Clinical Pathology 53rd Congress (Rio de Janeiro, Brazil). Organizing Committee AMP Member: Roberta Sitnik, PhD

AMP Membership Affairs Committee Annual Report, 2019

COMMITTEE MEMBERS:

Chair	Midhat S. Farooqi, MD, PhD
Member	Betsy A. Bove, PhD
Member	Yi Ding, MD, PhD
Member	James Fuller, PhD
Member	Lisa M. Haley, MS
Member	Cristiane Ida, MD
Member	Giovanni Insuasti-Beltran, MD
Member, Representative to Training & Education	Cynthia L. Jackson, PhD
Member	Irene Newsham, PhD
Member	Wanda Reygaert, PhD
Member	Angshumoy Roy, MD, PhD
Member	Yaolin Zhou, MD
Junior Member	Talent Theparee, MD
International Affairs Liaison	Rami Mahfouz, MD

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.

Ongoing Responsibilities Include:

- 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

2019 ACTIVITIES:

- Selected the winners of the Technologist Travel Awards for 2019
- Planned and enhanced the Speed Networking Events at the 2019 Annual Meeting & Expo
- Planned and hosted the New Member & First Timer Lunch at the 2019 Annual Meeting & Expo
- Developed committee member-driven projects to increase recruitment, retention, and member satisfaction. These ongoing projects include:
    - Using graphic design to better convey the value of membership
    - Working with the Program Committee to enhance technologist specific content at the Annual Meeting

    - Maximizing networking events at the Annual Meeting with improvements to the MAC speed networking event
    - Fostering membership opportunities for trainees in low income countries
    - Welcoming new members recruited through the Free Associate Membership pilot program
    - Cooperating with Molecular Genetic Technology undergraduate programs to provide access to AMP memberships to encourage participation in AMP early in their careers
- Continued work on the Free Associate Membership pilot program which offers free memberships to attendees at meetings where AMP exhibits for the purpose of assessing free Associate Membership as a tool for new member recruitment. In 2019 this pilot included members recruited at the USCAP and ACMG Annual Meetings.
- Worked closely with the International Affairs and Training & Education Committees to ensure that membership needs are met around the globe and through educational offerings.

AMP Nominating Committee Annual Report, 2019

COMMITTEE MEMBERS:

Chair	Kojo S. J. Elenitoba-Johnson, MD
Genetics Subdivision Representative	Bert Gold, PhD
Genetics Subdivision Representative	Qiulu Pan, MD, PhD
Hematopathology Subdivision Representative	David Viswanatha, MD
Hematopathology Subdivision Representative	Keyur Patel, MD, PhD
Infectious Diseases Subdivision Representative	Amanda Harrington, PhD
Infectious Diseases Subdivision Representative	Blake W. Buchan, PhD
Informatics Subdivision Representative	Carlos J. Suarez, MD
Informatics Subdivision Representative	Nefize Sertac Kip, MD, PhD
Solid Tumors Subdivision Representative	Shelby Melton, MD
Solid Tumors Subdivision Representative	Anna Yemelyanova, MD
President	Victoria M. Pratt, PhD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

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.

2019 ACTIVITIES:

The Nominating Committee nominated Officers and Committee Representatives for the 2019 annual elections.

AMP Professional Relations Committee Annual Report, 2019

COMMITTEE MEMBERS:

Chair	Jordan Laser, MD
Vice-Chair	Eric Q. Konnick, MD
Member	Linnea M. Baudhuin, PhD
Member (*Ex officio* – EAC Chair)	Samuel Caughron, MD
Member	Jill Hagenkord, MD
Member	Robert F. Klees, PhD
Member	Roger Klein, MD, JD
Member	Amy Lo, MD
Member	Elaine Lyon, PhD
Member	Jill Murrell, PhD
Member	George J. Netto, MD
Member	Nirali M. Patel, MD
Member (*Ex officio* – President)	Victoria M. Pratt, PhD
Member	David Viswanatha, MD
Member (*Ex officio* – President-Elect)	Karen Weck, MD
Member	Barbara Zehnbauer, PhD
Junior Member	Betty Chung, DO, MPH, MA
Junior Member	Jason Rosenbaum, MD
International Affairs Committee Liaison	David E. Barton, PhD
AMP Rep. to FASEB Science Policy Committee *(Ex Officio)*	Betsy A. Bove, PhD

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.

2019 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 the Roundtable on Genomics and Precision Health at the National Academies of Sciences, Engineering, and Medicine. 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 and Megan Anderson Brooks of Innovation Policy Solutions, LLC (IPS), 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 Director of Public Policy and Advocacy, Tara Burke, AMP Policy Analyst, Sarah Thibault-Sennett 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 2019 continued to be regulatory oversight of laboratory developed testing procedures (LDPs), also known as laboratory developed tests (LDTs). Since FDA announced their decision not to finalize their draft guidance for LDPs, conversations about LDP oversight have shifted to Congress. AMP remains actively engaged with legislators on Capitol Hill. AMP maintains that updating the Clinical Laboratory Improvement Amendments (CLIA) oversight will preserve a flexible system that fosters innovation and is also the most streamlined, cost-effective approach to addressing clinical and analytic validity and establishing enhanced transparency.

LDP advocacy efforts in 2019 involved communicating concern about a draft bill, released by Reps. Bucshon and DeGette in late 2018, entitled "The Verifying Accurate Leading-edge IVCT (In Vitro Clinical Test) Development Act of 2018" (VALID Act). The VALID Act draft creates a single regulatory pathway at the FDA for both LDPs and in vitro diagnostic tests (IVDs). The framework as written would exempt low risk tests from FDA premarket review, requires premarket review for what the co-sponsors consider to be high risk tests, and also proposes a voluntary precertification program for laboratories offering tests in a middle category that would allow those tests to be exempt from review if certain conditions were met. Laboratories would also have to comply with many other requirements including notification, quality system requirements, and adverse event reporting.

In early 2019, AMP submitted detailed comments on the VALID Act draft and expressed numerous concerns about the legislation. In addition to providing detailed comments, AMP continues to lead a diverse group of stakeholders who oppose VALID and FDA oversight of LDPs to bring their individual advocacy efforts into alignment and to amplify our message. AMP meets actively with the FDA and members of Congress, including the co-sponsors, to provide a key perspective …..advocate for the development of a modern and flexible oversight system that allows AMP's members to continue providing personalized care for their patients.

Draft Legislation to Change Section 101 of the Patent Law: Reigniting Gene Patent Concerns

AMP was the named plaintiff in the lawsuit, *AMP v. Myriad Genetics,* challenging patents on two genes associated with hereditary breast and ovarian cancer, *BRCA1* and *BRCA2*. At the time, Myriad Genetics held patents on *BRCA1* and *BRCA2*, enabling them to be the sole provider of this test and creating a testing monopoly, which highly restricted patient access and drove up the price of testing. In 2013, the Supreme Court decided unanimously that isolated human DNA is a product of nature and not eligible to be patented. Earlier this year, following a series of closed roundtable discussions, Senators Tillis (R-NC) and Coons (D-DE) and Representatives Collins (R-GA), Johnson (D-GA), and Stivers (R-OH) released draft legislation that proposed to radically alter Section 101 of the Patent Act and drastically broaden what would be patent eligible. The released language would shift the focus of Section 101 to favor those seeking patents by allowing patents on anything found to be useful. The draft proposed to expand patent eligibility by explicitly indicating that judicially-created exceptions to patentability for "abstract ideas," "laws of nature," or "natural phenomena" could not be used to determine patent eligibility. Moreover, the draft proposed to abrogate all court decisions that led to or supported those exceptions, including *Mayo Collaborative Servs. v. Prometheus (2012), AMP v. Myriad (2013), and Alice Corp. v. CLS Bank (2014)*.

While this proposal would have large reverberations across all sectors of technology, AMP is concerned such action could have serious consequences on the molecular diagnostic space if naturally-occurring DNA segments and/or gene-disease associations are allowed to be patentable again. In order to make AMP's voice heard in this discussion, AMP spearheaded a sign-on letter with the American Civil Liberties Union (ACLU) to strongly oppose the draft legislation to rewrite Section 101 of the Patent Act and to warn about the consequences of allowing

DNA and gene-disease associations to be patentable. Signers of the letter include those within the scientific, medical, and patient community, with approximately 200 organizations listed. While the sponsors of the legislation have since stated that it was not their intent to allow patenting of "DNA within the human body," AMP remains very concerned about the consequences of this evolving proposal, regardless of intent, and the potential effects that they could have on our field. AMP anticipates that the next draft of the legislative proposal will be released sometime in the next few months. In the meantime, AMP continues to work diligently with aligned stakeholders to lead efforts to educate others about this issue and advocate for naturally-occurring DNA segments and gene-disease associations to remain patent ineligible to Congressional offices.

Consumer Genomic Testing

In 2007, AMP released its first position statement on Consumer Genomic Testing (then referred to as Direct-To-Consumer Testing or DTC genetic testing), which concluded that healthcare related genetic testing should be available only through appropriately qualified health professionals who order tests from CLIA-certified laboratories. In 2015, AMP's position was revised to support clinically meaningful DTC genetic testing, as long as certain conditions were met.

This past year, a taskforce of the Professional Relations Committee determined that the landscape of Consumer Genomic Testing had evolved significantly to warrant a reexamination of AMP's 2015 position statement. In June, AMP released a newly revised position statement that includes considerations that are pertinent for today's Consumer Genomic Testing field. The statement includes updates to the aspects that AMP requires for clinically meaningful Consumer Genomics Tests, such as requiring all health-related claims to have well-established clinical validity and encouraging testing providers to recommend that consumers discuss clinically actionable results with their physicians. The statement reaffirms that testing providers must comply with CLIA statue and regulations, and that test validation and interpretation should be performed by board-certified molecular professionals. Additionally, the statement encourages testing providers to adhere to The Future of Privacy Forum's "Privacy Best Practices for Consumer Genetic Testing Services."

Best Practices in Pharmacogenomics

In September, AMP released a statement on the Best Practices in Pharmacogenomics to provide a set of conditions to ensure that pharmacogenomic tests are clinically meaningful and improve patient care and professional practices. The conditions include: all health-related pharmacogenomic claims must have well-established clinical validity; the pharmacogenomic testing provider must comply with the CLIA statue and regulations; the pharmacogenomic test report should be comprehensible by healthcare providers and include the interpretation of the findings, the significance of the results, as well as the limitations of the test; and a strong recommendation that patients should not change their treatment plan without first talking to their healthcare provider. Additionally, AMP encouraged the use of the gene-drug practice guidelines, such as those created by the international Clinical Pharmacogenetics Implementation Consortium (CPIC).

Patient Advocacy Group Engagement

Since 2016, AMP has held "Lunch and Learn" events with patient groups, with the objective of identifying and establishing relationships with relevant patient groups in oncology, inherited conditions, and infectious diseases. AMP aims to understand the goals and needs of the patient groups, identify ways we can work together, and effectively communicate that patient care is central to AMP members' practice. The events have been incredibly well-received with both the representatives from patient groups and AMP members excited by the things that were discussed.

In June, AMP held a Washington, D.C.-based lunch and learn hosted by **Dr. Karen Weck** with a focus on how the newly proposed legislation to redefine Section 101 of the Patent Act would affect gene patents and the field of molecular diagnostics. The next lunch and learn will take place at the Annual Meeting. The goals of these events are for the patient groups to gain a better understanding of why molecular pathology needs to be better incorporated into standard of care, the hurdles to achieving that, and how they can partner with AMP to make this a reality. Additionally, AMP is able to identify ways that they can engage and strengthen working

relationships with the patient community in order to create the bidirectional conversation that will result in professional practice that reflects patients' needs. The PRC is continuing these efforts and plans to continue this program in 2020 with the objective to finalize a new webpage devoted to patients on molecular diagnostic testing.

National Coverage Determination for NGS for Advanced Cancer for Medicare Beneficiaries

The PRC assisted the Economic Affairs Committee (EAC) in developing comments to CMS on the National Coverage Determination (NCD) for NGS for Advanced Cancer for Medicare Beneficiaries in 2018 and remained involved throughout additional advocacy efforts this year. When CMS published implementation guidance to the Medicare Administrative Contractors (MACs) earlier this year, stakeholders discovered that CMS included germline testing within the scope of the NCD. The implication of this interpretation is that both germline and somatic tumor NGS-based testing will become non-covered for Medicare beneficiaries with early-stage cancer. AMP spearheaded a sign-on letter to CMS opposing the interpretation, which resulted in CMS reconsidering the NCD. In May, AMP submitted comments that stressed that CMS should have never included germline testing for early stage cancer in the scope of the NCD and recommended that CMS delegate the authority to develop coverage policies for NGS-based germline testing for early stage cancers to the local MACs. AMP anticipates that CMS will release a Proposed Decision Memo in late October and plans to submit comments along with the other engaged stakeholders.

Capitol Hill

AMP continues to nurture existing and grow new relationships on Capitol Hill. Throughout 2019, AMP met with approximately 30 offices on Capitol Hill regarding topics including oversight and regulation of LDPs, the National Coverage Determination for NGS for Advanced Cancer for Medicare Beneficiaries, and proposed Section 101 Patent Reform. Specifically, AMP met with staff for Senate HELP and the offices of 15 other Senators. AMP also met with staff working for the House Judiciary Committee and the House Judiciary Subcommittee on Courts, Intellectual Property, and the Internet, in addition to the offices of 11 Representatives. Additionally, on November 5th, approximately 60 AMP members met with their elected representatives to discuss gene patents and LDP regulation and oversight as part of the AMP Advocacy Day during AMP 2019. During Advocacy Day, AMP requested meetings with representatives from 25 states: 50 Senate offices and 52 House offices.

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, Roger Klein, and Amy Lo**), National Academies of Sciences, Engineering, and Medicine Roundtable on Genomics and Precision Health (AMP representative **Dr. Vicky Pratt**), Federation of American Societies for Experimental Biology (FASEB) (AMP representative **Dr. Betsy Bove**), and the Cancer Leadership Council.

AMP Program Committee Annual Report, 2019

COMMITTEE MEMBERS:

Chair	Neal Lindeman, MD
Chair-Elect	Jane S. Gibson, PhD
Genetics Representative	Elaine B. Spector, PhD
Genetics Representative	Peter Kang, MD, MS, FCAP
Hematopathlogy Representative	Rashmi Kanagal Shamanna, MD
Hematopathlogy Representative	Mark D. Ewalt, MD
Infectious Diseases Representative	Jennifer Dien Bard, PhD
Infectious Diseases Representative	Esther Babady, PhD
Informatics Representative	Matthew Lebo, PhD
Informatics Representative	Angshumoy Roy, MD, PhD
Solid Tumors Representative	Christina Lockwood, PhD
Solid Tumors Representative	Rajyasree (Raj) Emmadi, MD
Technical Topics Representative	Fernanda Sabato, MS
Technical Topics Representative	C. Renee Webb, BS

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.

2019 ACTIVITIES:

Programming the 2019 Annual Meeting & Expo (25th Anniversary Celebration) from November 7-9, 2019 at the Baltimore Convention Center in Baltimore, MD.

AMP Publication & Communication Annual Report, 2019

COMMITTEE MEMBERS:

Chair	Paul G. Rothberg, PhD
JMD Editor-in-Chief	Barbara A. Zehnbauer, PhD
Test Directory Co-Editor	Nefize Sertac Kip, MD PhD
Test Directory Co-Editor	Annette Leon Meredith, PhD
Member	Mary C. Lowery-Nordberg, PhD
Member	Dahui Qin, MD, PhD
Member	Mohamadou Sene, BS, MB(ASCP)
Member	Shalini Verma, MD
Member	Shaochun Bai, PhD
JMD Managing Editor	Emily Essex
JMD Scientific Editor	Chhavi Chauhan, PhD

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 communicates via monthly conference calls.

2019 ACTIVITIES:

- Solicited and reviewed submissions for the AMP/CAP TODAY Case Report Program
- Continued support and feedback for Test Directory Editors and *Journal of Molecular Diagnostics* editorial team
- Began ongoing work on AMP Wikipedia Page
- Formally renamed as the Publications Committee after AMP membership approved a change to the Bylaws retitling the committee
- Solicited volunteer applications for new committee

AMP Strategic Opportunities Committee Annual Report, 2019

COMMITTEE MEMBERS:

Chair	Karen Weck, MD
Member	Michael Hadjisavas, PhD
Member	Annette S. Kim, MD, PhD
Member	Roger D. Klein, MD, JD
Member	Robert L. Nussbaum, MD
Member	Ester Stein, BS, MBA
Advisor	Jill Hagenkord, MD
Advisor	Terri E. Ozegovich, BS, MBA
Advisor	Christine K. Ward, PhD
President	Victoria M. Pratt, PhD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

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.

2019 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, 2019

COMMITTEE MEMBERS:

Chair	Cecilia C. S. Yeung, MD
Genetics Subdivision Representative	Yassmine Akkari, PhD
Genetics Subdivision Representative	Alanna Church, MD
Hematopathology Subdivision Representative	Rashmi S. Goswami, MD, PhD
Hematopathology Subdivision Representative	Kristin Hunt Karner, MD
Infectious Diseases Subdivision Representative	Preeti Pancholi, PhD
Infectious Diseases Subdivision Representative	Erin Graf, PhD
Informatics Subdivision Representative	Joshua F. Coleman, MD
Informatics Subdivision Representative	Sabah Kadri, PhD
Solid Tumors Subdivision Representative	Susan J. Hsiao, MD
Solid Tumors Subdivision Representative	Christian Kunder, MD, PhD
Junior Member	Brittany Coffman, MD
Junior Member	Cinthya Zepeda Mendoza, PhD
Medical Technologist Member	Mara Williams, MS
Medical Technologist Member	Barbara Anderson, MS
Membership Affairs Committee Liaison	Cynthia Jackson, PhD
International Affairs Committee Liaison	Roberta Sitnik, PhD

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 as well as technologist representatives, junior members, and liaisons from the International Affairs and Membership Affairs Committees (IAC and MAC). 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 2019):*** The T&E Committee organized an annual outreach course held just prior to annual meeting on November 6, 2019, 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 pre-analytic considerations in molecular pathology, followed by case studies presented by T&E members that illustrated a wide range of molecular diagnostic applications.

- ***Early Bird Sessions at the Annual Meeting & Expo - Case Studies presented by Trainees or Technologists:*** The T&E Committee hosted an opportunity for fellows, residents, postdocs, graduate students, or technologists who attended the AMP 2019 Annual Meeting & Expo to present an interesting and/or challenging case study during an Early Bird Session. Trainee/technologist presenters in 2019 were:

Case Studies in Genetics, Hemato-pathology and Solid Tumors (Thurs Nov 7)	Case Study: Somatic Mosaic IDH1 Mutation in a Case of Maffucci Syndrome	Diana Bryk, MD	New York Presbyterian Hospital - Columbia, New York, NY
	Case Study: Exome Reanalysis in a Patient with a Somatic CN-LOH in 17p and TP53 Mutation, and a Germline DNAJC21 Biallelic Mutation Associated with Myelodysplastic Susceptibility	Elan Hahn, MD	University of Toronto, Ontario, Canada
	Case Study: A Case of T-PLL with EZH2 Mutation; EZH2 the Sword or the Shield?	Panieh Terraf, PhD	Harvard Medical School - Brigham and Women's Hospital, Boston, MA
	Case Study: Ultra-hypermutated Pediatric Glioblastoma of Lynch Syndrome Mimicking Constitutional Mismatch Repair Deficiency Syndrome	Chen Yang, MD, PhD	Virginia Commonwealth University, Richmond, VA
	Case Study: B-lymphoblastic Leukemia with ZNF384 Gene Rearrangement	Shweta Bhavsar, MBBS, MD	University of Pittsburgh Medical Center, Pittsburgh, PA
	Case Study: 5q- in a Patient with Chronic Myelogenous Leukemia in Accelerated Phase	James Corines, DO	SUNY Upstate Medical University, Syracuse, NY
	Case Study: Molecular Diagnosis of MDS in a Non-diagnostic Bone Marrow Specimen	Jeffrey SoRelle, MD	University of Texas Southwestern Medical Center, Dallas, TX
	Case Study: The Role of Lymphoma Sequencing Panel in the Diagnosis of Pediatric-Type Follicular Lymphoma	Guang Yang, MD, PhD	University of Pennsylvania, Philadelphia, PA
	Case Study: Detection of Rare Fusion using Foundation One and Oncomine Tests: A Male in his 20's with an Aggressive Orbital Tumor	Terri Jones, MD	University of Pittsburgh Medical Center, Pittsburgh, PA
	Case Study: An Interesting Case Involving a CIC-NUTM1 Rearranged Epitheliod Tumor	Latrice Landry, PhD, MMSc, MS	Dana Farber Cancer Institute/ Brigham and Women's Hospital, Boston, MA
	Case Study: Microsatellites: Instability in an Apparently Stable World	Patrick Leach, BS	TriCore Reference Laboratories, Albuquerque, NM
	Case Study: A Case of Cutaneous Lymphoma with PCM1-JAK2 Rearrangement	Talent Theparee, MD	Stanford Healthcare, Stanford, CA

Case Studies in Hemato-pathology (Fri Nov 8)	Case Study: A Surprising Finding in Primary Cutaneous CD8-positive Aggressive Epidermotropic Cytotoxic T-cell Lymphoma	Mark Evans, MD	University of California, Irvine, CA
	Case Study: Clonal Selection Following FLT3 Tyrosine Kinase Inhibitor Treatment for Acute Myeloid Leukemia	Adam Fisch, MD, PhD	Massachusetts General Hospital, Boston, MA
	Case Study: Muddy Waters: A Report of Granulocytes Infusion Confounding Next-Generation Sequencing Interpretation	Tareq Qdaisat, MD	University of Nebraska Medical Center, Omaha, NE
	Case Study: Identification of a Cryptic ABL1 Rearrangement in a Refractory Acute Myeloid Leukemia Patient with Diploid Karyotype by Conventional Cytogenetics	Arash Ronaghy, MD, PhD	MD Anderson Cancer Center, Houston, TX

Case Studies in Solid Tumors (Sat Nov 9)	Case Study: Compound EGFR and BRAF Variants in NSCLC Against the Backdrop of Suspected MEN2A	Jeremy Adler, MD	Pennsylvania Hospital, Philadelphia, PA
	Case Study: EGFR-Mutated Lung Adenocarcinoma with Early Resistance to Osimertinib	Brennan Decker, MD, PhD	Brigham and Women's Hospital, Boston, MA
	Case Study: Expanded Next Generation Sequencing Panel Detects a Rare EGFR Kinase Domain Duplication in a Patient with Metastatic Lung Cancer	Jong Kim, MD	University of Pittsburgh Medical Center, Pittsburgh, PA
	Case Study: Pitfalls in Identification of Mismatch Repair Deficiency: An Unusual Pulmonary Intimal Sarcoma	Wanying Zhang, MD	New York Presbyterian Hospital, New York, NY

2019 Webcasts and Recorded Online Content (ROCs):

Date	Title	Speaker/T&E Moderator	NOTES (Registrants/Attendees)
Major Initiative: Tumor Mutational Burden II: Diagnostic Innovations and Clinical Implications			
June 6	**Tumor Mutational Burden:** Updates on Tumor Mutational Burden and the Immunotherapy Biomarker Landscape	Laura Tafe	469 / 203
August 15	**Tumor Mutational Burden:** Making TMB Relevant in the Clinic: Best Practices for TMB Calculation, Reporting, and Interpretation	Albrecht Stenzinger	699 / 306
Major Initiative: Targeting DNA Repair Pathways: Current and Future Implications of PARP Inhibitors			
July 18	Understanding the BRCA-Dependent DNA Repair Axis for Assessing Cancer Risk and Therapeutic Intervention	Ryan Jensen	370 / 152
August 29	Identifying Mutational Signatures of Homologous Recombination Deficiency to Predict PARPi Response	Peter Park	350 / 147
October 22	PARP Inhibitors in the Clinic: The Implications of Genetic Testing for Treatment Selection and Germline Counseling	Katherine Nathanson and Payal Shah	
Series Bundles			
January	**Liquid Biopsy**: A liquid biopsy content series using existing LMS content augmented with materials dictated by content-directors	Rashmi Goswami / Susan Hsiao	N/A
September	**Infectious Disease:** An infectious disease content series using existing LMS content augmented with materials dictated by content-directors	Preeti Pancholi /Sophie Arbefeville	N/A
Webinar Series: Horizons II - Hot Topics			
August 6	Applications of Long-read Sequencing Technology for Cancer Transcriptomics and to Understand Influenza Infection	Jesse Bloom and Angela Brooks /Cecilia Yeung	119 / 69
September 10	Using Machine Learning to Improve Variant Reporting	Jochen Lennerz / Sabah Kadri	323 / 160
December 10	Application of Geospatial Techniques in Analysis of Leukemias	Richard Hammer and Kelly Bowers / Kristin Karner	
Lab Management Series – Recorded Online Content			
ROC	Basics of Data Management and Analytics	Noah Hoffman and Patrick Mathias	N/A
ROC	Balancing the Laboratory Budget	Joseph Milano and Jacquelyn Roth	N/A
ROC	Lab Accreditation and Oversight	Cecilia Yeung	N/A
ROC	Ethical Issues in Molecular Pathology	Lauren Smith	N/A
Additional Webcasts			
September 5	Recommendations for Clinical CYP2C9 Genotyping Allele Selection: A Joint Recommendation of the Association for Molecular Pathology and College of American Pathologists	Stuart Scott / Yuan Ji	154 / 81
October 3	ID Bundle Teaser: Diagnosis of Sexually Transmitted Infections	Kimberle Chapin / Preeti Pancholi	202 / 116
ROC	Metagenomics in the Clinical Lab	Alex Greninger	For the ID Bundle

Education Initiatives

- ***Continuing Education credits (SAMs, CME, and CMLE):*** AMP offers Continuing Education credits for most educational activities. Accredited activities include the MGP Review Course (live and online), MPOC, live and enduring webinars, the 2019 Annual Meeting & Expo, and Recorded Online Content (ROC) lectures.

- ***Online education - AMPED™:*** The T&E Committee and staff spent significant time designing and developing educational materials for populating the online learning platform at educate.amp.org. Selected online educational offerings are complimentary for AMP members. Current content includes the a 5-webinar series on Tumor Mutational Burden, a 5-webinar series on NSCLC, and a 3-webinar series on PARP inhibitors. The site also features the online (enduring) 2019 MGP Review Course, 2017 and 2018 MPOC recordings, and 2018 Annual Meeting recordings.

- ***Course Bundles/AMP Certificate Programs:*** Also available on AMP*ED*™ are two new course bundles available as certificate programs. They are:

    1. Circulating tumor DNA testing – advances, challenges, and applications (i.e., "Liquid Biopsy") and

    2. Hot Topics in Infectious Diseases

  New content has also been recorded in 2019 for an upcoming bundle outlining an online curriculum for laboratory management.

- ***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.

- **Pocket Cards**: The T&E Committee continued expanding the "Molecular-in-My-Pocket" or "MIMP" reference card collection of subdivision topics and the successful oncology MIMP cards. Three new Oncology cards were made available in 2019 and the Training and Education Committee collaborated with the International affairs Committee to generate a new card called, ''*Establishing a Molecular Laboratory - Best Practices Around the Globe*." Cards are reviewed annually by T&E Committee members for accuracy and for any required updates. All MIMP Cards are available online, and hard copies are also distributed at the MGP Review Course, the Global Congress, the USCAP annual meeting, and AMP Central.

- **FISE Question Bank:** Continuing the collaboration with the MGP-PD Council, additional FISE exam questions were written by MGP faculty from many MGP-Fellowship institutions to cover a range of topics. The T&E Committee screens all questions annually. For each examination, a total of 45 questions randomly populated from a question bank of approximately 225 questions is given, yielding a different test each time. AMP staff provides non-attributed results to participating institutions at the beginning of the fellowship year (in October) and at the end of the year (in May/June).

Trainee Activities (Residents, Fellows, and Students)

- ***AMP 2019 Annual Meeting & Expo***

  Trainee and Technologists Luncheon and Book Drawing: The T&E junior and technologist members organized table discussion topics at the 2019 Training & Education Luncheon. Donated textbooks from AMP member authors were given away during the Trainee Luncheon.

- **Technologist Activities**
  - Technologist Career presentation at the Annual Meeting's Innovation Stage
  - Technologist mixer at AMP Central during the Annual Meeting
  - Updated technologist career development website
  - Ongoing planning of the development and coordination of resources for technologists

- **Awards**
  - Young Investigator Awards – 57 poster candidates
  - Technologist Poster Awards – 20 poster candidates
  - Technologist Travel Awards – 3 recipients (from Lebanon and USA)
  - International Trainee Travel Award (Supported by the Jeffrey A. Kant – AMP Education Fund) – Three recipients (from India and Canada)

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

  The MGP Program Directors (MGP PD) Council consists of Allison Cushman-Vokoun (Chair), Keyur Patel (Chair-Elect), and Shuko Harada (Past-Chair). 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. The Council worked with the T&E Committee to launch an in-service practice exam question bank for MGP Fellows.

- **Curriculum Development Task Forces**

  - ***Genomics Education for Primary Care Residents:*** This Task Force is led by Laura Tafe. 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. Other working group members are Yassmine Akkari, Maria Arcila, Devon Chabot-Richards, Anthony Snow and Preeti Pancholi.
  - ***MGP Fellow Training and Curriculum in Genomics Task Force:*** The Task Force is headed by co-leaders Jason Rosenbaum and Mark Ewalt and includes working group members Kristy Crooks, Jeff Gagan and David Wu. The manuscript is in the final stages and, upon completion, will be submitted to *JMD*. Additional authors are: Anna Berry, Alanna Church, Linda Jeng, Roger Klein, Mahesh Mansukhani, Federico Monzon, John Pfeifer, Hanna Rennert, Iris Schrijver, Laura Tafe, Vivianna Van Deerlin and David Wu.
  - ***Molecular Genetic Pathology (MGP) Curriculum Update (MGPCUP)*:** This task force is led by Karen Kaul and includes working group members Rashmi Goswami, Allison Cushman-Vokoun, Mark Ewalt, Harriet Feilotter, Julie Gastier-Foster, Jennifer Laudadio, Randy Olsen, Lauren Ritterhouse, and Jason Rosenbaum. The goal of this project is to prepare a set of recommendations and guidelines by which MGP training programs can develop curricula for MGP fellowship trainees.

Co-Sponsorships, Companion Meetings, and/or Collaborations

- ***United States and Canadian Academy of Pathology (USCAP) 2019***
  1. The AMP 2019 Companion Society Symposium, "*Practical Molecular Pathology: Considerations for your Practice",* was co-moderated by Yaolin Zhou and Jason Rosenbaum. Speakers were:
     - *Pre-analytic Variables that Impact Molecular Testing,* Sinchita Roy-Chowdhuri, MD, PhD
     - *Molecular Testing Pathways,* Tabetha Sundin, PhD
     - *Selection of Molecular Test Methodology,* Eric Duncavage, MD

  2. An AMP Short Course, *AMPlicons: Molecular Case Studies for the Practicing Pathologist* was co-presented by Annette Kim, MD, PhD and Cecilia Yeung, MD.

  3. 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

- ***American Society for Clinical Pathology (ASCP)***
  ASCP 2019 AMP Workshop: September 11-13 in Phoenix, AZ:
  Molecular Diagnostics Primer- Advanced Topics was presented by Susan Hsiao and Erin Graf

- ***College of American Pathologists (CAP)***
  CAP 2019 Course Presentations: September 21-24 in Orlando, FL
  The WHO and Beyond: The Myeloproliferative Neoplasms was presented by Kristin Karner and Rashmi Goswami

- ***Cambridge Health Institute (CHI) Conferences***

  - **Molecular Medicine Tri-Conference,** March 10-15, 2019, San Francisco, CA
    - **Short Courses:**
      SC12: Clinical Informatics: Returning Results from Big Data: Mark Routbort and Somak Roy
      SC3: NGS Assay Selection, Validation and Compliance: Birgit Funke, Karl Voelkerding, and Avni Santani

    - **Keynote Session:**
      LDT Regulation Debate Session Panel: What Should be the FDA's Role in Oversight of LDTs? A Town Hall Discussion: Victoria Pratt, Panelist

  - **Next Generation Dx Summit,** August 20-22, 2019, Washington, DC
    Reimbursement of Molecular Tests: Jennifer Dien Bard, Susan Butler-Wu, Kimberly Hanson, and Samuel K. Caughron

  - **Liquid Biopsy Summit,** June 17-19, 2019, San Francisco, CA
    Pre Conference Short Course: Advancing Liquid Biopsy Technologies from the Bench to the Clinic. Christopher Gocke, Christina Lockwood, and Mark Routbort

- ***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 Representatives: Maria Arcila and Christopher Watt.

AMP Subdivision Leadership Annual Report, 2019

SUBDIVISION LEADERSHIP

	Genetics	Hematopathology	Infectious Diseases	Informatics	Solid Tumors
Chair	Thomas Prior	Annette Kim	Frederick Nolte	Somak Roy	Roger Klein
Clinical Practice Committee	Jianling Ji	Noah Brown	Kenneth Muldrew	Justin Zook	Pranil Chandra
	Pinar Bayrak-Toydemir	Marian Harris	Daniel Cohen	Annette Meredith	Jonathan Earle
Nominating Committee	Bert Gold	David Viswanatha	Amanda Harrington	Carlos Jose Suarez	Shelby Melton
	Qiulu Pan	Keyur Patel	Blake Buchan	Nefize Sertac Kip	Anna Yemelyanova
Program Committee	Elaine Spector	Rashmi Kanagal-Shamanna	Jennifer Dien Bard	Matthew Lebo	Christina Lockwood
	Hyunseok Kang	Mark Ewalt	Esther Babady	Angshumoy Roy	Rajyasree Emmadi
Training & Education Committee	Yassmine Akkari	Rashmi Goswami	Preeti Pancholi	Joshua Coleman	Susan Hsiao
	Alanna Church	Kristin Karner	Erin Graf	Sabah Kadri	Christian Kunder

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 functions in an AMP advisory panel of discipline-specific subject matter experts convened to address issues of importance to their Subdivision. 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 and 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

2019 ACTIVITIES

Genetics - Addressed contemporary genetics topics as they relate to the clinical molecular diagnostics laboratory, including variant interpretation and classification, pharmacogenetics and forensics. Provided feedback to Scott Turner, AMP representative to the ACMG-led Interpretation of Sequence Variants Update Workgroup.

Hematopathology - Addressed topics in molecular hematopathology, including advances in translational research related to myelomas, MRD monitoring in hematologic malignancies, next-generation sequencing and immunology. Curated and provided a “Must Reads” list of hematopathology-relevant literature to the subdivision membership.

Infectious Diseases
Addressed infectious disease topics relevant to the clinical molecular diagnostics laboratory, including artificial intelligence related to diagnostic microbiology and liquid biopsy in infection. Hosted additional special sessions on Whole Genome Sequencing for Bacterial Strain Typing & Genomic Surveillance.

Informatics - Addressed topics related to development of bioinformatics pipelines for clinical next-generation sequencing and informatics tools in metagenomics. Hosted hands-on workshop session on routinely used laboratory bioinformatics tools.

Solid Tumors - Addressed topics related to clinical applications of circulating tumor cells, tumor mutational burden, liquid biopsies and other factors related to clinical practice of cancer.

Subdivision members provided invaluable assistance to the Economic Affairs Committee on drafting comments to proposed LCDs for Gastrointestinal Pathogen (GIP) Panels Utilizing Multiplex Nucleic Acid Amplification Techniques (NAATs) and drafting position statement on Consumer Genomic Testing. Subdivision Leadership also assisted the Professional Relations Committee in providing input for their efforts toward supporting the drafting of professional guidelines by federal and state regulatory organizations.

Members of the Subdivision Leadership hosted Open Forum sessions at the AMP 2019 Annual Meeting to engage their respective Subdivision members regarding challenges and opportunities for their community and explore how AMP might help to best address them. Members of the Subdivision Leadership also participated in the "Get involved with AMP" event at the Annual Meeting to engage with their respective Subdivision members and inform them of AMP's initiatives and projects in their interest areas.

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.