



## AMP 2015 Committee and Subdivision Annual Reports

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Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

## AMP Awards Committee Annual Report, 2015

### **COMMITTEE MEMBERS:**

Chair	Charles E. Hill, MD, PhD
Member	Kenneth Bahk, PhD
Member	Angela M. Caliendo, MD, PhD
Member	Karen L. Kaul, MD, PhD
Member	Tadd S. Lazarus, MD

### **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**

- 2015 Jeffrey A. Kant Leadership Award: Barbara A. Zehnbaauer, PhD
- 2015 Meritorious Service Award: Roger D. Klein, MD, JD
- 2017 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 to 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, continues to serve as AMP's representative.

*Submitted by Charles E. Hill, MD, PhD, Chair*

## AMP Clinical Practice Committee Annual Report, 2015

### COMMITTEE MEMBERS:

Chair	Marina Nikiforova, MD
Genetics Subdivision Representative	Carolyn S. Richards, PhD
Genetics Subdivision Representative	Birgit Funke, PhD
Hematopathology Subdivision Representative	Jennifer Crow, MD
Hematopathology Subdivision Representative	Annette Kim, MD, PhD
Infectious Diseases Subdivision Representative	Melissa B. Miller, PhD
Infectious Diseases Subdivision Representative	Linda Cook, PhD
Informatics Subdivision Representative	Somak Roy, PhD
Informatics Subdivision Representative	Christopher D. Coldren, PhD
Solid Tumors Subdivision Representative	Mary C. Lowery-Nordberg, PhD
Solid Tumors Subdivision Representative	Larry J. Jennings, MD, PhD
Junior Member	Bryan L. Krock, PhD
Junior Member	Arivarasan Karunamurthy, MD
Liaison from International Affairs Committee	Bibhu R. Das, PhD

### PURPOSE SUMMARY:

The Clinical Practice Committee (CPC) is comprised of representatives from each of AMP's subdivisions: 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. 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

- **May 2015:** *Do Circulating Tumor Cells, Exosomes and Circulating Nucleic Acids Have Clinical Utility for Molecular Pathologists? A Report of the Association for Molecular Pathology.* Led by Bert Gold with Milena Cankovic, Larissa V. Furtado, Frederick Meier, and Christopher D. Gocke, *The Journal of Molecular Diagnostics.* (<http://dx.doi.org/10.1016/j.jmoldx.2015.02.001>)
- **March 2015:** *Reporting Incidental Findings in Genomic Scale Clinical Sequencing: A Clinical Laboratory Perspective: A Report of the Association for Molecular Pathology.* In collaboration with representatives from the CPC, the Whole Genome Analysis Working Group and the Genetics Subdivision Leadership. Led by Madhuri Hegde with Sherri Bale, Pinar Bayrak-Toydemir, Jane Gibson, Linda Jo Bone Jeng, Loren Joseph, Jordan Laser, Ira M. Lubin, Christine E. Miller, Lainie F. Ross, Paul G. Rothberg, Alice K. Tanner, Patrik Vitazka, and Rong Mao, *The Journal of Molecular Diagnostics.* (<http://dx.doi.org/10.1016/j.jmoldx.2014.10.004>)
- **November 2015:** *Next-Generation Sequencing for Infectious Disease Diagnosis and Management: A Report of the Association for Molecular Pathology.* Led by Benjamin Pinsky with Martina Lefterova, Carlos Suarez and Niaz Banaei. Article in Press, *The Journal of Molecular Diagnostics.* (<http://dx.doi.org/10.1016/j.jmoldx.2015.07.004>)

- Update of the 2009 *AMP Assay Validation Report* and a new companion *AMP Assay Validation Resources* web page. In collaboration with CPC representatives and led by Linda Jo Bone Jeng with Larissa V. Furtado and Loren Joseph. 2015 AMP Web Publication; companion webpage constructed: [https://www.amp.org/committees/clinical\\_practice/ValidationResources.cfm](https://www.amp.org/committees/clinical_practice/ValidationResources.cfm)

**Manuscripts in Progress**

- *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. Submitted, *The Journal of Molecular Diagnostics.*

**Clinical Practice Guidelines, Workgroups, and Task Forces**

- **In development:** *Evaluation of Molecular Markers for Colorectal Cancer.* In collaboration with College of American Pathologists (CAP), American Society of Clinical Pathology (ASCP), Association for Molecular Pathology (AMP), and American Society of Clinical Oncology (ASCO).

	<b>AMP</b>	<b>ASCP</b>	<b>CAP</b>	<b>ASCO</b>
<b>Co-Chair</b>	Antonia Sepulveda, MD, PhD	Wayne W. Grody, MD, PhD	Stanley R. Hamilton, MD	Carmen Allegra, MD
<b>Expert Panelists</b>	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](http://www.amp.org/committees/clinical_practice/LungBiomarkerGuideline.cfm)

	<b>CAP</b>	<b>IASLC</b>	<b>AMP</b>
<b>Co-Chair</b>	Philip T. Cagle, MD	Yasushi Yatabe, MD, PhD	Neal I. Lindeman, MD
<b>Expert Panelists</b>	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:** *Framework for Addressing Clinical Utility of Molecular Diagnostic Testing.* Developed jointly by representatives from the CPC, Economic Affairs Committee, and

Professional Relations Committee. Co-chaired by Elaine Lyon and Loren Joseph with Milena Cankovic, Samuel Caughron, Pranil Chandra, Rajyasree Emmadi, Jill Hagenkord, Stephanie Hallam, Kay E. Jewell, Roger Klein, Jennifer Leib, Victoria M. Pratt, Paul Rothberg, and Robyn Temple-Smolkin.

- **In development:** *AMP 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).
- **In development:** *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, Mark Routbort (CAP) and Karl Voelkerding (CAP).
- **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 and Arivarasan Karunamurthy (Junior Member, CPC). Collaborations with other professional organizations pending at the time of this report.
- **In development:** *Copy Number Variation (CNV) Assessment for Large Next-generation Sequencing (NGS) Gene Panels*. 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 and Rebecca McClure.
- **In development:** *Variant Interpretation Test Across Labs (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.

#### 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

### **Additional Accomplishments**

- AMP hosted a Reference Materials Forum prior to the 2015 Annual Meeting on Tuesday, Nov 3, 2015 with representatives from CDC, NIST, and NCI.
- Multiple CPC and Scientific Subdivision members hosting or presenting in AMP Webinar events.
- CPC members provided input to the FDA Network of Experts.
- Larry Jennings is representing AMP at the November 12, 2015 FDA workshop: "Standards Based Approach to Analytical Performance Evaluation of NGS In Vitro Diagnostic Tests"

*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/](http://amp.org/committees/clinical_practice/) for more details.

**COMMITTEE MEMBERS:**

Chair	Aaron D. Bossler, MD, PhD
Vice Chair	Samuel K. Caughron, MD
Vice Chair, New Codes	Jill Hagenkord, MD
Vice Chair, Coverage	Richard D. Press, MD, PhD
Member	Dara L. Aisner, MD, PhD
Member	Pranil Chandra, DO
Member ( <i>Ex Officio</i> – PRC Chair)	Roger D. Klein, MD, JD
Member	Elaine Lyon, PhD
Member	Linda M. Sabatini, PhD, HCLD
Member	Michele Schoonmaker, PhD
Member	Ester Stein, MBA
Member	Katherine Tynan, 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, 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 utilization of and coverage for billing codes used in molecular pathology, to the potential economic impact of public policy decisions on molecular pathology practice. The Committee will interact with the American Medical Association and other interested organizations in order to achieve our common goals.

**2015 ACTIVITIES:**

CMS, which runs Medicare, has taken a heavy handed approach in denying coverage or reducing payment for many medically necessary molecular pathology tests. This creates 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 services that are vital to patient care.

**Genomic Sequencing Procedure (GSP) Reimbursement**

In 2014, CMS announced that it will gapfill all of the new Genomic Sequencing Procedure (GSP) CPT codes. The new codes were made available on January 1, 2015 and national payment rates go into effect January 1, 2016. To help estimate the cost basis of their GSP services, AMP initiated a micro-costing and health economic evaluation of several of these CPT codes. This project was overseen by a special committee, chaired by **Dr. Linda Sabatini** and comprised of Board and EAC members. AMP officially released the models in March 2015 for free on our website with over 400 downloads thus far. We hope members are utilizing these models to accurately calculate the cost of their GSP services and, therefore, effectively communicate value and cost to payers. AMP is currently conducting a survey. It is important that all who download the models complete this survey so we can determine use of the models and outcomes. Hampering the success of pricing efforts is emerging non-coverage decisions for multi-gene sequencing assays, so this will continue to be a major advocacy focus in 2016.

**Clinical Lab Fee Schedule (CLFS) and Gapfill Determinations**

During the summer, AMP provided written and oral comments to CMS on the CY2016 Clinical Lab Fee Schedule (CLFS) and 2015 Gapfill Determinations. **Dr. Aaron Bossler** represented AMP at the annual CLFS meeting at CMS

on July 16, 2015. He presented crosswalk recommendations for the 2016 CLFS molecular pathology procedures, 2015 molecular pathology and genomic sequencing procedure reconsiderations, and the new 2016 genomic sequencing procedures. AMP's recommendations were very well received and endorsed by other organizations such as AACC and CAP.

In September, CMS released the Calendar Year 2016 Clinical Laboratory Fee Schedule (CLFS) Preliminary Determinations and the Final Gapfill Payment Determinations for Calendar Year 2015. New 2016 Molecular Pathology Procedure CPT codes were crosswalked to existing codes, while CMS proposed that new 2016 Genomic Sequencing Procedures undergo the gapfill process. For the 2015 gapfill final determinations, a handful of codes were priced, including a few genomic sequencing procedures codes. However many of the codes remain unpriced. AMP submitted comments to CMS on these determinations in late October.

### **Advisory Panel on Clinical Diagnostic Tests**

Established by the Protecting Access to Medicare Act (PAMA), the Advisory Panel on Clinical Diagnostic Tests (The Panel) is to advise on various issues under PAMA including payment rates for various new tests, including whether to use crosswalking or gapfilling processes; 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. CMS convened the first meeting of the Panel on August 26, 2015. The purpose of the meeting was for the Panel to make recommendations on new test codes for the 2016 CLFS. **Dr. Aaron Bossler**, representing both AMP and CAP, presented a detailed explanation of the rationale for crosswalk recommendations for the 2016 CLFS molecular pathology procedures and the new 2016 genomic sequencing procedures. The second meeting of the Panel occurred on October 19, 2015. **Dr. Sam Caughron** presented on behalf of AMP. He thanked CMS for adopting many of AMP's crosswalk recommendations, asked CMS to reconsider AMP's crosswalk recommendations for a few molecular pathology codes, urged CMS to crosswalk the 2016 GSP codes and asked CMS to make the gapfill process more transparent. As the Panel continues to meet in 2016, AMP will be present to provide comment and expertise on molecular pathology tests.

The long overdue Protecting Access to Medicare Act (PAMA) proposed rule was released on September 25, 2015. AMP is currently reviewing the rule and will provide comments to CMS.

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

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

### **Palmetto's MoIDX Program:**

CMS contracted with Palmetto GBA for a trial coverage and payment program for the new CPT codes. Palmetto designed MoIDX, which includes McKesson-owned Z-Code Identifiers. Each laboratory in Palmetto's jurisdiction that would like to obtain coverage for a molecular test must meet the requirements of the MoIDX program. The list of problems with the program is long. The laboratory must obtain a Z-code to uniquely discriminate its test; and, if the test is an LDP, the laboratory must also submit a detailed dossier so that Palmetto GBA can apply an assessment of the assay validation data (analytical validity) as a major component of its determination of clinical utility, and thus Medicare coverage and pricing. Palmetto publishes a list of excluded tests on its website and often disregards the proper Local Coverage Determination (LCD) process. A number of the LCDs it does publish either dictate how to validate an assay (e.g., NGS) or encroach on the practice of medicine (Lynch and IHC). A multi-society coalition, which includes AMP, is working to address these multiple problems because they not only result in non-coverage/denial issues for the Palmetto jurisdiction, but they become national coverage determinations and strongly influence the decisions of the private payers. Most recently, AMP responded to a new policy by Palmetto entitled "Analytical Performance Specifications for Comprehensive Genomic Profiling."



AMP expressed numerous serious concerns including circumvention of the local coverage determination (LCD) process, strict testing limitations, and a prohibition against PhD scientists, which is in direct violation of the Social Security Act and CMS' regulations in both CLIA and the PFS.

### **CPT Codes**

The EAC CPT Work Group, led by **Dr. Jill Hagenkord**, advises on AMP position on new CPT code proposals submitted to the Pathology Coding Caucus (PCC). AMP submitted CPT code change proposals in November for 2016 publication. A number of them were accepted including Hereditary Neuroendocrine Disorders, Noonan Spectrum Disorders, Hereditary Colorectal Cancer Panel Edit, Hereditary Breast Cancer-Related Syndrome Panel and Ashkenazi Carrier Panel. In July, AMP submitted code change proposals for cardiac channelopathies and inherited cardiomyopathy.

### **Outside Organization Representation**

- **Jan Nowak** serves on the PCC, with **Jill Hagenkord** and **Sam Caughron** serving as Alternates.
- The AMA Molecular Pathology Advisory Group (MPAG) includes AMP members **Aaron Bossler, Roger Klein, Elaine Lyon, and Maria Bettinotti**.

## AMP Finance Committee Annual Report, 2015

### COMMITTEE MEMBERS:

Chair	Vivianna Van Deerlin, MD, PhD
President	Janina A. Longtine, MD
Past President	Elaine Lyon, PhD
President-Elect	Charles E. Hill, MD, PhD
Member	Mary C. Lowery-Nordberg, PhD
Member	Timothy T. Stenzel, MD, PhD
Member	Gail H. Vance, MD

### PURPOSE SUMMARY:

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, 2015

### COMMITTEE MEMBERS:

Chair	Lei Po (Chris) Wong, PhD
Member	Adewunmi Oluseye Adeoye, MD
Member	Sheik Mohammad Khorshed Alam PhD, MD
Member	David E. Barton, PhD
Member	Yoon-La Choi, MD PhD
Member	Renata A. Coudry, MD, PhD
Member	Bibhu R. Das, PhD
Member	Tze-Kiong Er, PhD
Member	Andrew P. Fellowes, PhD
Member	Jin-Yeong Han, MD, PhD
Member	Rami Mahfouz, MD, MPH
Member	Imran Mirza, MD
Member	Lynette Lin Ean Oon, MD
Member	Roberta Sitnik, PhD
Member	Ishwar Chander Verma, MBBS
Member	Denis Francis York, PhD
Liaison to and from AIPNA	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

### Historical Context

Though the majority of AMP members reside in the U.S., the AMP founding members desired to create a global organization. Today, AMP members can be found in all continents except Antarctica.

The IAWG was formed in early 2010 as a working group of the Membership & Professional Development Committee, now the Membership Affairs Committee (MAC), out of discussions in 2009 within that committee (Helen Fernandes and Rick Press co-Chairs) and the Clinical Practice Committee (particularly championed by Patrik Vitazka, junior member, and Iris Schrijver, Chair). From his place of residency in Slovakia, Patrik Vitazka served as the first IAWG Chair. A specific effort was made to construct the working group with members on the various continents residing outside of the United States. The initial IAWG members were Patrik Vitazka (Chair, Slovakia), David Barton (Ireland), BR Das (India), Rami Mahfouz (Lebanon), Andrew Fellowes (Australia), and Chris Wong (Hong Kong).

The initial project of the IAWG was a survey of non-U.S. members in April 2010 to ascertain demographics and needs. The goal was to use the results of the survey to set a roadmap of

projects that would over time increase the international membership base and address needs specific to the international community. Since that time, the group has successfully collaborated to form four AMP International Affiliate Organizations, support more than a dozen conferences outside the U.S. with AMP speakers, and further expand AMP's educational initiatives to Europe, Asia, and other continents beyond North America.

### **2015 Activities**

- Transitioned from a working group to a formal AMP International Affairs Committee
  - Related press release at:  
[http://www.amp.org/about/press\\_releases/documents/20150521\\_InternationalCommittee.pdf](http://www.amp.org/about/press_releases/documents/20150521_InternationalCommittee.pdf)
- Addition of the German Society for Pathology as an AMP International Affiliate
- First International Showcase event at the AMP 2015 Annual Meeting
- AMP speaker invitations at international conferences:
  - Helen Fernandes for the Molecular Pathology Association of India (MPAI) 4<sup>th</sup> Annual Conference, Kolkata, India
  - Helen Fernandes at the 2<sup>nd</sup> International Symposium on Personalized Medicine, Sao Paulo, Brazil
  - Patrik Vitazka at the 2015 Annual Meeting of Korean Society of Genetic & Molecular Diagnosis, Seoul, Korea

*Submitted by Chris Wong, Chair*

**COMMITTEE MEMBERS:**

Chair	Nirali M. Patel, MD
Member	Betsy A. Bove, PhD
Member	Neng Chen, PhD
Member	Yi Ding, MD, PhD
Member	Daniel H. Farkas, PhD, HCLD
Member	Midhat S. Farooqi, MD, PhD
Member	Matthew Hiemenz, MD
Member	Giovanni Insuasti, MD
Member	Ruth Ann Luna, PhD
Member	Alexander Craig Mackinnon, Jr., MD, PhD
Member	Ron M. Przygodzki, MD
Member	Avni Santani, PhD
Member ( <i>Ex Officio</i> – International Affairs Committee Chair)	Lei Po (Chris) Wong, PhD
President	Janina A. Longtine, MD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

**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

**2015 ACTIVITIES:**

- Successfully developed and launched a survey of members.
- Revised the membership structure to include a dedicated category for technologists as well as early career members.
- Identified groups of professionals whose work is related to molecular pathology.
- Began to prioritize and develop recruitment plans for identified groups of professionals whose work is related to molecular pathology.
- Continued to recruit newly certified MGPs and others emerging in the field.
- Identified meetings at which AMP should exhibit.
- Planned and hosted the first-time attendees / new members luncheon at the Annual Meeting.
- Developed and launched a “Pathway to Service in AMP” initiative.

- Planned and hosted the early career – pathway to service luncheon at the Annual Meeting.
- Updated the Get Involved section of the AMP website.
- Developed and launched an “AMP Ambassadors” initiative for the Annual Meeting.
- Selected the winners of the International Membership Grants.
- Selected the winners of the Technologist Travel Awards.
- Began to review and plan to update AMP member (and registrant) demographic data.

**COMMITTEE MEMBERS:**

Chair	Elaine Lyon, PhD
Genetics Subdivision Representative	Cindy L. Vnencak-Jones, PhD
Genetics Subdivision Representative	Hanna Rennert, PhD
Hematopathology Subdivision Representative	Karen P. Mann, MD, PhD
Hematopathology Subdivision Representative	Timothy C. Greiner, MD
Infectious Diseases Subdivision Representative	Richard L. Hodinka, PhD
Infectious Diseases Subdivision Representative	Susan M. Novak-Weekley, PhD
Informatics Subdivision Representative	Carlos J. Suarez, MD
Informatics Subdivision Representative	Annette Leon Meredith, PhD
Solid Tumors Subdivision Representative	Karen Weck, MD
Solid Tumors Subdivision Representative	George J. Netto, 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.

**2015 ACTIVITIES:**

The Nominating Committee nominated Officers and Committee Representatives for the 2015 annual elections.

**COMMITTEE MEMBERS:**

Chair	Roger D. Klein, MD, JD
Member	Stephen P. Day, PhD
Member	Rajyasree Emmadi, MD
Member	Andrea Ferreira-Gonzalez, PhD
Member	Jordan Laser, MD
Member	Elaine Lyon, PhD
Member	Roberta Madej, PhD, MBA
Member	Shelby Melton, MD
Member	Timothy J. O'Leary, MD, PhD
Member	Victoria M. Pratt, PhD
Member	Daniel E. Sabath, MD, PhD
Junior Member	Robert F. Klees, PhD
Liaison from International Affairs Committee	David E. Barton, PhD
AMP Representative to FASEB Science Policy Committee	Gregory J. Tsongalis, 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.

**2015 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 and Megan Anderson Brooks of CRD Associates, keeps the Committee informed of all policy and legislative activity, assists in drafting policy positions, provides advice regarding advocacy strategies, and guides AMP's presence on Capitol Hill. Jennifer Leib, Megan Anderson Brooks, AMP 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 2015 has been 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).”

AMP provided both oral and written comments to FDA on this draft guidance, expressing that medical device regulations are poorly suited for, and inapplicable to, the oversight of LDPs. The comments stressed that if the guidance is finalized as written, FDA would require laboratories, as medical device manufacturers, to submit applications for premarket review for thousands of laboratory developed testing services and AMP members will likely be unable to continue offering these tests; therefore, FDA will have in effect significantly diminished or eliminated patient and physician access to these services. Additionally, FDA’s proposal would not permit molecular pathology professionals the current flexibility to make improvements to already approved or cleared tests, such as analyzing specimens from minimally invasive procedures, essentially freezing outdated tests in time.

Throughout 2015, AMP submitted numerous comments to and engaged actively with both House Energy and Commerce Committee and Senate Committee on Health, Education, Labor and Pensions (HELP) regarding regulation of LDPs including comments to the House Energy and Commerce Committee on Draft Legislation on the Regulation of In Vitro Clinical Tests. AMP does not support this legislation and the comments summarize our concerns. AMP maintains that Laboratory Developed Procedures (LDPs) are professional services and thus are very distinct from distributed tests. To assist in discussion efforts about the various proposals circulating in Congress, AMP created a “Principles for Oversight of Laboratory Developed Procedures” which serves a checklist for any proposals or legislation that address regulation of LDPs.

The Senate Health, Education, Labor, and Pensions (HELP) Committee is in the process of drafting legislation that would provide avenues for enhanced support for medical innovation and patient access to new medicines and technologies. In an effort to support the Senate HELP Committee’s review of laboratory test regulation, a working group of the Committee developed a proposal to modernize the CLIA regulations and maintain oversight of LDPs under those regulations. AMP released the proposal on August 4, 2015. The working group is to be commended for wrestling with the issues and drafting a viable proposal that will provide reassurance that clinical validity is being assessed and information about LDPs is easily accessed by ordering physicians and the public, without elements that would curtail the ability of medical professionals to offer vital clinical services. 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.

### **Regulatory Oversight of Next Generation Sequencing Diagnostic Tests**

Early in 2015, FDA released a preliminary discussion paper entitled, “Optimizing FDA’s Regulatory Oversight of Next Generation Sequencing (NGS) Diagnostic Tests” and requested feedback from stakeholders on how FDA should regulate NGS diagnostic tests. AMP formed a working group to draft recommendations and provided both oral and written comments to FDA. AMP urged FDA to focus its attention on helping to ensure the performance characteristics of NGS instruments, reagents, and related software. AMP further recommended that FDA partner with private sector organizations and experts to set standards for FDA-cleared or approved instruments, test kits, and software. AMP emphasized that new regulatory initiatives must utilize an approach that is sufficiently flexible to readily accommodate the continual technological developments and exponentially increasing body of medical and scientific knowledge that characterizes NGS-based diagnostic tests in a timely manner.

FDA is now seeking feedback on more specific aspects of NGS diagnostic tests: a standards based approach to analytical performance evaluation and the use of databases for establishing the clinical relevance of human genetic variants. The working group continues to frame feedback to FDA on these issues.

### **Capitol Hill**

AMP has met with numerous offices on Capitol Hill regarding restrictions on the oversight and regulation of LDPs. Specifically, AMP has met with staff for Senators Alexander, Murray, Franken, Hatch, Bennet, and Burr and also met with staff working for Representatives, Blackburn, DeGette, Pallone, and Upton.

The 2014 AMP Annual Meeting was held near Washington, DC in November. Over 50 members visited Capitol Hill offices. Drs. Janina Longtine (2015 President), Elaine Lyon (2014 President), Roger Klein (Professional Relations Committee Chair) and Aaron Bossler (Economic Affairs Committee Chair) provided a lunchtime briefing for congressional staff. During their meetings, members emphasized the essential role of the molecular pathology professional and molecular testing to patient care. In addition, requests for FDA to utilize notice and comment rulemaking and for amendment(s) to PAMA were presented.

### **White Papers**

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

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

### **Genetic Information Nondiscrimination Act**

AMP joined over 60 other organizations in a letter to the Equal Employment Opportunity Commission (EEOC) on the EEOC Proposed Rule expressing concern that the Proposed Rule regarding the Americans with Disabilities Act (ADA) would erode long-standing and important protections afforded to employees under the ADA and would pave the way for weakening the GINA.

### **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 Shelby Melton and Roger Klein), IOM Roundtable on Translating Genomic-Based Research for Health (AMP representative Vicky Pratt), Federation of American Societies for Experimental Biology (FASEB) (AMP representative Greg Tsongalis), Cancer Leadership Council.

**COMMITTEE MEMBERS:**

Chair	Ted E. Schutzbank, PhD
Chair-Elect	Victoria M. Pratt, PhD
Genetics Subdivision Representative	D. Brian Dawson, PhD
Genetics Subdivision Representative	Josh Deignan, PhD
Hematopathology Subdivision Representative	Rachel L. Sargent, MD
Hematopathology Subdivision Representative	Rebecca McClure, MD
Infectious Diseases Subdivision Representative	Marie L. Landry, MD
Infectious Diseases Subdivision Representative	Alexandra Valsamakis, MD, PhD
Informatics Subdivision Representative	Mark J. Routbort, MD, PhD
Informatics Subdivision Representative	Eric William Klee, PhD
Solid Tumors Subdivision Representative	Catherine I. Dumur, PhD
Solid Tumors Subdivision Representative	Jennifer Laudadio, MD
Technical Topics Subdivision Representative	John P. Gibson, MS
Technical Topics Subdivision Representative	Amanda LeBlanc, MS

**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.

**2015 ACTIVITIES:**

Programming the 2015 Annual Meeting, “Realizing the Dream of Precision Medicine” from November 5-7, 2015 at the Austin Convention Center in Austin, Texas.

**COMMITTEE MEMBERS:**

Chair	Min Fang, MD, PhD
<i>JMD</i> 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)
Electronic Media Advisor	Shalini Verma, MD
Member	Shaochun Bai, PhD
Member	Timothy J. O'Leary, MD, PhD
President	Janina A. Longtine, MD
<i>JMD</i> Managing Editor	Audra E. Cox, PhD, ELS
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

**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.

**2015 ACTIVITIES:**

- Updated and managed the AMP Case Reports in CAP TODAY initiative.
- Reviewed and submitted four case reports for ultimate publication in CAP TODAY.
- Helped to beta test the AMP Test Directory.
- Provided input on the I am AMP Campaign
- Continued to review and monitor the AMP website, providing input as needed.
- Launched another Case Report submission cycle, receiving a record-breaking 13 submissions.

**COMMITTEE MEMBERS:**

Chair	Charles E. Hill, MD, PhD
Member	Steven I. Gutman, MD, MBA
Member	Karl V. Voelkerding, MD
Member	Ester Stein, BS, MBA
Board Member	Roger D. Klein, MD, JD
Board Member	Shuji Ogino, MD, PhD

**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.

**2015 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, 2015

### COMMITTEE MEMBERS:

Chair	Laura J. Tafe, MD
Genetics Subdivision Representative	Jill Hagenkord, MD
Genetics Subdivision Representative	Allison Cushman-Vokoun, MD, PhD
Hematopathology Subdivision Representative	Christopher D. Watt, MD, PhD
Hematopathology Subdivision Representative	Cecilia Ching Sze Yeung, MD
Infectious Diseases Subdivision Representative	Benjamin Pinsky, MD, PhD
Infectious Diseases Subdivision Representative	Colleen Kraft, MD
Informatics Subdivision Representative	Nilesh Dharajiya, MD
Informatics Subdivision Representative	Nefize Sertac Kip, MD, PhD
Solid Tumors Subdivision Representative	Maria E. Arcila, MD
Solid Tumors Subdivision Representative	Eric J. Duncavage, MD
Junior Member	Elizabeth Azzato, MD, PhD, MPH
Junior Member	Juan C. Gomez-Gelvez, MD
Medical Technologist Member	Tessara Baldi, BS
Liaison from the Membership Affairs Committee	Matthew Hiemenz, MD
Liaison from the International Affairs Committee	Rami Mahfouz, MD, MPH

### 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 2015):*** The T&E committee organized an annual outreach course held just prior to annual meeting which is 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 includes an overview of applications of molecular pathology, followed by case studies presented by T&E members. As of October 12, there were 57 registrants for the course.
- ***Molecular Genetic Pathology (MGP) Review Course:*** The T&E Committee identifies the Course Director for the MGP Review Course, which takes place every other year (odd years). The 2015 live course was directed by Iris Schrijver and was held April 30-May 3 in Bethesda, MD. An online, self-study course (a recorded version of the 2015 live course) is available through 2016 at:  
<http://www.amp.org/mgp2015/self-study.cfm>
- ***Early Bird Sessions at the Annual Meeting - Case Studies presented by Trainees or Technologists:*** An opportunity for fellows, residents, postdocs, graduate students, or technologists who are attending the AMP 2015 Annual Meeting to present an interesting and/or challenging case study during an Early Bird Session. Trainee/technologist presenters in 2015 are:

Case Studies in Genetics	Case Study: Towards Clinical Significance of Maternal Uniparental Disomy of Chromosome 20	Elizabeth J. Bhoj, MD, PhD	Children's Hospital of Philadelphia
	Case Study: FGFR2 Amplification in Colorectal Adenocarcinoma	Jamal H. Carter, MD	Washington University in St Louis
	Case Study: An Uncommon WT1 Mutation and XY-Genotype Detected in 22-Year Old FFPE Tissue of a Case of Congenital Nephrotic Syndrome Caused by Denys-Drash Syndrome	Guido M.J.M. Roeman, BSc	Maastricht University Medical Center
	Case Study: Rescue of a Severe Skeletal Dysplasia	Pamela J. Snyder, BS, MB (ASCP)	Wexner Medical Center
Case Studies in Solid Tumors	Case Study: A 38-Year Old Woman with a Rapidly-Enlarging Thigh Mass	Charlotte I. Wang, MD, PhD	Massachusetts General Hospital
	Case Study: A Tale of Two ALK False Negative Lung Adenocarcinoma Cases	Damon Olson, MD	University of Colorado Denver
	Case Study: Malignancy After Solid Organ Transplantation: A Question of Tumor Origin	Suzanne R. Thibodeaux, MD, PhD	Hospital of the University of Pennsylvania
	Case Study: Actionable KIT Mutation in High-Grade Neuroendocrine Carcinoma	Jason N. Rosenbaum, MD	Washington University in St. Louis
Case Studies in Infectious Diseases	Case Study: Norovirus GII.P17-GII.17 in the Canadian Province of Nova Scotia	Michael D. Carter, MD, PhD	Dalhousie Univeristy
	Case Study: Pigmentiphaga Chronic Otitis Media in a 9-Year Old Girl	Ryan J. Schmidt, MD, PhD	Brigham and Women's Hospital

	Case Study: Is IHC Still a Gold Standard in the Era of Ancillary Molecular Techniques for CMV Detection?	Rugvedita Parakh, MBBS, MD	University of Washington
Case Studies in Hematopathology	Case Study: Solving a 10-Year Old Enigma with NGS-Based Assay	Chi Young OK, MD	The University of Texas MD Anderson Cancer Center
	Case Study: Rare p230 Fusion Gene in CML Presenting with Myeloid Sarcoma and an Isocentric Chromosome 22 in a Previously Untreated Patient	Andrea Olofson, MD	Dartmouth-Hitchcock Medical Center
	Case Study: Chronic Eosinophilic Leukemia with t(5;12) and ETV6-ACSL6 Fusion Gene, a Potential Mimicker of Myeloid Neoplasm with PDGFRB Rearrangement	Javier De Luca-Johnson	University of Vermont Medical Center
	Case Study: Concomitant BCR-ABL1 Positive Chronic Myelogenous Leukemia Emerging in a Patient with MPL W515L Associated Primary Myelofibrosis	Juan C. Gomez-Gelvez, MD	Memorial Sloan-Kettering Cancer Center,

- **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, which includes the MGP Review Course (live and online), the MPOC, and the 2015 Annual Meeting. Continuing Medical Laboratory Education (CMLE) is provided for non-physicians.
- **Webinars:**

Date	Title	Speakers/T&E Moderators	Attendees
March 26	<b>Informatics 101-01</b> -Introduction to Bioinformatics for NGS Analysis	Donavan Cheng, PhD (Maria E. Arcila, MD)	282
May 7	<b>Informatics 101-02:</b> An Introduction to Bioinformatics Methodologies: How to Process NGS Data into Clinically Meaningful Results	Sharanya Raghunath, PhD (N. Sertac Kip, MD, PhD)	187



June 18	Next-Generation Sequencing (NGS) Technologies for HIV Drug Resistance Testing	Robert W. Shafer, MD (Benjamin Pinsky, MD, PhD)	149
July 1	<b>Informatics 101-03:</b> Development and Optimization of Genomic Analysis Pipelines Using Next Generation Sequencing Technologies	Raghu Metpally, PhD (N. Sertac Kip, MD, PhD)	188
Aug 11	NGS for the detection and characterization of bacteria from clinical specimens	Stephen J. Salipante, MD, PhD (Benjamin Pinsky, MD, PhD)	266
Aug 19	<b>Informatics 101-04:</b> Using Integrated Genome Viewer (IGV) to View Next Generation Sequencing Data	Ahmet Zehir, PhD (Jill Hagenkord, MD)	109
Sept 9	<b>Informatics 101-05:</b> Applications for clinicians and research models	Eric W. Klee, PhD (Christopher Watt, MD, PhD)	158
Sept 10	NGS 101: An Integrated Approach to Assay Selection and Validation	Avni B. Santani, PhD (Matthew Hiemenz, MD)	100
Oct 22	<b>Informatics 101-06:</b> Leveraging the Electronic Health Record to Implement Genomic Medicine	Marc S. Williams, MD (Nilesh Dharajiya, PhD)	TBD

### Trainee Activities (Residents, Fellows, and Students)

- **AMP 2015 Annual Meeting**
  - Annual Trainee Luncheon and Book Drawing: The T&E junior members organized a round robin discussion with junior and senior faculty members for the 2015 Trainee Luncheon on topics of getting a position after residencies and training fellowships. Donated textbooks from AMP member authors were given away at the Trainee Luncheon.
- **United States and Canada Academy of Pathology (USCAP)**
  - AMP Trainee Reception at USCAP 2015. Supported by the Jeffrey A. Kant – AMP Education Fund. Provided complimentary AMP Associated Memberships to four trainees new to AMP.

### Technologist Activities

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

### Special Courses

The Science Educator Workshop: Teaching Precision Medicine, Genomics, and Molecular Diagnostics in Your Classroom was held on November 4, 2015. The new, all-day workshop event targeted high school and college science teachers who live and/or work in the vicinity of Austin, Texas. 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.

### **Awards**

- Young Investigator Awards – 58 poster candidates (40 YIA poster candidates in 2014)
- Technologist Poster Awards – 26 poster candidates (23 poster candidates in 2014)
- International Trainee Travel Award – First awardee. Supported by the Jeffrey A. Kant – AMP Education Fund.

### **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 2015 Annual Meeting. T&E Chairs Laura Tafe (2014-2015) and Annette Kim (2016-2017) are 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 Marie DeFrances (Chair), David Wu (Chair-Elect), and Christopher Gocke. Dolores Lopez-Terrada is the incoming Chair-Elect. The MGP PD Council directs the discussions of the MGP Program Directors Working Group. In the fall of 2015, the MGP PD Council launched a survey to the MGP PD Working Group to gauge program directors' interest in having their program participate in the San Francisco Fellowship Match program. Highlights of the survey will be presented at the MGP PD meeting at the Annual Meeting, and discussions of priorities will continue.

### **Curriculum Development Task Forces**

- ***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. The manuscript will be submitted to *JMD* by the end of 2015. Other members are: Alanna Church, Linda Jeng, Roger Klein, Mahesh Mansukhani, Federico Monzon, John Pfeifer, Hanna Rennert, Iris Schrijver, Laura Tafe and Vivianna Van Deerlin.
- ***Molecular Pathology Residency Training:*** Chaired by Charles Hill, the Task Force (established October 2011) on developing a suggested molecular pathology curriculum for residents is in its final stages. The manuscript was submitted to *JMD* in June and conditionally accepted with revisions, which were resubmitted to *JMD* in September. Other authors are: Dara Aisner, Anna Berry, Brian Dawson, Randy Hayden, and Loren Joseph.
- ***Genomics Education for Primary Care Residents:*** Task Force established in August 2014, led by T&E Committee Chair Laura Tafe, with members Devon Chabot-Richards, and Maria Arcila. Their goal is to develop a modified basic genomics curriculum for primary care residents, *i.e.*, internal medicine, family practice, pediatrics to be published in a primary care-type journal, *e.g.*, *JAMA*.

### **Co-Sponsorships, Companion Meetings, and/or Collaborations**

- **United States and Canadian Academy of Pathology (USCAP) 2015**

The AMP 2015 Companion Society Symposium, “Next Generation of Pathology: Role of the Pathologist in NGS-Based Personalized Medicine,” was co-moderated by Marina Nikiforova and Eric Duncavage:

- *Introduction and Overview: Eric J. Duncavage, MD*
- *Overview of NGS Testing: From Sample Preparation to Data Analysis, Charles E. Hill, MD, PhD*
- *Applications of Next Generation Sequencing in Solid Tumors - Pathologist Perspective, John D. Pfeifer, MD, PhD*
- *Utility of NGS and Comprehensive Genomic Profiling in Hematopathology Practice, Maria E. Arcilia, MD*
- *NGS for Cancer Predisposition, Colin C. Pritchard, MD, PhD*
- *Summary: Future of Pathology in Era of Personalized Medicine, Marina Nikiforova, MD*

An AMP-USCAP co-sponsored course, “Molecular Diagnostic and Genomic Applications in Cancer: A Primer for the Pathologist”, was co-directed by Iris Schrijver, MD and George Netto, MD

- **Regional/Local Conferences**

- **Beaumont Symposium** – September 16-17 in Troy, MI. Organizers (AMP Members): Bobby Boyanton and John Gibson. AMP faculty included: Jill Hagenkord, John Pfeifer, and Roger D. Klein

- **American Society for Clinical Pathology (ASCP)**

- **ASCP 2015 AMP Workshop: October 28-30 in Long Beach, CA:** Cecilia Yeung and Nilesh Dharajia presented a Molecular Diagnostic Primer for Technologists.

- **College of American Pathologists (CAP)**

- **CAP 2015 Course Presentations:**
- *Beyond Single Gene Analysis: Paving the Way to Comprehensive Tumor Genomic Profiling*, presented by Neal Lindeman & Lynette Sholl
- *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 Liaisons Michelle Shiller and Maria Arcila.

- **Society for Laboratory Automation and Screening (SLAS):**

- **SLAS 2015 Course Presentations:**
- *Analyzing the Most Frequent Disease Loci in Targeted Patient Categories Optimizes Disease Gene Identification and Test Accuracy Worldwide*, presented by Roger Lebo
- *Tute Genomics: A Web-based Platform for Gene and Biomarker Discovery*, presented by Reid Robison

- **Cambridge Health Institute (CHI) Conferences**
  - **Molecular Medicine Tri-Conference**, February 15-20, 2015, San Francisco
    - **Short Courses:**
      - ***Validation and Compliance Considerations for an NGS Lab:*** Victoria M. Pratt, PhD, and Monica J. Basehore, PhD
    - **Keynote**
      - ***The Value of Molecular Diagnostics: A Discussion on Clinical Utility:*** Elaine Lyon, PhD, Paul Rothberg, PhD, and Milena Cankovic, PhD
        - Defining and measuring clinical utility from the point of view of both the clinician and the patient
        - MDx of malignancies to offer prognostic and predictive information useful for selecting the optimal therapy
        - Halting the “diagnostic odyssey” by selecting the appropriate genomic MDx for people, often children, with diseases that are difficult or sometimes seemingly impossible to diagnose  
Establishing the value of MDx as a modality that will not only improve health-care, but do so in a way that will lower costs in the long run
  - **Next Generation Dx Summit**, August 18-20, 2015, Washington, DC
    - **Plenary Session**
      - ***In the Best Interest of the Patient: Balancing Innovation and Regulation:*** Elaine Lyon, PhD, Stephen Day, PhD, Jordan Laser, MD, and Jamie McDonald, MS

**Newly Appointed Positions:**

- Dolores Lopez-Terrada to serve as MGP Program Directors’ Council 2016 Chair-Elect

*Submitted by Laura J. Tafe, Chair*

**SUBDIVISION LEADERSHIP**

	<b>Genetics</b>	<b>Hematopathology</b>	<b>Infectious Diseases</b>	<b>Solid Tumors</b>	<b>Informatics</b>
<b>Chair</b>	Siby Sebastian	Lynne Abruzzo	Michael Lewinski	Shuji Ogino	Alexis Carter
<b>Clinical Practice Committee</b>	Carolyn Sue Richards	Annette Kim	Melissa Miller	Mary Lowery-Nordberg	Somak Roy
	Birgit Funke	Jennifer Crow	Linda Cook	Larry Jennings	Christopher Coldren
<b>Nominating Committee</b>	Hanna Rennert	Karen Mann	Richard Hodinka	Karen Weck	Annette Meredith
	Cindy Vnencak-Jones	Timothy Greiner	Susan Novak-Weekley	George Netto	Carlos Jose Suarez
<b>Program Committee</b>	Brian Dawson	Rachel Sargent	Marie Louise Landry	Catherine Dumur	Eric Klee
	Joshua Deignan	Rebecca McClure	Alexandra Valsamakis	Jennifer Laudadio	Mark Routbort
<b>Training &amp; Education Committee</b>	Jill Hagenkord	Cecilia Yeung	Benjamin Pinsky	Maria Arcila	Nefize Sertac-Kip
	Allison Cushman-Vokoun	Christopher Watt	Colleen Kraft	Eric Duncavage	Nilesh Dharajiya

**PURPOSE SUMMARY:**

The Subdivision Leadership consists of an elected Chair and the elected Representatives to the Clinical Practice, Nominating, Program, and Training & Education Committees. The Subdivision Leadership charge is to identify and ascertain the needs of the subdivision membership and refer those needs to the appropriate committee(s) to address. AMP committees are then responsible for evaluating the recommendations and, if adopted as projects, prioritizing them and forming working groups to accomplish them.

**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.
- Advised or made recommendations to the various committees regarding the following manuscripts, working group projects and courses that were completed or initiated in 2015:
  - Manuscript: *Reporting Incidental Findings in Genomic Scale Clinical Sequencing: A Clinical Laboratory Perspective: A Report of the Association for Molecular Pathology*. Written in collaboration with representatives from the CPC, the CPC Whole Genome Analysis Working Group, and the Genetics Subdivision Leadership. Led by Madhuri Hegde with Sherri Bale, Pinar Bayrak-Toydemir, Jane Gibson, Linda Jo Bone Jeng, Loren Joseph, Jordan Laser, Ira M. Lubin, Christine E. Miller, Lainie F. Ross, Paul G. Rothberg, Alice K. Tanner, Patrik Vitazka, and Rong Mao. *The Journal of Molecular Diagnostics*, March 2015. <http://dx.doi.org/10.1016/j.jmoldx.2014.10.004>
  - New CPC Working Group: AMP Guidelines for Laboratory Detection and Interpretation of Intragenic (Exonic Level) Deletions/Duplications Working Group (Madhuri Hegde, Chair)
  - Molecular Genetic Pathology (MGP) Review Course: The T&E Committee identifies the Course Director for the MGP Review Course, which takes place every other year (odd years). The 2015 live course was directed by Iris Schrijver and was held April 30-May 3 in Bethesda, MD. An online, self-study course (a recorded version of the 2015 live course) is available through 2016 at: <http://www.amp.org/mgp2015/self-study.cfm>

## Hematopathology

- Addressed topics in molecular hematopathology, including advances in translational research, Next-Generation Sequencing and challenges with working with clinical genomic information.
- Advised or made recommendations to the various committees regarding the working group projects and webinars that were initiated in 2015:
  - New CPC Working Group: Myelodysplastic/Myeloproliferative Neoplasms (MDS/MPN) Working Group (Jennifer Crow, Chair)
  - Training & Education Committee has initiated discussions with the Society for Hematopathology (SH) regarding development of future webinar series focused on updates to the WHO Blue Book.

## Infectious Diseases

- Addressed infectious disease topics relevant to the clinical molecular diagnostics laboratory, including next-generation sequencing and emerging molecular infectious disease tests.
- Advised or made recommendations to the various committees regarding the following manuscripts and webinars that were completed or in development during 2015:
  - Next-Generation Sequencing for Infectious Disease Diagnosis and Management: A Report of the Association for Molecular Pathology. Led by Benjamin Pinsky with Martina Lefterova, Carlos Suarez and Niaz Banaei as a joint project of the Infectious Diseases Subdivision Leadership and the Clinical Practice Committee. *The Journal of Molecular Diagnostics*, November 2015. <http://dx.doi.org/10.1016/j.jmoldx.2015.07.004>
  - *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. Submitted, *The Journal of Molecular Diagnostics*.
  - Webinar: Next-Generation Sequencing (NGS) Technologies for HIV Drug Resistance Testing, June 2015. Presenter: Robert W. Shafer, Host: Benjamin Pinsky.

## Solid Tumors

- Focused on clinical applications and development of guidelines for Next Generation Sequencing (NGS) for somatic variants and other Clinical Practice Guidelines.
- Advised or made recommendations to the various committees regarding the following manuscripts, working group projects and webinars that were completed or initiated in 2015:
  - *Do Circulating Tumor Cells, Exosomes and Circulating Nucleic Acids Have Clinical Utility for Molecular Pathologists? A Report of the Association for Molecular Pathology*. Led by Bert Gold with Milena Cankovic, Larissa V. Furtado, Frederick Meier, and Christopher D. Gocke, *The Journal of Molecular Diagnostics*. May 2015. <http://dx.doi.org/10.1016/j.jmoldx.2015.02.001>
  - New CPC Working Groups:
    - AMP Interpretation of Sequence Variants in Somatic Conditions (Cancer) (Marilyn Li, Chair) with liaisons from ACMG, ASCO and CAP
    - Development of NGS Validation Guidelines for Somatic Variants (Larry Jennings, Chair) with liaisons from CAP
  - Webinars: NGS 101: An Integrated Approach to Assay Selection and Validation, Presenter: Avni B. Santani, Host: Matthew Hiemenz

## **Informatics**

- Inaugural year for Informatics Subdivision. Focused on clinical applications and development of guidelines for Next Generation Sequencing (NGS) for somatic variants and other Clinical Practice Guidelines.
- Advised or made recommendations to the various committees regarding the following manuscripts, working group projects and webinars that were completed or initiated in 2015:
  - New CPC Working Group: Developing Standards for NGS Bioinformatics Pipeline Validation: single nucleotide variants (SNVs), small indels ( $\leq 21$ bp) and multi-nucleotide variants (MNVs) Working Group (Somak Roy, Chair).
  - Webinars:
    - Informatics 101-01: Introduction to Bioinformatics for NGS Analysis, Presenter: Donovan Cheng, Host: Maria Arcila
    - Informatics 101-02: An Introduction to Bioinformatics Methodologies: How to Process NGS Data into Clinically Meaningful Results, Presenter: Sharanya Raghunath; Host: Nefize Sertac kip
    - Informatics 101-03: Development and Optimization of Genomic Analysis Pipelines Using Next Generation Sequencing Technologies, Presenter: Raghu Metpally; Host: Nefize Sertac Kip
    - Informatics 101-04: Using Integrated Genome Viewer (IGV) to View Next Generation Sequencing Data, Presenter: Ahmet Zehir; Host: Jill Hagenkord
    - Informatics 101-05: Applications for clinicians and research models, Presenter: Eric Klee; Host: Christopher Watt
    - Informatics 101-06: Leveraging the Electronic Health Record to Implement Genomic Medicine, Presenter: Marc S. Williams; Host: Nilesh Dharajiya

## **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.