

AMP 2013 Committee and Subdivision Annual Reports

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COMMITTEE MEMBERS:

Loren Joseph, MD, Chair
Linda Jeng, MD, PhD, Genetics Subdivision Representative
Paul Rothberg, PhD, Genetics Subdivision Representative
Jerald Gong, MD, Hematopathology Subdivision Representative
Jennifer Dunlap, MD, Hematopathology Subdivision Representative
Thomas Huard, PhD, Infectious Diseases Subdivision Representative
Matthew J. Bankowski, PhD, Infectious Diseases Subdivision Representative
Milena Cankovic, PhD, Solid Tumors Subdivision Representative
Marilyn M. Li, MD, Solid Tumors Subdivision Representative
Larissa V. Furtado, MD, Junior Member (new position in 2013)
Jane S. Gibson, PhD, Chair for the Whole Genome Analysis Working Group
Patrik Vitazka, MD, PhD, Liaison to the International Affairs Working Group

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. 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

- **April 2013:** *Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors* (April 2013). 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
- **September 2013:** *The Role of MGMT Testing in Clinical Practice: A Report of the Association for Molecular Pathology*. Milena Cankovic, Marina N. Nikiforova, Matija Snuderl, Adekunle M. Adesina, Neal Lindeman, Patrick Y. Wen, Eudocia Q. Lee. *J Mol Diagn.* 2013;15:539-555. Available at:
[http://www.journals.elsevierhealth.com/periodicals/jmdi/article/S1525-1578\(13\)00112-8/abstract](http://www.journals.elsevierhealth.com/periodicals/jmdi/article/S1525-1578(13)00112-8/abstract)
- **November 2013:** *Laboratory Practice Guidelines for Detecting and Reporting JAK2 and MPL Mutations in Myeloproliferative Neoplasms: A Report of the Association for Molecular Pathology*. Jerald Z. Gong, James R. Cook, Timothy C. Greiner, Cyrus Hedvat, Charles E. Hill, Megan S. Lim, Janina A. Longtine, Daniel Sabath, and Y. Lynn Wang. Available at:
[http://www.journals.elsevierhealth.com/periodicals/jmdi/article/S1525-1578\(13\)00131-1/abstract](http://www.journals.elsevierhealth.com/periodicals/jmdi/article/S1525-1578(13)00131-1/abstract)

Manuscripts in Progress

- **Working Title:** *Reporting Incidental Findings in Genomic Scale Clinical Sequencing: A Clinical Laboratory Perspective.* 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 Jeng, Loren Joseph, Jordan Laser, Ira Lubin, Rong Mao, Chris Miller, Paul Rothberg, Alice Tanner, and Patrik Vitazka.
- **Working Title:** *Do Circulating Tumor Cells, Exosomes and Circulating Nucleic Acids Have Clinical Utility for Molecular Pathologists?* Led by Milena Cankovic with Bert Gold, Chris Gocke, Larissa Furtado, and Fred Meier.

Clinical Practice Guidelines

- **In development:** *Evaluation of Biomarkers for Colorectal Cancer Biomarkers.* In collaboration with CAP, ASCP, and AMP.

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

Timeline:

Fall 2013: Literature Review
December 2013: Draft Recommendations
Winter 2014: Public Comment Period
Spring 2014: Revisions
Summer 2014: Coordinated Publication
Fall 2014: Presentations at Annual Meetings upon publication

Liaisons/Representation to other Organizations

- CAP Molecular Oncology Committee, Paul Rothberg
- CAP Cancer Biomarker Reporting Committee, Deborah Dillon
 - The committee published a reporting template for lung and colorectal cancer biomarkers in CAP's *Archives* journal (June 2013):
<http://www.archivesofpathology.org/doi/pdf/10.5858/arpa.2013-0319-CR>
- ACMG Interpretation of Sequence Variants, Julie Gastier-Foster and Elaine Lyon
 - An Open Forum will be hosted at the AMP 2013 Annual Meeting on Wednesday, November 13, 5:00pm-6:30pm, at the Hyatt Phoenix.
- NIST Genome in a Bottle, Vicky Pratt

FDA Approved/Cleared Molecular Diagnostic Tests

- In years past, AMP maintained a list of FDA approved molecular diagnostic tests. Instead maintaining its own list, the AMP website now has a direct link to the FDA site:
<http://www.amp.org/FDATable/>.

National Cancer Institute, National Institutes of Health

- January 10, NCI Workshop: Evidence Needed to Support the Clinical Utility of Molecular Diagnostics. Loren Joseph, Roger Klein, and Mary Williams attended for AMP.
<http://ncifrederick.cancer.gov/Events/moleculardiagnosics/agenda.asp>
- June 14: Response to an NCI RFI: RFI13-15: "Efficient Implementation of a Sequencing Network for the Proposed NCI MATCH Clinical Trial."

Sample Exchange

- The hematopathology and solid tumors subdivision representatives are working on a sample exchange for the validation of next-generation sequencing platforms. An online survey was sent to the membership in August 2013. The analysis and implementation of a plan are currently being discussed.

Webinar: AMP Variant Nomenclature Database

Webinar, 10/1/13 Linda Jeng, hosted by Chris Curtis, T&E Committee Member

Linda Jeng presented a webinar on October 1 on the AMP Variant Nomenclature Database as a resource for recommended nomenclature for sequence variants as well as a process for members to contribute and expand the database. The spreadsheet database includes the approved gene symbol, the reference sequence/version, the nucleotide change (cDNA), amino acid change, the commonly used/colloquial name, codon change, examples of standard nomenclature used for reporting and dbSNP reference, if available. The resource is posted securely for AMP members in the CHAMP Open Forum Library.

2013: Whole Genome Analysis Working Group: Jane Gibson, Chair

- Publication: “Opportunities and Challenges Associated with Clinical Diagnostic Genome Sequencing: A Report of the Association for Molecular Pathology” in the *Journal of Molecular Diagnostics*, November 2012. 14:6(525-540).
- Manuscript development nearing completion: *Reporting Incidental Findings in Genomic Scale Clinical Sequencing: A Clinical Laboratory Perspective*. In collaboration with representatives from the Clinical Practice Committee, the Whole Genome Analysis Working Group and the Genetics Subdivision Leadership. Led by Madhuri Hegde with Sherri Bale, Pinar Bayrak-Toydemir, Jane Gibson, Linda Jeng, Loren Joseph, Jordan Laser, Ira Lubin, Rong Mao, Chris Miller, Paul Rothberg, Alice Tanner, and Patrik Vitazka.
- Manuscript development in progress on NGS validation considerations in both inherited conditions and oncology.
- Exploring collaboration with CAP Personalized Healthcare Committee on developing a guidance or reference document on pre-analytical information that surgical/anatomic pathologists would use for NGS-based oncology testing of tumor tissue.
- Members or formal liaisons involved with other organizations/projects:
 - ACMG NGS Lab QA Working Group
 - ACMG Interpretation of Sequence Variants
 - CAP NGS Workgroup
 - CLSI, AMP members reviewed MM09 on Nucleic Acid Testing
 - CDC
 - NHGRI
 - NIST Genome in a Bottle

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.

Submitted by Loren Joseph, MD, Chair

AMP Training & Education Committee Annual Report, 2013

COMMITTEE MEMBERS:

Ted Schutzbank, PhD, Chair
Rong Mao, MD, Genetics Subdivision Representative
Christine Curtis, PhD, Genetics Subdivision Representative
Annette Kim, MD, PhD, Hematopathology Subdivision Representative
Harvey Greisman, MD, PhD, Hematopathology Subdivision Representative
Paula Revell, PhD, Infectious Diseases Subdivision Representative
Rangaraj Selvarangan, PhD, Infectious Diseases Subdivision Representative
Laura Tafe, MD, Solid Tumors Subdivision Representative
Jordan Laser, MD, Solid Tumors Subdivision Representative
Giovanni Insuasti, MD, Junior Member
Devon Chabot-Richards, MD, Junior Member
Caren Gentile, MS, BS, Medical Technologist Member
Rami Mahfouz, MD, MPH, Liaison to the International Affairs Working Group

PURPOSE SUMMARY:

The Training and Education (T&E) Committee is comprised of AMP members with expertise in one or more of the molecular specialties: genetics, hematopathology, infectious diseases, and solid tumors. It oversees important issues such as certification in molecular pathology, mentoring of trainees, and education in molecular pathology.

Molecular Genetics Pathology Program Directors

- **MGP Program Directors Working Group:** The MGP Program Director Council consists of Anna Berry (Chair), Federico Monzon, Margaret Gulley, Iris Schrijver, and Vivianna Van Deerlin. The MGP PD Council directs the discussions of the MGP Program Directors Working Group.

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. 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. Other members are: Ted Schutzbank (ex officio), Dara Aisner, Anna Berry, Brian Dawson, Randy Hayden, Loren Joseph, and Karen Kaul.
- **Molecular Pathology and Genomics for Medical Laboratory Scientists:** Co-chaired by Sara Taylor and Ted Schutzbank, the Task Force (established May 2012) is developing a training curriculum in molecular pathology and genomics for Clinical Laboratory Scientists. An online survey was developed in 2012 and targeted the directors/managers of Molecular Diagnostics laboratories to provide information about their expectations and needs concerning employee competencies. The results were analyzed by the task force during its development of an MLS curriculum. Other members

are: Katie Bennett, Josh Deignan, Ericka Hendrix, Susan Orton, and Shalini Verma. The manuscript is currently undergoing revisions with a plan to re-submit by November 30, 2013.

Certification in Molecular Diagnostics

The T&E Committee and the AMP staff are currently working with the ASCP Board of Certification (BOC) to determine the “business need” (ASCP’s wording) for a new certification in Molecular Diagnostics at the doctoral level. Ted Schutzbank, Kathy Mangold and Melinda Poulter will be representing AMP for these discussions, in addition to Mel Limson from the AMP staff.

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 2013 Annual Meeting. Laura Tafe is leading the effort and facilitating the panel and audience discussions. The roundtable panel of T&E Committee members includes Laura Tafe, Christine Curtis, and Devon Chabot-Richards. 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.

Awards

- Young Investigator Awards – 36 poster candidates this year (36 YIA poster candidates also in 2012)
- Technologist Poster Awards – 30 poster candidates (23 poster candidates in 2012)

Trainee Activities

Annual Trainee Luncheon and Book Drawing - The T&E junior members organized a panel discussion between MD and PhD Molecular Pathology faculty members for the 2013 Trainee Luncheon. Iris Schrijver, MD and Dan Farkas, PhD were the lead speakers. Thirteen donated textbooks were given away at the Trainee Luncheon.

Jeffrey A. Kant Education Fund

A six-member task force led by T&E Committee Chair Ted Schutzbank, with members Karen Weck, Rama Gullapalli, Marie C. DeFrances, Peter Kang, Jill Hagenkord and Federico Monzon. Their purpose was to recommend education and training initiatives to the Board that will utilize the Jeffrey A. Kant – AMP Education Fund.

Co-Sponsorships and/or Collaborations

- ***Society for Laboratory Automation and Screening (SLAS):***
 - **SLAS 2013** For the first time, AMP members were invited as presenters for the Diagnostics track at the SLAS 2013 annual meeting:
 - *Identification of Diagnostic Biomarkers with Novel Clinical Application*, presented by William Wachsman
 - *Diagnostics Tests and Personalized Medicine*, presented by Eric Duncavage
 - *Circulating Tumor Cells as a Biomarker to Monitor Cancer*, presented by Martin Fleisher

- **SLAS 2014** Collaboration continues with SLAS with the following AMP members and selected presentations for the SLAS 2014 annual meeting:
 - *How Circulating Tumor Cells Can Help Identify Targets for New Cancer Drugs*, presented by Martin Fleisher
 - *Parallel Multi-region Specific Next Generation and Big Dye DNA Sequencing*, presented by Bert Gold
- **USCAP:**

Five presentations were organized in a 2013 Companion Society session, “Integrating Advanced Sequencing and Genomic Results into the Surgical Pathology Report” and was co-moderated by Dan Jones and Ronald M. Przygodzki.

 - *Integrating FISH and Genomic Array into the Diagnostic Workup of Melanoma*, presented by Julie Reimann
 - *The Bone Marrow Comprehensive Report: Advances in Molecular and Cytogenetic Risk Stratification in AML and MDS*, presented by Daniel A. Arber
 - *HNPCC and the Molecular Cross Roads in CRC: Providing Guidance on Follow-Up Testing in MSI Tumors and Molecular Testing for Targeted Therapies*, presented by Antonia Sepulveda
 - *Approaches to Reporting Next Generation Sequencing Results for Solid Tumors*, presented by Federico A. Monzon
 - *How to Pull It All Together: Workflow and Report Design Considerations in Personalized Medicine*, presented by Dan Jones
- **2013 Mini-Symposium on Molecular Diagnostics** – March 13, 2013 in Dallas, TX, in collaboration with the Texas Society of Pathologists and the North Texas Society of Pathology. Speakers were Jennifer Hunt, MD, MEd and Elaine Lyon, PhD, FACMG.
- **Updates in Molecular Diagnostics and Genomic Medicine** – April 8, 2013 in Newark, NJ, in collaboration with the Department of Pathology and Laboratory Medicine at UMDNJ-New Jersey Medical School and the Departments of Pathology and Medical Education at Saint Barnabas Medical Center.
- **American Association for Clinical Chemistry 2013:** AMP was invited by Barbara Zehnbauser (AACC Co-Chair for Symposium Sessions) to participate in a late-breaking session at the AACC Annual Meeting & Clinical Lab Expo 2013 in Houston, Texas, for a session, “The Supreme Court Decision on Human Gene Patents and Its Implications.” Sandra Park, JD, Senior Staff Attorney, ACLU Women’s Rights Project, and Federico Monzon, MD, Baylor College of Medicine, represented AMP with assistance in preparations by Roger D. Klein, MD, JD, Department of Molecular Pathology, Cleveland Clinic and Chair, AMP Professional Relations Committee.
- **ASCP 2013 AMP Workshops:** Annette Kim, Kathy Mangold and Ted Schutzbank presented a course on molecular diagnostics for laboratory technologists.
- **CAP 2013 Course Presentations:** The four 2013 courses were:
 - *Molecular Hematopathology in the Era of Personalized Medicine*, presented by Megan Lim, Nathan Bailey and Kojo Elenitoba-Johnson

- *Molecular Testing Guidelines for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors*, presented by Neal Lindeman and Marc Ladanyi
- *A Practical Guide to Molecular Testing in Neoplastic Conditions of the Skin*, presented by Julia Bridge and Alexander Lazar
- *Beyond Single Gene Analysis: Paving the Way to Comprehensive Tumor Genomic Profiling*, presented by Neal Lindeman & Lynette Sholl

Educational Programs

- ***Molecular Pathology Outreach Course (MPOC 2013)***: For the past several years, the T&E committee has organized an 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 included an overview of applications of molecular pathology by invited speakers (Jennifer Hunt and John Pfeifer) followed by case studies presented by T&E members. As of October 23, 2013, there were 53 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 2013 live course was directed by Jennifer Hunt, and took place April 4-7 in Bethesda, MD. The online, self-study course is a recorded version of the live course and is available through 2014 at: <http://www.amp.org/mgp2013/self-study.cfm>
- ***Early Bird Sessions - Case Studies by Trainees***: A new opportunity for fellows, residents, postdocs, or graduate students who are attending the AMP 2013 Annual Meeting to present an interesting and/or challenging case study during an Early Bird Session. Trainee Presenters in 2013 were:
 - **Genetics**: Umut Aypar, Francine de Abreu, and Bryan Krock
 - **Hematopathology**: Elizabeth Azzato, Amir Behdad, Rashmi Kanagal-Shamanna, and Kitchener Wilson
 - **Infectious Diseases**: Malak Abedalthagafi, Daniel Rhoads, and Sanet Torres-Torres
 - **Solid Tumors**: Ina Geurts-Giele, Matthew Hiemenz, Eric Konnick, and Bradford Siegele
- ***Continuing Education credits (PACE, CME, and CMLE)***: AMP continues to apply for PACE credits (AMP Webinars), as well as CME credits via a joint sponsorship with ASCP, which includes the MGP Review Course (live and online), the MPOC, and the 2013 Annual Meeting. Continuing Medical Laboratory Education (CMLE) is provided for non-physicians.
- **Webinars:**

Date	Title	Speakers/Presenters	Attendees
Jan 7	Molecular Diagnostics in MDS and AML	Professor Ghulam J Mufti, DM FRCP, FRCPath and Annette S Kim, MD, PhD	212

Feb 26	Ins & Outs of Coding with the New Molecular Pathology CPT Procedure Codes	Aaron D Bossler, MD, PhD and Jan A Nowak, MD, PhD	319
April 19	Review of the Gene Patent Supreme Court Case	Sandra S Park, JD, Roger Klein, MD, JD and Ted Schutzbank, PhD	224
April 24	Lung Biomarker Guidelines presented by CAP, IASLC and AMP - Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors	Philip T Cagle, MD FCAP; Marc Ladanyi, MD; Neal I Lindeman, MD and Laura J. Tafe, MD (Moderator)	545
May 16	The Diagnostic Management Team: Optimizing Personalized Diagnostic Testing for Hematologic Malignancies	Adam Seegmiller, MD, PhD and Annette S Kim, MD, PhD	157
June 28	Association for Molecular Pathology v. Myriad Genetics, Inc.	Roger Klein, MD, JD, Sandra S Park, JD, and Ted Schutzbank, PhD	296
Sept 17	Incidental Findings in the Era of Whole Exome Sequencing: A View from the Laboratory	Sherri J. Bale, PhD and Rong Mao, MD	238
Oct 1	AMP Variant Nomenclature Database: Overview and Opportunities for the Future	Linda Jo Bone Jeng, MD, PhD and Christine Curtis, PhD	138
Oct 10	Applications of Human Genetic Testing in the Treatment of Infectious Diseases	Ted E. Schutzbank, PhD, D(ABMM) and Rangaraj Selvarangan BVSc, PhD, D(ABMM)	117
Dec 13	NGS Applications in Infectious Diseases	Noah Hoffman MD, PhD and Rangaraj Selvarangan BVSc, PhD, D(ABMM)	TBD

- **2013 Newly Appointed Positions:**

- Caren Gentile as the T&E Committee's first Medical Technologist member (2013-2014)
- Charlie Hill as AMP representative to the APC Fellowship Directors Ad Hoc Committee
- Anna Berry as AMP representative to NHGRI's Inter-Society Coordinating Committee
- Marina Nikiforova to serve as USCAP Companion Meeting Co-Moderator for 2014-2015

Submitted by Ted E. Schutzbank, Chair

AMP Subdivision Leadership Annual Report, 2013

SUBDIVISION LEADERSHIP

	Genetics	Hematopathology	Infectious Diseases	Solid Tumors
Chair	Madhuri Hegde	Megan Lim	Helen Fernandes	Marina Nikiforova
Clinical Practice Committee	Linda Jeng	Jerald Gong	Thomas Huard	Milena Cankovic
	Paul Rothberg	Jennifer Dunlap	Matthew Bankowski	Marilyn Li
Nominating Committee	Ramakrishnan Sasi	Dan Arber	Bobby Boyanton	Vivianna Van Deerlin
	Samuel Caughron	James Cook	Christine Ginocchio	Neal Lindeman
Program Committee	Anthony Shrimpton	Raja Luthra	Michael Lewinski	Ernst-Jan Speel
	Siby Sebastian	Dan Sabath	David Hillyard	Ronald Przygodzki
Training & Education Committee	Rong Mao	Annette Kim	Paula Revell	Laura Tafe
	Christine Curtis	Harvey Greisman	Rangaraj Selverangan	Jordan Laser

PURPOSE SUMMARY:

The Subdivision Leadership consists of a Chair and 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.

Genetics

- Addressed contemporary genetics topics as they relate to the clinical molecular diagnostics laboratory, including next-generation sequencing, whole genome and exome sequencing, and incidental findings.
- Content developed/provided by sessions at the Annual Meeting, a manuscript in development, and webinars, including:
 - The AMP Variant Nomenclature Database: Overview and Opportunities for the Future (October 2013)
 - Incidental Findings in the Era of Whole Exome Sequencing: A View from the Laboratory (September 2013)

Hematopathology

- Emphasized practical aspects and challenges for clinical laboratories on developing and implementing next-generation sequencing at the 2013 Annual Meeting, and managing diagnostics related to hematology via two webinars:
 - Molecular Diagnostics in MDS and AML (January 2013)
 - The Diagnostic Management Team: Optimizing Personalized Diagnostic Testing for Hematologic Malignancies (May 2013)

Infectious Diseases

- Highlighted emerging and novel clinical diagnostic methods for microbial identification at the 2013 Annual Meeting
- Discussed how members of other infectious disease-related organizations, such as Clinical Virology Symposium (CVS), Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC), American Society for Histocompatibility and Immunogenetics (ASHI), and the Infectious Diseases Society of America (IDSA), might mutually benefit the AMP subdivision interests and membership.
- Initiated discussions on clinical applications for next-generation sequencing for concurrent identification of microorganisms and their resistance genes.

Solid Tumors

- Focused on clinical applications of next-generation sequencing and other technologies with sessions at the Annual Meeting, as well as at the Companion Society Meeting at USCAP.
- Continuing initiatives for the improvement of clinical practice, including:
 - a contemporary review (in progress) on the Clinical Utility of Circulating Tumor Cells and Cell-Free Nucleic Acids for Molecular Pathologists; and
 - the development of clinical practice guidelines for the Evaluation of Biomarkers for Colorectal Cancer, in collaboration with the College of American Pathologists, the American Society for Clinical Pathology, and AMP.
- Initiated a new learning opportunity for trainees to present interesting and/or challenging cases from each subdivision at the Early Bird sessions at the AMP 2013 Annual Meeting.

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.

Submitted by the Subdivision Chairs,

Madhuri Hegde, Megan Lim, Helen Fernandes, and Marina Nikiforova

Economic Affairs Committee (EAC)

COMMITTEE MEMBERS:

Aaron D. Bossler MD PhD, Co-Chair
Jan A. Nowak MD PhD, Co-Chair
Samuel Caughron MD PhD, Member
Jill Hagenkord MD, Member
Roger D. Klein MD JD, Professional Relations Committee Chair & Liaison (*ex officio*)
Elaine Lyon PhD, Member
Paul A. Raslavicus MD, Member
Linda Sabatini PhD, Member
Michele Schoonmaker PhD, Member
Ester Stein, BS, MBA
Katherine Tynan PhD, Member
Dara Aisner, MD, PhD, Junior Member

The EAC is comprised of members from academic medicine, community practice, commercial reference, and commercial product manufacturing. Aaron Bossler and Jan Nowak are Co-Chairs of the EAC.

The Economic Affairs Committee has been productively engaged since the last AMP Annual Meeting in several areas. Reimbursement for molecular pathology tests including pricing and coverage is AMP's primary advocacy issue. AMP is working on this issue independently, as well as with fellow professional associations and other coalitions. Additionally, several AMP members serve on the AMA's Molecular Pathology Advisory Group as that organization works to implement coding for genomic sequencing procedures. In addition, AMP continues to advocate regarding the critical role of the professional in molecular diagnostics tests.

Coverage Issues

On behalf of several professional associations, AMP submitted comments to CMS in October regarding the intertwined issues of gap filling process and coverage determination in particular by the MoIDX program, http://www.amp.org/publications_resources/position_statements_letters/2013AMPPositionStatements.cfm. The letter to National CMS Administrator, Marilyn Tavenner, included a request to meet to discuss AMP's concerns and recommendations for changes to the MoIDX program, Medicare's policy for coverage of molecular diagnostic tests, and the assignment of payment rates to those tests via the "gap filling" process. AMP brought these issues to the attention of the National CMS along with the Regional Offices that oversee the Medicare Administrative Contractors so that these issues can be rectified and meet the instructions as set by CMS and the statutory requirements.

In addition, AMP drafted comments that were submitted in response to the following Medicare Administrative Contractor (MAC) Draft Local Coverage Determinations (LCDs):

WPS - Molecular Diagnostic Testing (PATH-037) (DL33219)

Novitas - Biomarkers Overview (DL33640 and DL33638)

First Coast - Molecular Pathology Procedures for Human Leukocyte Antigen (HLA) Typing (DL33732)

First Coast - Molecular Pathology Procedures (DL33703)

Palmetto - Genetic Testing for Lynch Syndrome (DL33779)

Palmetto - Molecular Diagnostic Tests (MDT) (DL33599)

Physician Fee Schedule (PFS) Rule and Gapfill Pricing

The EAC has been actively expressing concerns throughout the year regarding the implementation of and pricing process for the new Molecular Pathology CPT Codes, which went into effect on January 1, 2013, including:

- December 2012: Provided preliminary comments to CMS on the **2013 PFS Final Rule** which expressed disappointment with the placement of all of the molecular pathology procedures on the CLFS and noted concerns regarding 1) creation of a single HCPCS G-code, G0452, to recognize physician work related to a large number of procedures with varying Relative Values recommended by the AMA; and, 2) the notion that some of the molecular pathology procedures are “automated” and produce obvious results, precluding the need for professional work.
- February 2013: Presented a webinar on the “Ins & Outs of Coding with the New Molecular Pathology CPT Procedure Codes;”
- March 2013: Called AMP members to action regarding the **2013 PFS Final Rule**, in which CMS directed the regional Medicare Administrative Contractors (MACs) to assign reimbursement values to the new molecular pathology CPT codes using whatever information they had access to. This is the “**gapfill**” process. Several MACs released their preliminary fee schedules that significantly underpriced many molecular tests. Members were asked to provide their regional MAC with data that could be used to set appropriate reimbursement values; direct the MAC to use the information submitted by the AMA and developed through the RUC mechanism for assigning reimbursement values; and to communicate with their senators and congressmen so that they are aware of the jeopardy this issue is bringing to the delivery of molecular diagnostic services and personalized medicine in their legislative districts.
- July 2013: Submitted comments to CMS to explain its concerns about the **gapfill** process for pricing and reimbursement and to recommend modifications moving forward that included:
 - 1) addressing the lack of reimbursement for services rendered in 2013 by instructing all MACs to cover molecular pathology codes and retroactively pay from the start of 2013;
 - 2) reduction in preliminary payment amounts lower than cost with a request to review unsustainable reimbursement levels;
 - 3) lack of transparency in the gapfill process requesting explanation of how interim pricing was set and the details of the rationale involved;
 - 4) failure to address the professional work required to provide interpretation and a clinically actionable report by using a single HCPCS G-code, G0452 unlike the RUC data that specifically recognized varied professional effort.
- August 2013: Submitted comments to CMS regarding concerns with the **2014 Proposed PFS Rule**. The proposed Rule included a provision to bundle tests and cap reimbursement for certain services in the PFS at the Outpatient Prospective Payment System (OPPS) rates for 2013. AMP joined seven other pathology organizations to provide an initial response regarding general concerns with the impact this rule could have to patient access to testing.
- October 2013: Presented lengthy and detailed documentation on pricing and coverage issues and requested a meeting with CMS officials including Ms. Tavenner, Mr. Hartstein, and Dr. Jacques to discuss concerns and recommendations about the Palmetto Molecular Diagnostics (MoIDX) Services Program and Medicare coverage as well as their impact on Gap Fill Pricing for Molecular Pathology Procedures.

The Final Rule is expected to be published in late November, 2013, and new rates will be effective beginning January 1, 2014. The EAC will continue to advocate and inform AMP members on the impact to the profession and patient care.

Proposal for NGS related CPT Codes

The EAC developed a framework proposal to address CPT coding for Genomic Sequencing Procedures, which was submitted to the AMA CPT Editorial Panel. AMP posted the proposal on its website and collected comments to pass along to the panel. AMA has engaged with stakeholders during the development process. The AMA Molecular Pathology Advisory Group is currently developing CPT code proposals based on the AMP proposal for genomic sequencing procedures in time for the next submission deadline (October, 28) to the AMA CPT Editorial Panel. Several AMP members serve on the AMA Molecular Pathology Advisory Group.

Interfacing with CMS

- During the 2013 Clinical Laboratory Fee Schedule Public Meeting on July 10, AMP presented **crosswalk recommendations** for new codes 81161, 812XX, and 876XX.
- AMP continues to advise CMS **on Medically Unlikely Edits** (MUEs); the most recent comments were submitted by AMP in April of this year.
- AMP sent nominations for the appointment of Sam Caughron, Jill Hagenkord, Jennifer Hunt, and Linda Sabatini to the CMS Medicare Coverage Advisory Committee (MEDCAC).

Outside Organization Representation

- **Aaron Bossler** serves on the AMA Molecular Pathology Advisory Group. The members of this group provide expertise to the CPT Editorial Panel and the Pathology Coding Caucus (PCC).
- **Jan Nowak** replaced Dr. Bossler on the PCC, with **Jill Hagenkord** and **Sam Caughron** serving as Alternates. AMP continues to provide recommendations to the CAP Pathology Coding Caucus (PCC) as needed for new molecular pathology CPT codes. The CAP PCC is the first step in reviewing CPT code change proposals for new pathology CPT codes.
- AMP members appointed to the AMA Molecular CPT Work Group are **Aaron Bossler, Roger Klein, Elaine Lyon, Jan Nowak, and Vicky Pratt**. The new AMA Molecular Pathology Advisory Group (MPAG) includes AMP members **Aaron Bossler, Roger Klein, Elaine Lyon, and Maria Bettinotti**.
- AMP is a member of the Coalition to Strengthen the Future of Molecular Diagnostics (CSFMD), though declined to co-sign their letter to CMS regarding the gapfill process because it advocated for differential pricing for testing using FDA approved/cleared kits and LDTs. As noted in AMP's October comments to CMS, the MoIDX program is distinguishing services not on the basis of any recognized system of nomenclature or coding, but rather on privately supplied supplementary designators, which are used to differentiate among clinically equivalent services which are otherwise identically coded under HIPAA-approved systems of nomenclature. By requiring the use of the NOC code for FDA-approved versions of a test, vs. use of the CPT code for other tests, the median prices that are being used to establish the National Limitation Amounts for the CPT codes are distorted due to the exclusion of the FDA approved version.

AMP's position statements and letters are available publicly on the AMP website at http://www.amp.org/publications_resources/position_statements_letters/index.cfm. The EAC area of the website is <http://www.amp.org/committees/economics/>.

Professional Relations Committee (PRC)

COMMITTEE MEMBERS:

Roger D. Klein MD JD, Chair	Timothy J. O'Leary MD PhD, Member
Stephen P. Day PhD, Member	Vicky Pratt PhD, Member
Rajyasree Emmadi MD, Member	Daniel Sabath MD PhD, Member
Andrea Ferreira-Gonzalez PhD, Member	Robert F. Klees PhD, Junior Member
Elaine Lyon PhD, Member (President-Elect)	David E. Barton, PhD, <i>ad hoc</i> Member (Liaison IAWG)
Roberta Madej MS MBA, Member	Jennifer Leib, Consultant
Shelby Melton MD, Member	

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.

In 2013, the PRC continued to monitor the activities of, and in some cases work with, federal agencies and panels such as HHS, FDA, AHRQ, CLIAC, USPTO, President's Commission for the Study of Bioethical Issues, as well as policy committees such as IOM. The committee responded to requests for comments, attended conferences, and discussed and commented on many federal agency draft guidance documents, policies and reports, as well as numerous proposed federal laws. In addition, the PRC's LDT Working Group completed its re-examination of the oversight of Laboratory Developed Tests (LDTs); the paper will be published in the January 2014 issue of *The Journal of Molecular Diagnostics (JMD)*.

After extensive discussion, the committee drafts AMP's policy positions and comments to federal agencies (other than reimbursement, which is the purview of the Economic Affairs Committee) and members of Congress. Additionally, AMP is able to mobilize quickly to respond to time-sensitive policy developments. AMP's government relations consultant, Jennifer Leib of HealthFutures, 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. Approximately once a month, Jennifer Leib, 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. AMP maintained active with interactions on Capitol Hill and met with 14 congressional staff offices (5 Senate, 9 House). On one day, a morning of Congressional meetings was followed by a Congressional briefing on the implications of the AMP v. Myriad decision. Over 100 attendees were present, most of whom were hill staff. AMP and members made additional contacts with Congress by signing onto coalition letters and sending emails regarding this year's challenges with reimbursement. Jennifer Leib also assists AMP with drafting press releases related to its advocacy efforts.

The PRC's two working groups completed their tasks in 2013:

- **LDT Working Group:** A white paper re-examining the complexities involved with oversight of LDTs has been accepted for publication by *The Journal of Molecular Diagnostics* and is anticipated in the January 2014 issue. The LDT Working Group consisted of Andrea Ferreira-Gonzalez (Chair), Rajyasree Emmadi, Stephen Day, Robert Klees, Roger D. Klein, Elaine Lyon, Jan Nowak, Victoria Pratt, Mary Williams, and Jennifer Leib.
- **Industry Member Task Force (IMTF):** The Task Force submitted to the Board in July its report, which assesses whether AMP activities meet the needs of its industry members and provides recommendations for areas of improvement. The Board is addressing the recommendations. The Task Force also assisted the PRC by drafting comments on the FDA Draft Guidance on Molecular Diagnostic Instruments with Combined Functions that were submitted to FDA on July 8. AMP believes this Guidance is a step forward in that FDA is formalizing the use of open channels on instruments. The Industry Member Task Force included: Roberta Madej (Chair & PRC liaison); Wendy Benson; Bryan Cobb; Steve Day (PRC liaison); David Ellis; Renee Howell; Jennifer Leib; Roger Klein (PRC Chair); Lynne Rainen; Jennifer Skeen; and Anita Suresh.

In September, the Board approved the formation of an Industry Member Advisory Group (IMAG) to provide input and recommendations to the PRC on responses to FDA draft guidances to industry and other issues of importance to AMP industry members.

AMP's position statements and letters may be found on the AMP website at

http://www.amp.org/publications_resources/position_statements_letters/index.cfm. The committee reviews previously drafted documents no less than every five years to determine if they should be retired.

2013 Interactions with Federal Agencies:

- **AHRQ:** AMP has long emphasized the involvement of molecular experts in the preparation and / or review of the Agency for Healthcare Research and Quality's Technology Assessments. AMP commented on the AHRQ Draft Report, "Update on Genetic Tests Currently Available for Clinical Use in Common Cancers" indicating concerns with methodical flaws in the data gathering process that have led to gaps in the report's findings that may have been avoided by including pathologists with subspecialty expertise in molecular pathology, *i.e.*, the medical practitioners who are largely responsible for performing and interpreting molecular tests in solid and hematopoietic tumors, as well as geneticists with subspecialty interests in hereditary cancer syndromes, in drafting and reviewing the report.
- **FDA:**
 - **LDTs:** FDA Commissioner Margaret Hamburg alluded to future FDA regulation of "high risk" LDTs at the 2013 ASCO Annual Meeting, citing LabCorp's OvaSure as a specific example of a "flawed" test. Her comments on LDTs were juxtaposed next to a discussion of recently approved companion diagnostics, raising concern that some or all LDTs for "companion analytes" could potentially fall within the scope of a future FDA guidance regulating high risk tests. AMP has been working with FDA to educate officials about clinical laboratory practices and operations, and has emphasized the infeasibility of mandating the use of specific assays with particular drugs because of the multiplicity of potential drugs and assays platforms. Additionally, LDTs offer important benefits to patients through the rapid introduction of assays in response to new medical discoveries, enhanced flexibility in performance due to the ability to continually modify assays, and increased innovation stemming from the relative ease in incorporating new test methods and knowledge. AMP will continue to work diligently with FDA on this issue in order to achieve the best outcomes for our patients. Additionally, LDTs offer an important benefit to patients by rapid assay introduction following discovery of a medically important variant-drug relationship, *e.g.* KRAS, as well as through their greater flexibility in performance, and the innovation they drive. AMP will continue to work diligently with FDA on this issue in order to achieve the best outcomes for our patients.

- **Draft Guidance Comments:**
 - AMP commented on the draft guidance for Management of Cybersecurity in Medical Devices indicating that while recognizing the importance of cybersecurity for electronic medical records, diagnostics instrumentation and test systems, standards should not prevent qualified professionals from utilizing, maintaining, and/or repairing the systems.
 - AMP submitted comments on the draft guidance on Molecular Diagnostic Instruments with Combined Functions. AMP believes this is a step forward in that FDA is formalizing the use of open channels on instruments.
- **President's Commission for the Study of Bioethical Issues:** AMP responded to the request for public comment on the ethical, legal, and social issues raised by incidental findings that arise from genetic and genomic testing, imaging, and testing of biological specimens conducted in the clinical, research, and direct-to-consumer contexts. AMP offered its expertise to assist in the Commission's efforts and encouraged the Commission to review guidelines and statements from pathology and genetic professional societies engaged in the practice of genomic medicine. AMP believes genetic testing is best pursued in a medical setting in which pre-test and post-test genetic counseling are available. The likelihood of incidental findings, and the reporting dilemmas they entail, presents yet another argument in support of this position, and argues against the advisability of direct-to-consumer large-scale genetic testing.

2013 Efforts Regarding Legislation:

- **Health IT Reform Act:** AMP endorsed again in the new Congress H.R. 1309, the Health Information Technology Reform Act, which would address the lack of alignment between the regulations implementing meaningful use standards and pathology practice by excluding pathologists from EMR-related incentive payments and penalties.
- **"PhD Billing":** The placement of the molecular pathology CPT codes on the CLFS removed the principle need (in the eyes of Congress) to introduce legislation to designate non-physician doctoral scientists with appropriate training and experience as Qualified Health Care Practitioners, permitted to bill Medicare directly from the Physician Fee Schedule for interpretive services for tests in the Molecular Pathology section of the CPT® codebook. AMP continues to explore ways to advocate regarding the essential role of professional work in molecular pathology testing.
- **Travel Restrictions for Federal Employees:** AMP continues to monitor and engage Congress and federal agencies on policies that restrict federal employees' educational travel. AMP continues to specifically advocate for a legislative exemption for conferences for which the primary purposes are scientific collaboration and medical education.
- **H.R. 3116, the MODERN Cures Act of 2013:** The language is similar to last year's bill (H.R. 3497) minus language on the gap fill process, which is now in a bill introduced by Rep. Roskam (H.R. 2085, The Diagnostic Innovation Testing and Knowledge Advancement Act of 2013). The bill includes sections on creating a common lexicon for diagnostics, incentives for development of diagnostics, and dormant therapies. AMP is studying the potential impact of this legislation, but has not taken a position on it.
- **PopVox:** AMP implemented the online media tool PopVox.com to aid our legislative efforts and increase awareness of our positions. PopVox.com (<https://www.popvox.com/orgs/amp>) provides a curating interface for anyone - including Congressional staff, the public and the media - to access and understand AMP's positions. It enables House and Senate staff to easily research the views of stakeholders on issues and pending legislation.
- **Reimbursement:** Armed with positions and comments drafted by the Economic Affairs Committee (EAC), AMP visited members of Congress to inform them of the impact from the gapfill process, payment denials, and proposed cuts to payments for 38 anatomic pathology procedures in the Physician Fee Schedule (PFS), including FISH. Multiple pathology and laboratory associations, including AMP, sent Calls for Action to their members asking that they contact their senators and representatives in Congress regarding the proposed reductions. As a

result of member contacts and visits to Congressional offices, 27 bipartisan members of the House and 21 in the Senate co-signed a letter to CMS expressing serious concerns with the proposals.

- **H.R. 2085, The Diagnostic Innovation Testing and Knowledge Advancement Act of 2013 (Rep Roskam):** Endorsed by AdvaMedDx, this legislation attempts to increase transparency in the gapfill process through the formation of an advisory committee and requiring CMS to provide the justification for the pricing. Additionally, the bill includes a list of additional factors that CMS must consider during gapfill, which attempts to shift the process to value-based pricing. Although increased transparency in the process would be beneficial, AMP supports the AMA RUC process and thus, has not endorsed this legislation.
- **Sunshine Act:** The Act took effect on August 1st. CMS held a webinar Aug. 8 to review the new rules and you can find the slide deck here: <http://www.cms.gov/Outreach-and-Education/Outreach/NPC/Downloads/2013-08-07NPC-OpenPayments.pdf>. AMP is working with exhibitors to facilitate compliance with the new rules.
- **Appropriations:** On October 17, the President signed bi-partisan legislation to end the government shutdown and raise the debt ceiling. The legislation—H.R. 2775—extends funding for federal programs at current, post-sequester levels through January 15th and raises the debt ceiling through February 7th. As a condition for passing the legislation, the House and Senate leadership agreed to hold a budget conference—the first in four years—to negotiate a top line discretionary funding level and potentially address sequestration. The conferees, led by Budget Committee Chairmen Senator Patty Murray and Representative Paul Ryan met for the first time on October 30th and will meet again on November 13th. There is a general interest in working together to replace sequestration for at least one year with offsets, to be determined. The conferees must produce a plan no later than December 13th, though House and Senate Appropriations Committee Chairmen Senator Barbara Mikulski and Representative Hal Rogers have urged the conferees to produce an agreement no later than December 2nd to allow appropriators time to write final FY 2014 spending bills. Until the conferees come to an agreement on the topline discretionary funding level—and what to do about sequestration—it's difficult to anticipate what the final funding levels might be for defense and nondefense discretionary programs.

Other Organizations

AMP continues to participate in a variety of policy discussions with other professional societies, laboratory groups, as well as coalition groups.

- **European Parliamentary Committee Regulations:** AMP member David Barton, liaison to PRC from the AMP International Affairs Working Group, informed the PRC that the framework on IVDs in Europe is being rewritten based on the Global Harmonization Task Force classification. Language from AMP has been helpful in the past and AMP will continue to assist its European members where possible.
- **Personalized Medicine Coalition:** AMP contributed to the Personalized Medicine Coalition's drafting of a white paper on the oversight of LDTs. The document summarized the complexity of the policy issue and described stakeholder positions, including AMP's.
- **IOM Roundtable on Translating Genomic-Based Research for Health:** As of September 1, AMP is a sponsoring member and Vicky Pratt will represent AMP on the Roundtable.
- **Federation of American Societies for Experimental Biology (FASEB):** AMP became a FASEB member on July 1. Greg Tsongalis has been appointed to AMP's seat on FASEB's Board of Directors and will serve as AMP's initial representative on the Science Policy Committee.
- **Global Alliance:** In July, AMP joined 70 other organizations as a founding partner to create a global alliance that will enable responsible sharing of genomic and clinical data.

Gene Patents:

- The Supreme Court of the United States handed down a unanimous decision on June 13, 2013 favoring the plaintiffs in the landmark case, Association for Molecular Pathology *et al.* v. Myriad Genetics, Inc. *et al.* The decision helps to relieve hindrances to clinical molecular testing and barriers to innovation. Roger Klein, Mary Williams, and Jennifer Leib attended the oral arguments in April 2013. View the AMP Press Release online at http://www.amp.org/documents/20131306_SCOTUSAMPvMYRIAD.pdf.
- On July 11, 2013, AMP and ACLU held a briefing to educate members of Congress on the AMP v. Myriad Genetics United States Supreme Court decision. More than 100 people attended the briefing, which is three times what is typical for such an event. On the same day, PRC Chair, Roger Klein, and AMP Government Relations Consultant, Jennifer Leib, met with the majority and minority leadership of the House and Senate Judiciary Committees and other offices active on the issue of gene patents.
- Roger Klein represented AMP at the second U.S. Patent & Trademark Office (USPTO) roundtable to discuss the impact of gene patents on the ability of patients to access confirmatory (2nd opinion) testing. This is a part of a Congressional mandated study.
- AMP provided written comments on the Public Roundtable on Genetic Diagnostic Testing in January 2013.

AMP Membership Affairs Committee – 2013 Annual Report

The AMP Membership Affairs Committee (MAC) provides recommendations to Council 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. To expand its International outreach efforts, the MAC formed the International Affairs Working Group (IAWG).

Committee Members

Shuji Ogino, Chair
Nirali Patel, Chair-Elect
Pritish Bhattacharyya, AIPNA Liaison
Neng Chen
Ephrem Lip Hon Chin, CCCLW Liaison
Shefali Janak Desai
Jennifer Laudadio
Dakai Liu
Craig MacKinnon
Lynne Rainen
Patrik Vitazka, IAWG Liaison
Chris Wong, IAWG Chair

The Membership Affairs Committee (MAC) and the International Affairs Working Group (IAWG) have been busy in 2013 and successfully achieved a number of milestones, including:

1. Conducted a Survey of AMP Members
In March of 2013, a Survey Task Force was formed, Chaired by Jennifer Laudadio and consisting of Ephrem Lip Hon Chin, Elaine Lyon, Shuji Ogino, and Nirali Patel. By April of 2013, the group had developed and launched a very impactful survey of AMP members. The results of the survey, although not necessarily surprising, confirmed the following:
 - A. Members rely on AMP for its influence on key decision makers and within the field of molecular pathology.
 - B. Members look to AMP for the highest quality education in the field of molecular pathology.
 - C. One of the primary benefits of membership is networking with peers, particularly via CHAMP.Members also indicated via the survey that grants and awards for achievement in the field should be a high priority for AMP. As a result of that input, AMP is launching a new Awards Committee in 2014.
2. Developed and Launched a New Dues Structure for 2014
Based in part on information gleaned from the member survey, the MAC essentially overhauled the membership dues structure resulting in lower rates for International members and trainees. These new rates go into effect for 2014.
3. Launched the International Affiliate Program
One initiative that had been on the plate for the International Affairs Working Group (IAWG) is a method for establishing a formal relationship and education exchange with molecular diagnostic-related organizations outside of the United States. In 2013, the

International Affiliate Program was successfully launched and welcomed the following AMP International Affiliate Organizations:

- A. The Hong Kong Society for Molecular Diagnostics (March 2013)
- B. The Korean Society for Laboratory Medicine (April 2013)
- C. The Molecular Pathology Association of India (June 2013)

International outreach continues to expand for the IAWG and they look forward to welcoming more Affiliates in 2014 and the years to come.

- 4. Welcomed a new IAWG Chair and Bade Farewell to the IAWG Founding Chair
Chris Wong became the new IAWG Chair in early 2013, taking the reins from Patrik Viztaka, the IAWG founding Chair and now Honorary Member of the IAWG. Patrik's efforts brought the group to fruition and served to develop and implement educational initiatives across the globe. Chris has continued to champion the International outreach started by Patrick and the IAWG.

AMP Publications Committee – 2013 Annual Report

The task of the Publications committee is to review and monitor all AMP associated documents, whether print or electronic, that are generated by either AMP staff or AMP members under the AMP name or with AMP resources. The Publications Committee is also responsible for the implementation of periodic updates to the various committee and subdivision homepages(s) on the AMP website. To assist with AMP's electronic media presence, particularly CHAMP, the Publications Committee developed an advisory group specifically related to electronic media.

Committee Members

Steve Schichman, Chair
Alexis Carter, AMP Test Directory Editor
Chhavi Chauhan, *JMD* Scientific Editor
Audra Cox, *JMD* Managing Editor
Mary Lowry-Nordberg, AMP Website Editor
Tim O'Leary, *JMD* Editor-in-Chief
Dahui Qin, Electronic Media Advisor
Mohamadou Sene, Electronic Media Advisor
Shalini Verma, Electronic Media Advisor

The Publications Committee (Pubs) and the Electronic Media Advisors (EMAs) embarked on a number of important initiatives in 2013, including:

1. Developed Case Reports for publication in CAP TODAY

This initiative was successfully launched in early 2013 and to date has yielded the following two Case Reports in CAP TODAY:

Importance of screening for Lynch syndrome in patients with EC A 48-year-old woman with endometrial cancer

August 2013

Erik G. Jenson, MD
Gregory J. Tsongalis, PhD
Laura J. Tafe, MD

Multilocus sequencing for rapid identification of molds

February 2013

Desiree Marshall, MD
Dhruba J. SenGupta, PhD
Daniel R. Hoogestraat, MB(ASCP)
Karen Stephens, PhD
Brad T. Cookson, MD, PhD
Cecilia C.S. Yeung, MD

The feedback from AMP and CAP members alike has been tremendous and CAP & AMP look forward to continuing the project in 2014.

2. Monitored the AMP Website

Some minor but effective cosmetic changes were applied to the AMP website this year to update the "look and feel" of the site. The result is a crisper, cleaner, more easily navigated site. In addition, the group worked with AMP staff to update specific sections of the site including the web library and other resources. The website is a "living document" that will continue to be reviewed and updated by the Pubs Committee.

3. Reviewed Updates for the Test Directory
Alexis Carter has worked diligently along with Mary Williams and other volunteers to significantly update the AMP Test Directory. The Pubs Committee reviewed and provided feedback on a demo of the new Test Directory and looks forward to the launch in the first half of 2014.
4. Surveyed AMP Members on CHAMP 2.0
The upgrade in AMP members' communication system from an email based system to more of a social media environment was met with lively input from AMP members. To take advantage of the input and establish a plan of action, the Electronic Media Advisors developed and launched a survey of members regarding their use of CHAMP 2.0. The most important finding was the level of frustration encountered by a significant percentage of AMP members with the new system – there were too many clicks required and some of the simplicity was lost with the new system. With that information in mind, the EMAs and the Pubs Committee developed a plan of action to address the challenges.
5. Researched and Began Implementation of a new CHAMP Platform
Based on input from AMP members and their own personal experience with using the CHAMP 2.0 system, the EMAs and the Pubs Committee thoroughly researched options for a CHAMP platform that would meet the clearly defined needs and requirements of AMP members. A solid solution has been identified and will be in place in early 2014.
6. Volunteered to Serve as “Beta Testers” for the new Association Management System (AMS)
Another significant enhancement for AMP is a new AMS. Members and others utilize the AMS when renewing membership or registering for AMP events online. The EMAs and members of the Pubs Committee have volunteered to serve as testers for the new system when it is launched later in 2013. AMP members will experience the enhanced system when renewing their membership for 2014.

Nominating Committee

COMMITTEE MEMBERS:

Iris Schrijver MD, Chair

Ramakrishnan Sasi PhD, Genetics Representative

Sam Caughron MD, Genetics Representative

Daniel Arber MD PhD, Hematopathology Representative

James R Cook MD PhD, Hematopathology Representative

Bobby L. Boyanton MD, Infectious Diseases Representative

Christine C Ginocchio PhD, Infectious Diseases Representative

Vivianna Van Deerlin MD PhD, Solid Tumors Representative

Neal Lindeman MD, Solid Tumors Representative

The Nominating Committee nominated Officers and Committee Representatives for the annual elections and recommended the recipients of the AMP Award for Excellence in Molecular Diagnostics, AMP Leadership Award, and the AMP Meritorious Service Award.

Program Committee

2013 Committee Members:

Franklin Cockerill MD, Chair
Charles E Hill MD PhD, Chair-Elect
Madhuri Hegde PhD, Genetics Subdivision Chair
Anthony E Shrimpton PhD, Genetics Subdivision Representative
Siby Sebastian PhD, Genetics Subdivision Representative
Megan S Lim MD PhD, Hematopathology Subdivision Chair
Raja Luthra PhD, Hematopathology Subdivision Representative
Daniel E Sabath MD PhD, Hematopathology Subdivision Representative
Helen Fernandes PhD, Infectious Diseases Subdivision Chair
Michael A Lewinski PhD, Infectious Diseases Subdivision Representative
David Hillyard MD, Infectious Diseases Subdivision Representative
Marina N Nikiforova MD, Solid Tumors Subdivision Chair
Ernst-Jan M Speel PhD, Solid Tumors Subdivision Representative
Ronald M Przygodzki MD, Solid Tumors Subdivision Representative
Lara M Brusca MS, Technical Topics Representative
Kimberly A Lebel BS MB(ASCP), Technical Topics Representative

Strategic Opportunities Committee

2013 Committee Members:

Elaine Lyon PhD, Chair
Steven Gutman MD MBA, Member
Marc Ladanyi MD, Member
Karl Voelkerding MD, Member
Roger Klein MD JD, *Ad Officio* Board Member
Shuji Ogino MD PhD, *Ad Officio* Board Member

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

- 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.