AMP 2014 Committee and Subdivision Annual Reports

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Mary Steele Williams, MNA, MT(ASCP)SM, CAE	Executive Director (*Ex Officio*, non-voting)

AMP Awards Committee Annual Report, 2014

COMMITTEE MEMBERS:

Debra G. B. Leonard, MD, PhD	Chair
Kenneth Bahk, PhD	Member
Angela M. Caliendo, MD, PhD	Member
Karen L. Kaul, MD, PhD	Member
Tadd S. Lazarus, MD	Member
Jennifer L. Hunt, MD, MEd	Ex Officio

PURPOSE SUMMARY:

The Awards Committee oversees 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.

Historical Context

The Awards Committee was established in 2013 as an *ad hoc* committee to assess the division of responsibility in overseeing AMP recognition awards rather than the Nominating Committee, whose primary focus is to compile the election ballot for volunteer leadership within the AMP membership. In June 2014, the Board approved the recommendation by the Awards Committee to become an ongoing committee. In September 2014, the Board appointed the 2015 President-Elect to serve as the 2015 Chair of the Awards Committee.

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

- 2014 Jeffrey A. Kant Leadership Award: Elaine Lyon, PhD
- 2014 Meritorious Service Award: Aaron D. Bossler, MD, PhD
- 2016 Award for Excellence in Molecular Diagnostics: Eric S. Lander, PhD

AMP Clinical Practice Committee Annual Report, 2014

COMMITTEE MEMBERS:

Loren Joseph, MD	Chair
Carolyn Sue Richards, PhD	Genetics Representative
Paul G Rothberg, PhD	Genetics Representative
Jennifer Dunlap, MD	Hematopathology Representative
Annette Kim, MD, PhD	Hematopathology Representative
Matthew J. Bankowski, PhD	Infectious Diseases Representative
Melissa B. Miller, PhD	Infectious Diseases Representative
Marilyn M. Li, MD	Solid Tumors Representative
Mary C. Lowery-Nordberg, PhD	Solid Tumors Representative
Larissa V. Furtado, MD	Junior Member
Bryan Krock, PhD	Junior Member
Jane Gibson, PhD, FACMG	Chair for the Whole Genome Analysis Working Group
Bibhuranjan (BR) Das, PhD	International Affairs Working Group Liaison

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

- **September 2014:** *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. Article in press, *The Journal of Molecular Diagnostics*.

- **September 2014:** *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. Submitted, *The Journal of Molecular Diagnostics*.

Manuscripts in Progress

- 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. November 2014 AMP Web Publication; companion webpage currently under construction.

- *Framework for Addressing Clinical Utility of Molecular Diagnostic Testing: A Report of the Association for Molecular Pathology.* In collaboration with representatives from the CPC, Economic Affairs Committee, and Professional Relations Committee. Led by Loren Joseph and Elaine Lyon with Milena Cankovic, Samuel Caughron, Pranil Chandra, Rajyasree Emmadi, Jill Hagenkord, Stephanie Hallam, Kay E. Jewell, Roger Klein, Jennifer Leib, Jan Nowak, Victoria M. Pratt, Paul Rothberg, and Robyn Temple-Smolkin.

- *Practical Considerations for Implementation of Next Generation Sequencing Assays*. In collaboration with representatives from the CPC and the Whole Genome Analysis Working Group. Led by Jane Gibson with Bert Gold, Ira Lubin, Patrik Vitazka, Andrea Ferreira-Gonzalez.

- *Next-Generation Sequencing for Infectious Disease Diagnosis and Clinical Management.* In collaboration with Infectious Diseases representatives from the CPC and Subdivision Leadership Benjamin Pinsky and Matt Bankowski.

Clinical Practice Guidelines

- **September 2014:** AMP Board approved a Clinical Practice Guidelines Development Policy developed by the CPC to support and encourage AMP's active role in development of multiple types of guidelines, both within AMP and in collaboration with other organizations.

- **In development:** AMP Interpretation of Sequence Variants in Somatic Conditions (Cancer) Chaired by Marilyn Li with anticipated participation with ACMG and CAP.

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

	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 2014: Literature Review & Presentations at Annual Meetings
Saturday session at 2014 AMP Annual Meeting – see program for information
November 2014: Draft Recommendations
Winter 2014: Public Comment Period
Spring 2015: Revisions
Summer 2015: Coordinated Publication in x, y, z
Fall 2015: Presentations at Annual Meetings upon joint publication

- **In development:** Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors – Update of the April 2013 guideline developed jointly by the College of American Pathologists (CAP), the International Association for the Study of Lung Cancer (IASLC), and the Association for Molecular Pathology (AMP). J. Mol Diagn. 2013:15:415-453. For more information: http://www.amp.org/committees/clinical_practice/LungBiomarkerGuideline.cfm

	CAP	IASLC	AMP
Co-Chair	Philip T. Cagle, MD	Yasushi Yatabe, MD, PhD	Neal I. Lindeman, MD

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
- AMP-American Society for Hematology Exploratory Guidelines Workgroup, Annette Kim
- ACMG Incidental Findings in Inherited Diseases Update Workgroup, Carolyn Sue Richards

Additional accomplishments

- Kojo Elenitoba-Johnson and CPC Chair Loren Joseph co-moderated a two-day Genomics Roundtable in April 2014 co-sponsored by the American Society of Clinical Oncology, AMP, and the College of American Pathologists to discuss issues related to oncology clinical practice and genomic laboratory medicine. AMP members Annette Kim and John Pfeifer presented and AMP was represented by Marilyn Li and Ron Przygodzki.
- AMP hosted a Reference Materials Forum prior to the 2014 Annual Meeting on Tuesday, Nov 11, 2014 with representatives from CDC, NIST, and NCI.
- Hematopathology and Solid Tumors Subdivision representatives are actively developing & implementing interlab sample exchanges for the validation of next-generation sequencing platforms.
- Multiple CPC / WGA members hosting or presenting in AMP Webinar events

Whole Genome Analysis Working Group: Jane Gibson, Chair

- Developed and implemented AMP member and international surveys on reference material needs. Results of the surveys were highlighted at the August 2014 NIST Genome In A Bottle Workshop and during the AMP Reference Materials Forum November 11, 2014.
- September 2014: Andrea Ferreira-Gonzalez (as AMP representative) and Ira Lubin were speakers at the FDA Public Workshop: Next Generation Sequencing Standards Workshop.
- CPC recommended to the Board that future clinical practice matters in whole exome / genome analysis / next generation sequencing should be implemented and developed by AMP within the CPC and declared the original charge of the WGA to be completed. The WGA was officially dissolved in October 2014. The CPC and the Board of Directors wishes to acknowledge and thank WGA Chair Jane Gibson and all WGA members for their volunteer service to AMP.

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.

AMP Economic Affairs Committee Annual Report, 2014

COMMITTEE MEMBERS:

Aaron D. Bossler, MD, PhD	Economic Affairs Committee Co-Chair
Jan A. Nowak, MD, PhD	Economic Affairs Committee Co-Chair
Samuel K. Caughron, MD	Vice Chair
Jill Hagenkord, MD	Vice Chair, New Codes
Richard D. Press, MD, PhD	Vice Chair, Coverage
Pranil Chandra, DO	Member
Linda M. Sabatini, PhD HCLD	Member
Michele Schoonmaker, PhD	Member
Ester Stein, BS, MBA	Member
Dara L. Aisner, MD, PhD	Junior Member
Erica Miller, JD	Consultant
Katherine Tynan, PhD	Consultant
Elaine Lyon, PhD	President
Roger D. Klein, MD, JD	Professional Relations Committee Chair

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.

2014 ACTIVITIES:

Reimbursement for molecular pathology tests is AMP's primary advocacy issue, and the EAC has been addressing problems with denial of coverage and the Palmetto Molecular Diagnostic Services (MolDX) Program. 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

Representatives from AMP, CAP, AMA, ACMG, ASCLS, ASCP, ASHI, NFXF, and WDA have been meeting with CMS to outline problems with the MolDx Program, the way CMS is proceeding with the molecular pathology CPT codes, and to make recommendations for improved reimbursement policies. This is a large and broad stakeholder group that is working very hard to protect patient access to necessary testing and health care professionals' ability to provide that care. At the request of Tamara Syrek-Jensen, Director, CMS Coverage and Analysis Group, the multi-society coalition provided a plan that included Key Recommendations for Medicare Coverage of MolDx and NGS Services. Representatives from the AMP EAC conducted follow-up meetings with Tamara Syrek-Jensen in April and September to discuss Medicare Coverage of MolDx and NGS Services and AMP's concerns with the expansion of the Palmetto MolDx program, PAMA implementation, and retroactive

payments for CPT Tier 1 and 2 codes. In addition, AMP met with Melissa Harris, Medicaid coverage, and Janet Freeze, Medicaid pricing, in early April.

From July 2013 through May 2014, AMP drafted and/or submitted comments in response to 14 dLCDs by MACs and of those, 26% of the requests resulted in changes in the final LCD. Based on the positive impact of the comments, the EAC continues to respond to dLCDs, across various jurisdictions, with comments submitted or to be submitted on at least 8 more dLCDs before the end of 2014.

In addition to commenting on dLCDs and engaging directly with CMS, staff of our coalition organizations are meeting to discuss possible strategies regarding the expansion of MolDx. We are also engaged in responding to the FDA's proposed guidance on FDA oversight of Laboratory Developed Tests (LDTs) and the "Protecting Access to Medicare Act of 2014" (PAMA). After the passage of PAMA, AMP invited Dan Todd, Professional Staff on the Senate Finance Committee to participate in the EAC teleconference to discuss and clarify provisions in the legislation.

Physician Fee Schedule (PFS) Rule and Crosswalk Pricing

AMP commented on the final rule entitled "Medicare Program; Revisions to the Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revision to Part B for CY 2014" focusing on Payment for Molecular Pathology Services and Policies Regarding Technological Changes.

In response to strong opposition from AMP, other pathology and laboratory associations, and members of Congress, in its final 2014 Physician Fee Schedule (PFS) rule, CMS did not apply Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) rates to set the practice expense relative value units for the PFS. If enacted it would have cut reimbursement an average of 25 percent. Responding to intense lobbying efforts and constituent requests, many members of Congress co-signed letters to CMS Administrator Marilyn Tavenner that were instrumental in stalling this devastating proposed policy.

AMP submitted comments on the proposed 2015 Physician Fee Schedule. The comments focused on:

1. Not using hospital cost data in developing practice expense relative value units (RVUs).
2. Concerns with modifying the process to establish values for new, revised, and potentially misvalued codes.
3. Recommendations for improvements to the local coverage determination process for clinical diagnostic laboratory testing, including not reducing the draft comment period.
4. Numerous concerns regarding the Palmetto MolDx program.
5. Discouraging revocation of the Sunshine Act reporting exclusion for continuing medical education (CME) activities.

The comments in their entirety can be accessed via this link: http://www.amp.org/publications_resources/position_statements_letters/documents/AMPComments2015PhysicianFeeSchedule2014-09-02Web.pdf

During the public meeting for the new Clinical Laboratory Fee Schedule (CLFS) services on July 14, AMP was represented by **Aaron Bossler** and **Roger Klein** who commented regarding pricing for the new Gene Sequencing Procedure (GSP, aka NGS) CPT codes and CLFS reform provision in the PAMA bill, respectively. AMP presented crosswalk recommendations for new molecular tier 1 codes (FLT3, MLH1, PCA3/KLK3), genomic sequencing procedures, and microbiology codes along with its stance on PAMA.

Microcosting and Health Economic Evaluation of Genomic Sequencing Procedures

AMP and its members have a vested interest in ensuring that various Genomic Sequencing Procedures (GSPs) are appropriately and fairly valued moving forward. Therefore, AMP retained Boston Healthcare Associates and Tynan Consulting, in collaboration with the AMP membership to develop transparent and reference-able cost data and health economic valuations to share with payers and other healthcare providers. It is the largest project in AMP's history.

The microcosting data from this project will be a valuable tool for AMP members and others involved in providing these results to patients, particularly for submission of cost information to CMS and commercial insurance carriers.

In addition, AMP recognizes that demonstrating the *value* of next generation sequencing assays will be critical to establishing fair reimbursement. As part of the project we will also perform health economic modeling of next generation sequencing assays for a number of indications. The modeling will attempt to estimate and compare the cost-utility of next generation sequencing technology with that of current standard testing and medical intervention algorithms so that their value proposition is fully understood.

AMP is grateful for the work of its Economic Affairs Committee (EAC), co-chaired by Drs. **Aaron Bossler** and **Jan Nowak**, and for the oversight of this project by a special committee, chaired by Dr. **Linda Sabatini** and comprised of Board and EAC members. The results of this project will be announced to AMP members by this group and is anticipated by the end of this year.

CPT Codes

The EAC CPT Work Group advises on AMP position on new CPT code proposals submitted to the Pathology Coding Caucus (PCC). The Work Group has also designed new code proposals for disorder specific multigene panels that will be submitted to the AMA CPT Editorial Panel in November 2014.

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'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/.

AMP Finance Committee Annual Report, 2014

COMMITTEE MEMBERS:

Vivianna Van Deerlin, MD, PhD	Chair
Elaine Lyon, PhD	President
Janina A. Longtine, MD	President-Elect
Jennifer L. Hunt, MD, MEd	Past President
Mary C. Lowery-Nordberg, PhD	Member
Timothy T. Stenzel, MD, PhD, FACMG, FCAP	Member
Gail H. Vance, MD	Member

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 Membership Affairs Committee Annual Report, 2014

COMMITTEE MEMBERS:

Nirali M. Patel, MD	Chair
Pritish Bhattacharyya, MD	Member
Neng Chen, PhD	Member
Ephrem Lip Hon Chin, MBA, BTech(Hon)	Member
Shefali Desai, MS	Member
Daniel H.Farkas, PhD, HCLD	Member
Matthew Hiemenz, MD	Member
Jennifer Laudadio, MD	Member
Dakai Liu, MD, PhD	Member
Ruth Ann Luna, PhD, MB(ASCP)CM	Member
Alexander Craig Mackinnon, Jr., MD, PhD	Member
Avni Santani, BS, PhD	Member
Elaine Lyon, PhD	President
Lei Po (Chris) Wong, PhD	International Affairs Working Group Chair

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

2014 ACTIVITIES:

Developed and launched initiatives to retain MGP Fellows as members of AMP.

At the Board's request, the MAC implemented processes to reach out to and retain MGP Fellows as members of AMP. A letter from the President was sent to all recently certified MGPs and the MAC has instituted regular communication with current Fellows and others in training to welcome and invite them to participate in AMP.

Selected Technologist Travel Award and International Membership Grant Winners.

One key role of the MAC to is review applications for and select winners of the Technologist Travel Award and International Membership Grant. This year, the MAC also recommended to the Board that the number of Technologist Travel Awards each year be increased from three to five beginning in 2015.

Hosted Three Specialty Lunches and One Early Bird Session at the AMP 2014 Annual Meeting.

A first for the MAC – as part of the larger initiative of welcoming those in training and early career members, the MAC organized and a luncheon session for new AMP members and those new to the Annual Meeting as well as a special session for Trainees to meet and talk with Dr. Eric Green. Additionally, the MAC hosted an early bird session designed for early career attendees. Lastly, the IAWG hosted a luncheon especially for attendees outside of North America.

Developed a Formal Application and Review Process for International Educational Support.
The primary function of the IAWG, a working group of the MAC, is to extend AMP's educational initiatives to audiences outside of North America. To this end, the group developed and launched a formal application and review process for organizations and conference organizers to request support from AMP in the form of speakers and/or funding.

Supported International Education via the International Affairs Working Group (IAWG) of the MAC.
This year, the IAWG supported molecular diagnostic education at events in Hong Kong, India, Korea, and Pakistan by providing speakers and/or funding. The IAWG also awarded complimentary registration to the AMP Online MGP Review Course to five selected AMP International members.

AMP Nominating Committee Annual Report, 2014

COMMITTEE MEMBERS:

Jennifer L. Hunt, MD, MEd	Chair
Samuel K. Caughron, MD	Genetics Representative
Cindy L. Vnencak-Jones, PhD	Genetics Representative
James R. Cook, MD, PhD	Hematopathology Representative
Karen P Mann, MD, PhD	Hematopathology Representative
Christine Ginocchio, PhD	Infectious Diseases Representative
Richard L. Hodinka, PhD	Infectious Diseases Representative
Neal Lindeman, MD	Solid Tumors Representative
Karen Weck, MD	Solid Tumors Representative

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.

2014 ACTIVITIES:

The Nominating Committee nominated Officers and Committee Representatives for the 2014 annual elections.

AMP Professional Relations Committee Annual Report, 2014

COMMITTEE MEMBERS:

Roger D. Klein, MD, JD	Chair
Stephen P. Day, PhD	Member
Rajyasree Emmadi, MD	Member
Andrea Ferreira-Gonzalez, PhD	Member
Jordan Laser, MD	Member
Elaine Lyon, PhD	Member
Roberta Madej, BS, MS, MBA	Member
Shelby Melton, MD	Member
Timothy J. O'Leary, MD, PhD	Member
Victoria M. Pratt, PhD	Member
Daniel E. Sabath, MD, PhD	Member
Robert F. Klees, PhD	Junior Member
Jennifer R. Leib	Consultant
David E. Barton, PhD	International Affairs Working Group Liaison
Janina A. Longtine, MD	President-Elect

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.

2014 ACTIVITIES:

The PRC continues to monitor the activities of, and in some cases work with, federal agencies and panels such as FDA, CMS, USPTO, 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 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. (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 Tests (LDT)
"Revisiting Oversight and Regulation of Molecular-Based Laboratory-Developed Tests: A Report of the Association for Molecular Pathology" by Andrea Ferreira-Gonzalez, *et al*., was published in the January issue of JMD, online at http://jmd.amjpathol.org/article/S1525-1578%2813%2900221-3/pdf. AMP reaffirmed its position that, for the vast majority of molecular tests, oversight should be under CLIA, which can potentially be improved to address concerns regarding transparency, clinical validity and adverse event reporting. In the paper, AMP also introduced the term "Laboratory Developed Procedure" (LDP) to emphasize that these tests are medical services. AMP encourages all its members to adopt the use of the term.

In early July, five Senators sent a letter to the Office of Management and Budget (OMB) in the White House pressing them to publish the draft guidance documents establishing a framework to regulate LDTs. AMP subsequently met with those offices to discuss this policy issue. Specifically, AMP met with staff for Senators Durbin (D-IL), Brown (D-OH), Warren (D-MA), and Markey (D-MA). In the visits, AMP confirmed that the Senators do not have a position on the FDA regulation of LDPs, but rather, they are concerned about the delay in the OMB finalizing regulations and cited the LDT guidance documents as an example. Shortly thereafter, the FDA gave notice that the Draft Guidance documents would be issued.

On October 3, 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 has reviewed and analyzed the policy and intends to submit comments while continuing to meet with Hill offices and the FDA to express its concerns.

Based on the draft guidance documents, AMP hosted a webinar, "FDA Laboratory Developed Test (LDT) Draft Guidance and the Potential Impact on Clinical Practice." This webinar provided an overview of the key concepts in the draft framework and an analysis of the potential impact on clinical practice.

At the annual meeting, a special session was held, "Framework for Oversight of LDTs: A Conversation with FDA" to enable AMP members to interact directly with FDA staff.

Interactions with Federal Agencies
AMP supported comments made by the American Society for Histocompatibility and Immunogenetics (ASHI) on the draft guidance for Recommendations for Premarket Notification (510(k)) Submissions for Nucleic Acid-Based Human Leukocyte Antigen (HLA) Test Kits Used for Transfusion and Transplantation, recommending that manufacturers of HLA typing kits continue to follow the FDA guideline "Replacement Reagent and Instrument Family Policy," without having to submit a 510(k) and that they consult with ASHI before finalizing the guideline.

In a letter to Jeffrey Shuren, MD, JD, Director, Center for Devices and Rediological Health, AMP requested that the FDA prohibit the inclusion of patient management instructions or other medical recommendations in the product labeling for in vitro diagnostic tests, based on concerns that the April 24, 2014 Roche cobas® HPV test approval letter included medical practice recommendations. While AMP does not oppose HPV as a primary screening test and has no position on this particular test, AMP reacts to indications that FDA may be attempting to regulate the practice of medicine.

AMP presented comments at the July 2014 Clinical Laboratory Fee Schedule meeting regarding the implementation of Section 216 of the Protecting Access to Medicare Act of 2014 (PAMA) entitled, "Improving Medicare Policies for Clinical Diagnostic Laboratory Tests." Specifically, AMP's comments focused on encouraging CMS to interpret burdensome test reporting provisions of PAMA in a manner that would be least burdensome for clinical laboratories. AMP recommended: exempting hospitals, health systems, academic medical centers and other small laboratories from reporting requirements, and attempting to obtain test and pricing data from payers; restricting monetary penalties, which can be up to $10,000 per "misrepresentation or

omission" per day, to intentional errors; establishing low volume, low expenditure thresholds to exempt hospital and other small molecular laboratories from reporting; limiting data collection periods to minimize reporting burdens on laboratories; requiring inclusion of only those discounts that can readily be ascertained and attributed; utilizing CPT codes to the extent possible for mandated issuance of HCPCS codes; recognizing a test's contribution to patient care in order to ensure appropriate valuation; and continuing to use multiple contractors to process test claims and establish test coverage policies.

Efforts Regarding Legislation

- In April, Congress passed a law that provides a 12-month patch to the correction to the Sustainable Growth Rate (SGR) formula that would have implemented substantial cuts in physician payments (http://www.gpo.gov/fdsys/pkg/BILLS-113hr4302ih/pdf/BILLS-113hr4302ih.pdf). The "SGR patch" contains reforms to the Clinical Laboratory Fee Schedule (CLFS). AMP issued a letter to Senate Majority Leader Harry Reid ahead of the Senate vote outlining concerns with Section 216, "Improving Medicare Policies for Clinical Diagnostic Laboratories" of H.R. 4302, the "Protecting Access to Medicare Act of 2014" (PAMA). The letter noted that the section disadvantages hospital-based laboratories, disregards the CPT code process, conflicts with existing law, and creates confusion among stakeholders. The entire letter can be read here: http://www.amp.org/publications_resources/position_statements_letters/documents/ReidletterreSGRpatch_Final.pdf

  Despite displeasure with much of Section 216, several of AMP's requests over the past year were included in the law. Most significantly, molecular pathologists are referenced specifically in the language. In fact, we are the only medical specialty group identified. This this is a direct reflection of AMP's lobbying to ensure that molecular pathologists are included in all federal advisory panels focused on laboratory testing. This makes it likely AMP will have a voice on the newly created advisory panel advising CMS on future coverage and payment determinations for laboratory tests.

- AMP has engaged in the 21st Century Cures initiative sponsored by Chairman Fred Upton and Representative Diana DeGette to identify opportunities to help spur innovation. AMP responded to the request for comments to the white paper entitled "21st Century Cures: A Call to Action." **Frank Cockerill** (in his position at Mayo) participated in the 21st Century Cures Roundtable on Personalized Medicine on July 23, during which he noted AMP by name, the critical need for appropriate payment, and indicated that appropriately qualified PhDs should be recognized as Qualified Healthcare Practitioners for molecular pathology procedures. Additionally, AMP submitted written testimony to the September 9, hearing on "21st Century Cures: Examining the Regulation of Laboratory Developed Tests" regarding the proposed FDA oversight and regulation of LDTs.

- In response to the Coburn-Heitkam substitute S. 1347, Conference Accountability Act, AMP sent a letter to Chairman Thomas Carper and Senator Tom Coburn, AMP requested that any legislation restricting federal employee travel include an exemption for scientific and medical meetings the primary purpose of which is continuing medical education (CME). Later in the year, AMP signed on to a letter with more than 130 other organizations to Majority Leader Harry Reid and Republican Leader Mitch McConnell urging that they oppose S. 1347, the "Conference Accountability Act of 2014" due to restrictions on medical and scientific meetings that would limit educational offerings available to federal employees.

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.

Capitol Hill

AMP has met with numerous offices on Capitol Hill regarding restrictions on federal employee travel, coverage and reimbursement of molecular diagnostics, and the oversight and regulation of LDPs. Specifically, AMP has

met with staff for Senators Brown, Carper, Coburn, Durbin, Reid, and Warren and also met with staff working for Representatives, Burgess, DeGette, Paulsen, Price, Schock, and Upton.

Over 70 AMP members will participate in **AMP Advocacy Day** on November 12, 2014! Participants will educate Congressional offices on the value of molecular testing and the critical role of the molecular professional to positively impact patient care. In addition, they will communicate the following AMP's requests:

- Direct FDA to engage in the transparent notice and comment rulemaking process regarding its proposed framework for oversight of LDTs, which will require the Agency to conduct an economic impact study.
- Amend the "Protecting Access to Medicare Act of 2014" (PAMA) to remove the comprehensive reporting burden from laboratories. Congress should instruct CMS to develop a method to sample claims to collect the required data. If Congress chooses not to do this, it is imperative that PAMA be amended to protect laboratories from penalties that unintentionally omit reportable data. In addition, the legislation should also be amended to clarify that new software or other infrastructure systems do not have to be purchased to successfully report or provide a timeline under which upgrades can be made in stages. The threat of penalties of $10,000 per day should be eliminated for those laboratories that make good faith efforts to comply with reporting requirements.

White Papers

The Professional Relations, Economic Affairs and Clinical Practice Committees joined forces to draft two white papers this past year. The first seeks to provide a framework of evidence necessary to demonstrate clinical utility. The concept of "clinical utility" is complex, and includes factors and has impact beyond reimbursement. The second paper explores the negative impact to patient care of current, proposed, and anticipated regulations, including new coverage and pricing policies and changes to oversight of LDTs.

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), the Coalition to Strengthen the Future of Molecular Diagnostics, 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), Global Alliance for Genomics and Health, as well as AdvaMedDx. In 2014, AMP became a member of the Cancer Leadership Council.

Gene Patents

AMP provided comments to the United States Patent and Trademark Office's (USPTO) Guidance for Determining Subject matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products asking that the USPTO acknowledge and adhere to the Supreme Court holdings in *Mayo v. Prometheus* and *AMP v. Myriad*. The letter was endorsed by the American Society for Clinical Pathology and Breast Cancer Action.

AMP signed onto amicus and supplemental briefs filed by the ACLU for *University of Utah Research Foundation et. al. v. Ambry Genetics Corporation*.

AMP Program Committee Annual Report, 2014

COMMITTEE MEMBERS:

Charles E. Hill, MD, PhD	Chair
Ted Schutzbank, PhD	Chair Elect
Siby Sebastian, PhD	Genetics Representative
D. Brian Dawson, PhD	Genetics Representative
Daniel E. Sabath, MD, PhD	Hematopathology Representative
Rachel L. Sargent, MD	Hematopathology Representative
David R. Hillyard, MD	Infectious Diseases Representative
Marie Landry, MD	Infectious Diseases Representative
Ron M. Przygodzki, MD	Solid Tumors Representative
Catherine I. Dumur, PhD	Solid Tumors Representative
Kimberly Ann Lebel, MT, MB(ASCP)	Technical Topics Representative
John P. Gibson, MS, SV(ASCP), CLSp(MB), CLAS-MDx	Technical Topics Representative

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.

2014 ACTIVITIES:

Programming the 2014 Annual Meeting, “Realizing the Dream of Precision Medicine” from November 12 - 15, 2014 at the Gaylord National Resort & Convention Center, National Harbor, MD.

AMP Publication and Communication Committee Annual Report, 2014

COMMITTEE MEMBERS:

Min Fang, MD, PhD	Chair
Timothy J. O'Leary, MD, PhD	JMD Editor-in-Chief
Alexis Carter, MD	Test Directory Editor
Mary C. Lowery-Nordberg, PhD	Website Editor
Dahui Qin, MD, PhD	Electronic Media Advisor
Mohamadou Sene, BS, MB(ASCP)	Electronic Media Advisor
Shalini Verma, MD	Electronic Media Advisor

PURPOSE SUMMARY:

The Publication and Communication (P&C) Committee is comprised of the Chair, *JMD* editor, Website Editor, Test Directory Editor, Electronic Media Advisors, as well as other volunteers from the AMP membership.

The P&C oversees the public presentation of AMP in electronic and print media, *i.e.,* the AMP website, the AMP Web Library, the AMP online Community (CHAMP), the AMP Newsletter (*AMPlifications*), and other publications other than *The Journal of Molecular Diagnostics (JMD),* which, because it is co-owned with the American Society for Investigative Pathology (ASIP), is overseen by a Joint Journal Oversight Committee. The P&C also oversees AMP's communications initiatives as led by AMP staff and consultant(s) as needed.

The Committee may recommend policies and budgets for the AMP's publications, whether by ownership or by affiliation, and whether in print or electronic form. Such publications may include a newsletter, scientific journals, special publications and any other publications commonly produced by scientific societies.
The Committee meets monthly by conference call, face-to-face before the annual meeting, and by electronic communication.

2014 ACTIVITIES:

Selection and Successful Implementation of new CHAMP Platform.

The process of researching new solutions for the CHAMP platform began in 2013 and after careful review and testing by the Committee and AMP leadership, a new platform was launched early this year. The biggest benefit of the new solution is not having to login to post or reply to a message.

Solicitation, review, and submission of six new AMP Case Reports for *CAP TODAY* magazine.

This initiative is one of the primary roles of the AMP Publication and Communication Committee (P&C) – the outcome of which is of great benefit to AMP members and others in the field. Visit www.amp.org/casereports for details.

Website Content Oversight.

The AMP electronic Media Advisors (EMAs), a sub-group of the P&C, have begun to review and revise the AMP website in order to achieve the overall goal of content that is recent, relevant, and of value to AMP members and others with an interest in AMP. The EMAs began with the "Publications & Resources" section and has made significant revisions resulting in a more user-friendly experience.

Beta Tested the revised AMP Test Directory.

Alexis Carter, MD, AMP Test Directory Editor and member of the P&C, brought the revised version of the Directory to the P&C for them to test. The Test Directory is a valuable asset and the group looks forward to having it go live on www.amp.org.

Helped to Develop the AMP Media Relations Campaign.
Prior to 2014, the P&C was simply the "Publications" Committee. The addition of "Communication" to the committee's name and purpose increased the scope to include providing guidance and input on AMP's communications initiatives. There is a significant campaign being rolled out in early 2015 and the P&C is excited to help with development and provide input.

AMP Strategic Opportunities Committee Annual Report, 2014

COMMITTEE MEMBERS:

Janina A. Longtine, MD	Chair
Steven Gutman, MD, MBA	Member
Marc Ladanyi, MD	Member
Karl V. Voelkerding, MD	Member
Roger D. Klein, MD, JD	Board Member
Shuji Ogino, MD, PhD	Board Member

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.

2014 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, 2014

COMMITTEE MEMBERS:

Laura J. Tafe, MD	Chair
Christine A. Curtis, PhD	Genetics Representative
Jill Hagenkord, MD	Genetics Representative
Harvey Greisman, MD, PhD	Hematopathology Representative
Christopher D. Watt, MD, PhD	Hematopathology Representative
Rangaraj Selvarangan, PhD	Infectious Diseases Representative
Benjamin Pinsky, MD,PhD	Infectious Diseases Representative
Jordan Laser, MD	Solid Tumors Representative
Maria E. Arcila, MD	Solid Tumors Representative
Devon Chabot-Richards, MD	Junior Member
Elizabeth Azzato, MD, PhD	Junior Member
Caren Gentile, MS	Medical Technologist Member
Rami Mahfouz, MD, MPH	International Affairs Working Group Liaison
Matthew Hiemenz, MD	Membership Affairs Committee Liaison

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 education and certification in molecular pathology and mentoring of trainees.

Educational Programs

- ***Molecular Pathology Outreach Course (MPOC 2014):*** 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 by invited speakers (Iris Schrijver and John Pfeifer), followed by case studies presented by T&E members. As of October 19, there were 68 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 will be directed by Iris Schrijver and is scheduled for April 30-May 3 in Bethesda, MD. An online, self-study course (a recorded version of the 2013 live course) is available through 2014 at: http://www.amp.org/mgp2013/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 2014 Annual Meeting to present an interesting and/or challenging case study during an Early Bird Session. Trainee presenters in 2014 are:

Case Studies in Solid Tumors	Case Study: Neuroendocrine Carcinoma	George E. Miles, MD, PhD	Washington University St. Louis
	Case Study: Follicular Carcinoma of Thyroid	Arivarasan Karunamurthy, MD	University of Pittsburgh Medical Center
	Case Study: Gestational Trophoblastic Disease	Justyna Sadowska, BS, MBA	Memorial Sloan Kettering Cancer Center
	Case Study: A 56 Year-old Man with Multiple Lung Nodules *(title updated post-call)*	Jonathan A. Nowak, MD, PhD	Brigham and Women's Hospital
Case Studies in Genetics	Case Study: SOX5-Related Disorder	Kristin McDonald Gibson, PhD	The Children's Hospital of Philadelphia
	Case Study: Using Chromosomal Microarray Analysis to Diagnose a Microdeletion Syndrome	Scott A. Turner, PhD	Geisel School of Medicine at Dartmouth College
	Case Study: Using Whole Exome Sequencing to Diagnose Vici Syndrome	Erik J. Zmuda, PhD	Nationwide Children's Hospital
	Case Study: Analysis of a Variant of Unknown Significance in the SHOX Region	Jennifer A Keller-Ramey, PhD	University of Chicago
Case Studies in Infectious Diseases	Case Study: Treatment-resistant Acanthamoeba Keratitis	Waseem Qais Anani, MD	University of Pittsburgh Medical Center
	Case Study: HSV Encephalitis	Leomar Y. Ballester, MD, PhD	Baylor College of Medicine/Texas Children's Hospital
Case Studies in Hematopathology	Case Study: Molecular Analysis of the RHD Gene	Deepu Alex, MD, PhD	Medstar-Georgetown University Hospital
	Case Study: Clonal Rearrangement of the TCRG Gene and Minimal Residual Disease Detection	Tessara Baldi, BS	Memorial Sloan Kettering Cancer Center

	Case Study: CALR Mutation Analysis of Blood	Rogan Rattray, MS	Oregon Health and Science University
	Case Study: Synchronous Lung Adenocarcinoma and Primary Pulmonary MALT Lymphoma	Jinjuan Yao, MD, PhD	Memorial Sloan Kettering Cancer Center

- ***Continuing Education credits (PACE, CME, and CMLE):*** AMP continues to offer 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 2014 Annual Meeting. Continuing Medical Laboratory Education (CMLE) is provided for non-physicians.

- ***Webinars:***

Date	Title	Speakers/Presenters	Attendees
March 27	Next-Gen Sequencing for the Detection of Chromosomal Rearrangements: From Discovery to Clinical Practice	Marina N. Nikiforova, MD, FCAP, and Jordan S. Laser, MD	252
April 24	Interpretation of Sequence Variants	C. Sue Richards, PhD, Elaine Lyon, PhD, Madhuri Hegde, PhD, and Jill Hagenkord, MD	273
May 08	Development of Consensus Reference Material Tools for Development and Validation of Clinical NGS Tests	Lisa Kalman, PhD, Birgit Funke, PhD, Melissa Landrum, PhD, Justin Zook, PhD, and Christopher Watt, MD, PhD	169
July 23	NGS 101: NGS for the Clinic	Birgit H. Funke, PhD, FACMG, and Devon Chabot-Richards, MD	388
Sept 11	NGS 101: Viewing and Interpreting Sequencing Data	Patrik Vitazka, MD, PhD, and Christopher Watt, MD, PhD	110
Sept 16	FDA Laboratory Developed Test (LDT) Draft Guidance and the Potential Impact on Clinical Practice	Roger Klein, MD, JD, Jennifer Leib, and Elaine Lyon, PhD	458
Sept 23	Molecular Diagnostics for Global Health	Ellen Jo Baron, PhD, D(ABMM), and Benjamin Pinsky, MD, PhD	94
TBD	NGS 101: An Integrated Approach to Assay Selection and Validation	Monica Basehore, PhD, FACMG, and Matthew Hiemenz, MD	TBD
Oct 29	NGS 101: Nomenclature in the Context of Next Generation Sequencing	Robert Daber, PhD, and Jordan Laser, MD	TBD
Nov 7	NGS 101: The Role of the Pathologist in Reporting & Communicating Accurate and Succinct Results in the Genomic Era	Colin C Pritchard, MD, PhD, and Benjamin Pinsky, MD, PhD	TBD

Trainee Activities (Residents, Fellows, and Students)

- ***AMP 2014 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 2014 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.
  - Amazing Molecular Party Trainee Ticket Drawing for 5 trainees. Supported by the Jeffrey A. Kant – AMP Education Fund.

- ***United States and Canada Academy of Pathology (USCAP)***
  - First-time AMP Trainee Reception at USCAP 2014. Supported by the Jeffrey A. Kant – AMP Education Fund

Awards

- Young Investigator Awards – 40 poster candidates (36 YIA poster candidates in 2013)
- Technologist Poster Awards – 23 poster candidates (30 poster candidates in 2013)
- International Trainee Travel Award was launched. 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 2014 Annual Meeting. T&E members Christopher Watt and Benjamin Pinsky are leading the effort and facilitating the panel and audience discussions. The roundtable panel of T&E Committee members includes Christopher Watt, Benjamin Pinsky, and Laura Tafe. 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 Federico Monzon (Chair), Marie DeFrances (Chair-Elect), Anna Berry, Christopher Gocke and David Wu. The MGP PD Council directs the discussions of the MGP Program Directors Working Group. In the fall of 2014, the MGP PD Council launched a survey to the MGP PD Working Group to identify needs for MGP fellowship programs in an effort to understand differences between programs and gather resources to enhance fellowship education. Highlights of the survey will be presented at the MGP PD meeting at the Annual Meeting, and discussions of priorities will continue in 2015.

Curriculum Development Task Forces

- ***Molecular Pathology and Genomics for Medical Laboratory Scientists:*** Co-chaired by Sara Taylor and Ted Schutzbank, the Task Force (established May 2012) published an AMP Report, "Molecular Pathology Curriculum for Medical Laboratory Scientists," in the May 2014 issue of the *Journal of Molecular Diagnostics.* The paper provided recommendations for a molecular diagnostics curriculum at both the baccalaureate and master's levels of education. The recommendations "address the critical need of educating future medical laboratory scientists appropriately in order to manage the growing and changing realm of molecular diagnostic

testing" (S. Taylor). Other authors are Katie Bennett (co-first author), Joshua Deignan, Ericka Hendrix, Susan Orton, and Shalini Verma.

- ***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 2014. 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 will be submitted to *JMD* by the end of 2014. Other members are: Ted Schutzbank (ex officio), Dara Aisner, Anna Berry, Brian Dawson, Randy Hayden, Loren Joseph, and Karen Kaul.

- ***Genomics Education for Primary Care Residents:*** A newly established task force 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.*

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.

Co-Sponsorships, Companion Meetings, and/or Collaborations

- ***United States and Canadian Academy of Pathology (USCAP) 2014***
  The AMP 2014 Companion Society Symposium, "***How Research is Necessary to Becoming an Excellent Pathologist,"*** was co-moderated by Ronald M. Przygodzki and Marina Nikiforova:
  - *Introduction and Overview: Marina N. Nikiforova, MD*
  - *Clinical Translational Research in Molecular Genetics Applied to Standard Surgical Pathology Practice, Sydney D. Finkelstein. MD*
  - *Use of Next Generation Sequencing to Discover Novel Mutations in Thyroid Cancer: Impact on Research and Clinical Practice, Yuri Nikiforov, MD, PhD*
  - *Whole Genome Copy Number Aberrations in Chronic Lymphocytic Leukemia: Steven A. Schichman MD, PhD*
  - *Proteolytic Mechanisms in Lymphomagenesis: Kojo Elenitoba-Johnson MD*
  - *Integration of Research into Clinical Practice Ronald M. Przygodzki, MD, Department of Veterans Affairs, Washington, DC*

- ***Regional/Local Conferences***
  - ***Cancer Biomarkers Conference*****,** March 22 at the Houston Methodist Research Institute; Phil Cagle. Speakers included AMP members Angela Bartley, Stan Hamilton, Neal Lindeman, Jan Nowak, and guest panelist, Jennifer Hunt, AMP Past President.

- ***Beaumont Symposium*** – September 16-17 in Troy, MI. Organizers (AMP Members): Bobby Boyanton and John Gibson. AMP faculty included: Jennifer Hunt, Laura Tafe, and Glenn Palomaki.

- ***American Society for Clinical Pathology (ASCP)***
  - ***ASCP Task Force for PhD Certification in Molecular Diagnostics – Molecular Biology Job Analysis***. AMP representatives: Ted Schutzbank, Kathy Mangold, and Melinda Poulter.
  - ***ASCP 2014 AMP Workshop: October 8 in Tampa, FL:*** Jane Gibson presented a course on molecular diagnostics for laboratory technologists. Giovanni Insuasti and Ted Schutzbank assisted in the development of the presentation.

- ***College of American Pathologists (CAP)***
  - T&E member Jordan Laser assisted in co-organizing a CAP '14 Scientific Plenary Session, **"Molecular Medicine – Can We Afford It?**
  - ***CAP 2014 Course Presentation:*** *Beyond Single Gene Analysis: Paving the Way to Comprehensive Tumor Genomic Profiling,* a 2-hour short session presented by Neal Lindeman & Lynette Sholl.

- ***Society for Laboratory Automation and Screening (SLAS)***:
  - ***SLAS 2014:*** AMP members were invited as presenters for the Molecular Diagnostics track at the SLAS 2014 annual meeting:
    - *Parallel Multi-Region Specific Next Generation and Big Dye DNA Sequencing,* presented by Bert Gold
    - *How Circulating Tumor Cells Can Help Identify Targets for New Cancer Drugs,* presented by Martin Fleisher
  - ***SLAS 2015:*** Collaboration continues with SLAS with the following AMP members and selected presentations for the SLAS 2015 annual meeting:
    - *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 9-14, 2014, San Francisco
    - **Short Courses:**

      Starting an NGS Lab Part I: Technical Considerations
      - Evolution of NGS Labs and Choosing the Right Instruments: Madhuri Hegde, PhD, FACMG
      - Quality Control/Quality Assurance and Validation/Compliance: Monica J. Basehore, PhD, FACMG
      - Incorporating Bioinformatic Tools and Pipelines in Medical NGS: Birgit H. Funke, PhD, FACMG

      Starting an NGS Lab Part Ii: Practical and Business Aspects
      - Navigating the Regulatory Environment: Victoria M. Pratt, PhD, FACMG
      - CPT Coding and Reimbursement: Jill Hagenkord, MD
      - Gene Patents and Implications for Lab Testing and Patients: Roger Klein, MD, JD

- **Keynote**
  - ***CPT Coding:*** Jill Hagenkord, MD and Elaine Lyon, PhD with Chris L. Jagmin, MD
    - Overview of CPT codes
    - Transitioning to the molecular pathology codes from the clinical laboratory's perspective
    - Understanding rationale behind new CPT codes

- **Next Generation Dx Summit,** August 19-21, 2014, Washington, DC
  - **Plenary Session**
    - ***Next-Generation Sequencing in Clinical Practice: Case Reports of Clinical Utility and Reimbursement:*** Elaine Lyon, PhD, Andrea Ferreira-Gonzalez, PhD, and Madhuri Hegde, PhD

2014 Newly Appointed Positions:

- Eric Duncavage to serve as USCAP Companion Meeting Co-Moderator for 2015-2016.
- Giovanni Insuasti to serve the ASCP RISE Committee for 2014-2015.

AMP Subdivision Leadership Annual Report, 2014

SUBDIVISION LEADERSHIP

	Genetics	Hematopathology	Infectious Diseases	Solid Tumors
Chair	Madhuri Hegde	Lynne Abruzzo	Helen Fernandes	Shuji Ogino
Clinical Practice Committee	Carolyn Sue Richards	Annette Kim	Melissa Miller	Mary Lowery Nordberg
	Paul Rothberg	Jennifer Dunlap	Matthew Bankowski	Marilyn Li
Nominating Committee	Cindy Vnencak-Jones	Karen Mann	Richard Hodinka	Karen Weck
	Samuel Caughron	James Cook	Christine Ginocchio	Neal Lindeman
Program Committee	D. Brian Dawson	Rachel Sargent	Marie Louise Landry	Catherine Dumur
	Siby Sebastian	Dan Sabath	David Hillyard	Ronald Przygodzki
Training & Education Committee	Jill Hagenkord	Annette Kim	Benjamin Pinsky	Maria Arcila
	Christine Curtis	Christopher Watt	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 2014 Annual Meeting
  - Plenary: Genetic Etiology of Human Diseases: Role of Epigenetics and Distal Regulatory Regions
  - Symposia: Copy Number Variations (CNV) in Genetic Variability and Human Diseases
  - Early Birds: Challenging Case Studies in Genetics; Preimplantation Genetic Diagnosis
  - Workshops: Patient Advocate (cosponsored by Genetics Subdivision)

- Manuscript in development, and webinars, including:
  - Manuscript: *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. Article in press, *The Journal of Molecular Diagnostics*.
  - AMP Webinars:
    - Interpretation of Sequence Variants - April 24, 2014. Presenters: C. Sue Richards, Elaine Lyon, and Madhuri Hegde. Host: Jill M. Hagenkord
    - Next-Gen Sequencing for the Detection of Chromosomal Rearrangements: From Discovery to Clinical Practice - March 27, 2014. Presenter: Marina N. Nikiforova. Host: Jordan S. Laser.

Hematopathology

- Addressed topics in molecular hematopathology, including next-generation sequencing, test utilization, and need for standardized reference materials in oncology.

- Emphasized practical aspects and challenges for clinical hematopathology laboratories at the 2014 Annual Meeting, and managing diagnostics related to hematology:
    - Plenary: Molecular Mechanisms in Hematopoiesis and Leukemia
    - Symposia: Array Technologies in Hematologic Malignancies
    - Workshop: Update: CAP and ASH Guidelines for Molecular Testing of Acute Leukemia
    - Early Bird: Challenging Case Studies in HemePath

- Initiated discussions with ASH leadership regarding development of future guidelines addressing test utilization patterns and diagnostic / clinical utility in hematologic malignancies (AMP liaison Annette Kim).

- Developing & implementing interlab sample exchanges for the validation of next-generation sequencing platforms.

Infectious Diseases

- Addressed infectious disease topics relevant to the clinical molecular diagnostics laboratory, including next-generation sequencing and emerging infectious diseases.

- Highlighted diagnostic methods for microbial identification and test utilization at the 2014 Annual Meeting:
    - Plenary: Global and Personalized Response to Influenza
    - Workshop: Testing for HPV Driven Tumors
    - Early Birds: Value and Cost Effectiveness of Molecular Respiratory Testing; Challenging Case Studies in Infectious Diseases
    - Symposia: Molecular Diagnostics for Fungal Infections

- Discussed how members of other infectious disease-related organizations, such as Clinical Virology Symposium (CVS), American Society for Microbiology (ASM), and the Infectious Diseases Society of America (IDSA), might mutually benefit the AMP subdivision interests and membership.

- AMP Webinars
    - MERS - Situational Update and Laboratory Testing – June 13, 2014. Presenter: Kirsten St. George. Host Rangaraj Selverangan
    - Molecular Diagnostics for Global Health - September 23, 2014 Presenter: Ellen Jo Baron. Host: Benjamin Pinsky.

- Initiated discussions on clinical applications resulting in two manuscripts currently under development:
    - Next-Generation Sequencing for Infectious Disease Diagnosis and Clinical Management. In collaboration with Infectious Diseases representatives from the CPC and Subdivision Leadership Benjamin Pinsky and Matt Bankowski.
    - Review of MALDI-TOF MS in the Clinical Microbiology Laboratory with Susan Butler-Wu and Christopher Doern supported by Melissa Miller.

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:
    - Plenary: Precision Medicine
    - Early Birds: Genome in a Bottle; Challenging Case Studies in Solid Tumors
    - Workshop: Patient Advocate (cosponsored by Genetics Subdivision)
    - Symposia: Cell Free Circulating DNA

- Continuing to support initiatives for the improvement of clinical practice, including:
    - Manuscript: *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. Submitted, *The Journal of Molecular Diagnostics*.
    - Guidelines projects in development:
        - AMP Interpretation of Sequence Variants in Somatic Conditions (Cancer) Chaired by Marilyn Li with anticipated participation with ACMG and CAP
        - Evaluation of Biomarkers for Colorectal Cancer Biomarkers. In collaboration with CAP, ASCP, AMP, and ASCO.
        - Molecular Testing Guideline for Selection of Lung Cancer Patients for EGFR and ALK Tyrosine Kinase Inhibitors – Update of the April 2013 guideline developed jointly by CAP, the International Association for the Study of Lung Cancer (IASLC), and AMP
    - Developing & implementing interlab sample exchanges for the validation of next-generation sequencing platforms.

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.