

AMP Clinical Practice Committee Report, 2012

Genetics: Siby Sebastian and Linda Jeng

- Developed an online survey to assess current practice in using PCR for in Fragile X testing.

Hematopathology: Cyrus Hedvat and Jerald Gong

- Preparing a multi-author manuscript on laboratory practice guidelines for detecting and reporting *JAK2* and *MPL* mutations in myeloproliferative neoplasms

Infectious Disease: Kathleen Montone and Thomas Huard

- Considering a paper on some aspect of mass spec technology for diagnostics in ID

Solid Tumors: Loren Joseph and Milena Cankovic

- Development of Clinical Practice Guidelines
 - Under the AMP leadership of Neal Lindeman and in collaboration with CAP and IASLC, clinical practice guidelines for non-small cell lung cancer biomarkers are under final review for publication.
 - Under the AMP leadership of Federico Monzon and in collaboration with CAP, ASCP, and ASCO, clinical practice guidelines for colorectal carcinoma biomarkers are in progress.
 - Loren Joseph is the AMP representative for the practice guidelines on pancreaticobiliary cytology produced by the Papanicolaou Society of Cytopathology.
- Under the guidance of Milena Cankovic, a manuscript on the role of *MGMT* testing in clinical practice is in final review prior to submission to *JMD*.
- Published in *JMD* March 2012: "Relevance, Pathogenesis, and Testing Algorithm for Mismatch Repair-Defective Colorectal Carcinomas," William K. Funkhouser, Ira M. Lubin, Federico A. Monzon, Barbara A. Zehnbaauer, James P. Evans, Shuji Ogino, Jan A. Nowak

AMP Mutation Nomenclature Database: Linda Jeng, Fernanda Sabato, and Michelle Dolan have continued to develop an AMP 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 2.0 Open Forum Library.

Whole Genome Analysis Working Group: Jane Gibson, Chair

- March: Accepted a collaboration request from the NHGRI of the NIH to participate in developing and supporting a new grant program, "Clinically Relevant Genetic Variants Resource: A Unified Approach for Identifying Genetic Variants for Clinical Use."
- May: Co-organized an NCI Workshop Meeting, "Next Generation DNA Sequencing as a Tool for Clinical Decision-making in Cancer Patient Management." Jane Gibson presented, "NGS in the Clinic-Considerations for Molecular Pathologists."
- August: Provided feedback on the New York State Department of Health draft guidelines on Next Generation Sequencing in oncology.
- August: Participated in the NIST's "Genome in a Bottle" Workshop Meeting on developing human genome reference material.

- Publications:
 - *JMD*, November: “Opportunities and Challenges Associated with Clinical Diagnostic Genome Sequencing,” Schrijver, et al.
 - A Viewpoint article to be submitted to *JAMA*, “Clinical Diagnostic Next Generation Genome Sequencing: Considerations for the Clinician.”
- Liaisons to/from: ACMG, CAP Next Generation Sequencing Workgroup, CAP Molecular Oncology Committee, ClinVar, CDC, CLSI, and NHGRI

International Affairs Working Group: Patrik Vitazka, Chair

- Monitoring Sample Exchange Program that was launched in 2011. Identifying ways to market and increase usage by the AMP membership.

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 Janina Longtine, MD, Chair

Economic Affairs Committee (EAC)

COMMITTEE MEMBERS:

Jeffrey A. Kant MD PhD, Chair
Aaron D. Bossler MD PhD, Member and PCC Representative
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
Jan A. Nowak MD PhD, Member
Paul A. Raslavicus MD, Member
Linda Sabatini PhD, Member
Michele Schoonmaker PhD, Member
Katherine Tynan PhD, Member
Jon ten Bosch 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 have been appointed interim co-Chairs of the EAC. It is currently unknown who will be appointed to the many committees and work groups upon which Jeff Kant served.

The Economic Affairs Committee has been productively engaged since the last AMP Annual Meeting in several areas.

The new Molecular Pathology CPT Codes will become effective January 1, 2013. The new system of molecular CPT codes is based on a framework developed by AMP EAC in 2009 anticipating a need for a novel coding system. In 2010 The AMA CPT Editorial Panel established the Molecular Pathology Working Group to address the (lack of) transparency associated with the extant 'stacking codes.' AMP members serving on the Working Group included Jeff Kant, Roger Klein, Vicki Pratt, Elaine Lyon, Aaron Bossler, and Jan Nowak. In parallel with the Working Group efforts, the EAC continued discussions of reimbursement issues, coding "conundrums", and assisted CAP in collecting data for appropriate test code valuation. The Committee tracked the introduction of new molecular CPT codes through Aaron Bossler who represent AMP on the Pathology Coding Caucus (PCC). The EAC presented a webinar on the new codes in April 2012, now archived in the members-only area of the AMP website. CMS will announce placement of codes on the Clinical Laboratory or the Physician Fee Schedule in early November. AMP and several other professional societies have advocated for placement of most or all of these codes on the Physician Fee Schedule because the data from the large majority of the assays requires professional interpretation to be useful to a clinician.

A Framework Proposal for NGS related CPT Codes is being developed by the EAC. Tier 1 and tier 2 molecular pathology CPT codes do not provide an easy solution to code clearly and accurately for newer assays that have been developed to simultaneously target multiple genes or genomic regions using next gen sequencing

Outside Organization Representation: EAC provides a representative from AMP to the Pathology Coding Caucus (Aaron Bossler MD PhD). In addition, AMP members are appointed to the AMA Molecular CPT Work Group (Aaron Bossler, Jeff Kant, Roger Klein, Elaine Lyon, Jan Nowak, and Vicky Pratt). The new AMA Molecular Pathology Advisory Group (MPAG) will include AMP members Roger Klein, Elaine Lyon, and Maria Bettinotti.

Legislation: Appropriately Qualified PhDs as Qualified Healthcare Providers for Qualified Molecular Diagnostics Interpretive Services. AMP is leading a coalition of seven professional associations (AACC, ACLA, ACMG, ASCP, ASHI, CAP) to obtain amendment to the Social Security Act to designate appropriately trained PhD doctoral scientists as Qualified Healthcare Providers, able to bill Medicare directly for molecular pathology CPT codes (only) on the Physician Fee Schedule (PFS). Achieving consensus on legislative language took over a year of hard work. Members of Congress are interested in sponsoring or supporting legislation, presuming at least some of the molecular pathology codes are placed on the PFS. It is possible that this legislation could be passed during the lame duck session this fall, in time for implementation with the new CPT codes in January.

Interfacing with CMS:

- Jeff Kant presented AMP Crosswalk recommendations for 8766XX1, 2, 3, and 879XX 1 and 2 at the July 16 CMS Clinical Lab Fee Schedule meeting.
- AMP nominated Sam Caughron, Jill Hagenkord, Jennifer Hunt, Linda Sabatini to the CMS Medicare Coverage Advisory Committee (MEDCAC).
- CMS replaced Palmetto with Noridian as their contractor for the J-1 (now renamed “E”) region. AMP has had a good relationship with Palmetto Medical Director Elaine Jeter and will seek to build a similarly good relationship with the Noridian Medical Director.

Potential New Projects in 2013

- The EAC will closely monitor the implementation of the new CPT codes anticipating questions and addressing problems that become apparent, as well as the appropriate placement of new molecular tests through the Molecular Pathology Advisory Group (MPAG).
- Monitor implementation of PhD recognition as qualified healthcare providers with particular attention to PQRS incentives and penalties.
- Work with the Clinical Practice Committee to develop a basis to request CPT code(s) for 'higher level' interpretation of molecular assays, i.e., integrated reports
- Reconvene the “Reimbursement Policy Think Tank” begun in September 2011. The EAC will continue to engage other interested parties to better understand alternative viewpoints on laboratory test pricing and reimbursement.

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/>.

Membership Affairs Committee (MAC)

COMMITTEE MEMBERS:

Shuji Ogino MD PhD, Chair

Helen Fernandes PhD, Past-Chair [or Member, whichever is more appropriate here]

Ephrem Chin MBA, Member

Shefali Janak Desai MS, Member

Jennifer Laudadio MD, Member

Nirali Patel MD, Member

Robyn Temple-Smolkin PhD, Member

Pritish Bhattacharyya MD, Member (Liaison to and from the Association of Indian Pathologists in North America, AIPNA)

Bibhu Das PhD, Member (Liaison from the International Affairs Working Group, IAWG)

The committee name change and overall mission: Early this year a Bylaws revision approved by the membership changed the committee name from "Membership and Professional Development Committee (MPDC)" to "Membership Affairs Committee (MAC)". The committee task remained the same, which is to help AMP respond to the needs of its members with diverse backgrounds and facilitate the development of leaders in the field of molecular pathology. In the past year, the committee focused great efforts on membership growth and retention, as well as diversity in membership and on committees, including junior members and technologists.

AMP volunteers: The MAC assists in the volunteer application process for appointed positions and, in 2012. Requests for volunteers for specific projects and/or committees are solicited through CHAMP 2.0. Over the past year we had more than thirty enthusiastic applicants for AMP appointed positions.

AMP awards - recognition of members: The MAC received Board approval in 2011 for a new "Meritorious service Award." This award is now managed by the Nominating Committee. The MAC is now working to define an "Outstanding Investigator Award" to recognize unique and exceptional research accomplishments in the molecular pathology field. The MAC also plans to draft a proposal for an "Excellent Educator and Mentor Award" to recognize important contributions to training, education and mentoring in our rapidly growing field of molecular pathology.

International Relationships:

International Affairs Working Group (IAWG)

http://www.amp.org/committees/membership_prof_dev/iawg/index.cfm: This group, chaired by Patrik Vitazka, has been instrumental in promoting visibility for AMP at the global level. The group established and manages the Sample Exchange Program and supports AMP members interested in organizing international meetings.

International meetings: Over the past year the MAC has requested support from AMP for four international meetings, which is double the number of last year. See international meetings below:

(http://www.amp.org/committees/membership_prof_dev/iawg/IAWGAMPOutreachProgram.cfm).

- 1) **International Symposium on Molecular Pathology** in New Delhi, India, January 28-29, 2012. IAWG member B.R. Das was on the Organizing Committee, which invited Iris Schrijver to be the AMP-supported speaker. This meeting was also supported by AIPNA. Other AMP member speakers included Raj Dewar, Helen Fernandes, and Patrik Vitazka.
- 2) **The Australasian Mutation Detection & Molecular Genetics Society of Australasia** in Port Douglas, Australia, September 17-21, 2012. IAWG member Andrew Fellowes was on the Organizing Committee, which invited Madhuri Hegde to be the AMP-supported speaker.
- 3) **Molecular Pathology of Solid Tumors: Cancer Diagnostics and Targeted Treatment Prediction** in Uppsala, Sweden, September 24-25, 2012. Organized by the **Swedish Pathology Society and Swedish Cancer Society**, the meeting included attendees from Sweden, Norway, Denmark and Finland. AMP member Johan Botling was on the Organizing Committee, which invited Shuji Ogino to be the AMP-supported speaker. AMP member Shashikant Kulkarni also presented.
- 4) **Slovak Society of Medical Genetics and Slovak Medical Association 23rd Annual Meeting** in Bratislava, Slovakia, September 26-28, 2012. IAWG Chair Patrik Vitazka was on the Organizing Committee, which invited Shuji Ogino to be the AMP-supported speaker. This conference on clinical genetics, with International attendance, featured a 2-hour AMP symposium. Other AMP member speakers included Patrik Vitazka, Shashikant Kulkarni and IAWG member David Barton.

AMP supported speakers are expected to promote AMP activities and membership during their talk and visit to the host country. Ideally, the AMP member will also have the opportunity to interact with trainees to encourage them in their training efforts. The IAWG is preparing materials to assist all AMP members on the organizing committee for conferences taking place outside of North America to apply for travel support for an AMP member speaker.

International Membership Grant Program: Seven non-U.S. members were awarded membership grants for 2012. The recipients of these grants enjoy all of the privileges of AMP membership, with online-only access to JMD. The seven grantees also received

complimentary registration to the annual meeting. The seven recipients of the 2012 International Membership Grant are:

- 1) Abolfazi Dashtban-Roozbehani, MSc, BSc
Pasteur Institute of Iran
Tehran Iran
- 2) Julio Alexander Diaz-Perez, MD, MS
University of Santander
Bucaramanga, Colombia
- 3) Kalal Iravathy Goud, PhD
Apollo Hospitals
Hyderabad, India
- 4) Bharat Rekhi, MDz
Tata Memorial Hospital
Mumbai, India
- 5) Sandhya Sundaram, MD
Sri Ramachandra University
Chennai, India
- 6) Wai-Ting Hui
Hong Kong, China
- 7) Eva Weismanova, PhD
St. Elizabeth Cancer Institute
Bratislava, Slovakia

Technologist Travel Award: The MAC selected awardees for the AMP Technologist Travel Award – which provides \$1,500 in travel assistance to the annual meeting for non-doctoral technologists who do not receive travel support from their institutions. The 2012 Technologist Travel Award recipients are:

- 1) Jacqueline Bruce
Brigham & Women's Hospital
Boston, MA
- 2) Ericka Hendrix
Texas Tech University Health Sciences Center
Lubbock, TX
- 3) Erik Samayoa
UCSF Medical Center
San Francisco, CA

AMP Liaisons: The MAC maintains a list of liaisons that serve in various capacities in related organizations. The MAC surveys AMP members annually to identify possible contact points with other organizations relevant to the AMP mission.

Nominating Committee

COMMITTEE MEMBERS:

Timothy J. O'Leary MD PhD, Chair

Qiulu Pan PhD, Genetics Representative

Ramakrishnan Sasi PhD, Genetics Representative

Daniel Arber MD PhD, Hematopathology Representative

Rita M. Braziel MD, Hematopathology Representative

Bobby L. Boyanton MD, Infectious Diseases Representative

Robyn Temple-Smolkin PhD, Infectious Diseases Representative

Antonia Sepulveda MD PhD, Solid Tumors Representative

Vivianna Van Deerlin MD PhD, Solid Tumors Representative

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

Program Committee

2012 Committee Members:

Daniel H Farkas PhD, Chair
Franklin Cockerill MD, Chair-Elect
Ira Lubin PhD, Genetics Subdivision Chair
Madhuri Hegde PhD, Genetics Subdivision Chair-Elect
James R Cook MD PhD, Hematopathology Subdivision Chair
Megan S Lim MD PhD, Hematopathology Subdivision Chair-Elect
Lance R Peterson MD, Infectious Diseases Subdivision Chair
Helen D Fernandes PhD, Infectious Diseases Subdivision Chair-Elect
Federico Monzon MD, Solid Tumors Subdivision Chair
Marina N Nikiforova MD, Solid Tumors Subdivision Chair-Elect
Leonard (Tad) M Holtegaard BS CLSp(MB), Technical Topics Representative
Lara M Brusca MS, Technical Topics Representative (2012-2013)

Strategic Opportunities Committee

2012 Committee Members:

Kenneth Bahk PhD, Chair
Russel K Enns PhD, Member
Steven Gutman MD MBA, Member
Marc Ladanyi MD, Member
Karl Voelkerding MD, Member
Jennifer Hunt MD, MEd, President-Elect and Liaison to the Board (*ex officio*)

The Strategic Opportunities Committee (SOC) carries out the activities listed below and provides relevant reports and recommendations to the Board

- 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.

Professional Relations Committee (PRC)

COMMITTEE MEMBERS:

Roger Klein MD JD, Chair

Stephen P. Day PhD, Member

Rajyasree Emmadi MD, Member

Andrea Ferreira-Gonzalez PhD, Member

Jennifer Hunt MD MEd, (President-Elect)

Elaine Lyon PhD, Member

Roberta Madej MS MBA, Member

Shelby Melton MD, Member

Jan Nowak MD PhD, Member

Timothy J. O’Leary MD PhD, Member

Vicky Pratt PhD, Member

Daniel Sabath MD PhD, Member

Robert F. Klees PhD, Junior Member

Jennifer Leib, Consultant

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 influence 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 2012, 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 recommended AMP members for panel vacancies as appropriate. The committee discussed many federal agency draft guidance documents, policies and reports, as well as numerous proposed federal laws.

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 appropriate, 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. Presidential election years are always particularly quiet, both on Capitol Hill and in the agencies, but AMP maintained an active interaction and met with 19 congressional staff offices (8 Senate, 11 House). Jennifer Leib also assists AMP with drafting press releases related to its advocacy efforts.

The PRC formed two new working groups in 2012:

- **LDT Working Group:** AMP first issued its official position regarding the oversight of laboratory developed tests in January 2010. Since that time, other groups have provided proposals to increase oversight and/or modify the regulatory pathways for lab tests. The group is considering these proposals, and will modify AMP's position if needed. The group intends to complete its work by the end of the year.
- **Industry Member Task Force:** AMP operates under the view that the role of AMP for its members employed by for-profit diagnostics manufacturers is education and exchange of ideas, including among these laboratory science, as well as advocacy for clear and consistent regulatory requirements. The AMP strategic plan calls for the AMP Board to assess whether AMP activities meet the needs of this member segment adequately within the context of this role. The Task Force will meet at the AMP annual meeting and is expected to complete its report and recommendations by July 2013.

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.

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. After an April meeting and several follow up emails, AMP has been added to the AHRQ Center for Outcomes and Evidence contact database. AMP is eagerly awaiting the opportunity to review or assist with a Technology Assessment. The PRC notes that the agency is currently under fiscal pressure, with one budget-cutting legislative proposal pending in Congress going so far as to eliminate AHRQ.
- **FDA:**
 - **LDTs:** The FDA "framework" draft guidance on oversight of laboratory developed tests is in administrative review at the White House Office of Management and Budget. The recently enacted Food and Drug Administration Safety and Innovation Act (i.e. the user fee reauthorization bill) mandates that FDA notify Congress 60 days before they issue any guidance on LDTs.
 - AMP nominated Dr. Timothy O'Leary to serve on the Science Board to the FDA.
- **SACHDNC:** AMP applied for an open non-voting position on the Secretary's Advisory Committee on Heritable Disorders in Newborns and Children at the end of 2012, and will apply for a voting seat when one opens in future years.
- **President's Commission for the Study of Bioethical Issues:** AMP will submit comments.

Legislation:

- **Appropriations:** Automatic sequester cuts are scheduled to take place in January that could result in dramatic reductions (8.2%) to health care related programs including the NIH, CDC, and

FDA. After the elections, challenges to draft alternatives will be complicated by the fact that the SGR Medicare physician payment fix, Bush tax cuts, the payroll tax, unemployment benefits and a host of other tax breaks are all scheduled to expire Dec. 31. Additionally, Congress passed a six-month continuing resolution to fund the government through March 2013, but will need to pass appropriations bill for the remainder of the year. Many are advocating for Congress to pass legislation to undo the sequester and resolution of these issues seems likely following the elections in November.

- **Health IT bill:** AMP endorsed H.R. 4066, the Health Information Technology Reform Act, which would remove pathologists from the incentives & penalties associated with compliance to the “meaningful use” requirements now scheduled to take effect in 2014 (delayed one year).
- **“PhD Billing”:** The AMP-led seven-member coalition of laboratory professional associations (AACC, ACLA, ACMG, AMP, ASCP, ASHI, and CAP) visited House Ways and Means and Senate Finance Committee members to seek sponsors for legislation to designate non-physician doctoral scientists with appropriate training and experience as Qualified Health Care Practitioners, who would be permitted to independently bill Medicare from the Physician Fee Schedule for interpretive services for tests in the Molecular Pathology section of the CPT® codebook. It is AMP’s position that the codes should be placed on the PFS because professional interpretation is necessary to render the raw lab data relevant for clinician use. This legislation will resolve ambiguities related to the potential requirement for physician involvement in reporting of these tests if they are placed on the physician fee schedule. In addition, the creation of G-codes by CMS has been advocated, which would provide an administrative solution to this potential problem.
- **TEST Act:** AMP endorsed H.R. 6118, the Taking Essential Steps for Testing Act of 2012, which would remove a requirement that CMS revoke the CLIA certificate of a laboratory that inadvertently refers a proficiency testing sample to another laboratory for testing.
- **Travel Restrictions for Federal Employees:** AMP is actively opposing legislation that could severely restrict the ability of federal employees to attend scientific and medical conferences. Although the most recent House version of this legislation is less threatening to conference activities than previous House and Senate versions, AMP continues to seek a carve-out for scientific and medical conferences where the primary purpose is continuing medical education.
- **User Fee reauthorization bill:** Enacted in 2012, the Food and Drug Administration Safety and Innovation Act mandates that FDA notify Congress 60 days before they issue any guidance documents on LDTs.
- **H.R. 3497, the MODDERN Cures Act:** AMP met with the lead sponsor of this legislation that incentivizes the development of companion products and modifies the reimbursement of advanced diagnostics. AMP is studying the potential impact of this legislation, but has not endorsed it.

Other Organizations

- **Global Harmonization Task Force:** AMP member David Barton, liaison to PRC from the AMP International Affairs Working Group, apprised AMP of discussions in European organizations

regarding regulation of industry. The PRC continues to watch international developments and is prepared to engage when appropriate.

- **PCORI:** AMP commented on PCORI's draft research methodology report.

Gene Patents:

- 2012 was an active year for the courts. The ACLU and Public Patent Foundation (on behalf of AMP and the other plaintiffs) petitioned the U.S. Supreme Court to grant certiorari in the suit over the validity of patents on BRCA1 and BRCA2. Following its decision in *Mayo v. Prometheus*, the High Court accepted the case and immediately remanded it to the Court of Appeals for the Federal Circuit (CAFC) for reconsideration. The CAFC reached essentially the same conclusions as in its initial decision, in a 2-1 decision again upholding the validity of the BRCA1 and BRCA1 gene sequence patents. On September 25, AMP and the other plaintiffs again petitioned the U.S. Supreme Court for certiorari in the case.
- The America Invents Act mandated the U.S. Patent & Trademark Office (USPTO) to study effective ways to provide independent, confirming genetic diagnostic test activity where gene patents and exclusive licensing for primary genetic diagnostic tests exist. The USPTO was instructed to issue a report by June 16, 2012. The USPTO held public hearings; AMP and numerous other groups and individuals provided testimony (see http://www.uspto.gov/aia_implementation/genetic-testing-comments.jsp). However, on August 28, the Department of Commerce sent a letter to the House and Senate Judiciary Committee leadership stating that they believe that further review, discussion and analysis are required before the report can be finalized. The USPTO plans to organize an additional public hearing in late Fall 2012, review the comments received during the last year, and then finalize its recommendations to Congress.

AMP Publications Committee Report

October 2012

Newsletter

Following the “retirement” in 2011 of our hard-working *AMP Newsletter* co-Editors, the AMP Newsletter was converted to a staff-produced, committee chair-reviewed html “AMP News” that is distributed six times per year. The goal of the reformat was to streamline the layout to focus on AMP’s primary initiatives as defined by the strategic plan and provide more frequent updates on the tremendous accomplishments of the AMP volunteers. The name of the newsletter will be updated as well. A contest to select a new name was launched in June. The winner(s) will be announced at the Annual Meeting.

Articles published in the *Molecular Edge* – an AMP article in *ADVANCE for Administrators of the Laboratory*:

- *MDx & the Internet*, Mary C. Lowery Nordberg, PhD
- *Measurement of IL28 Genotype*, Phillip Ruiz, MD, PhD
- *DTC Testing Controversy*, Blane Womack, MS, MB(ASCP), and Barbara Sawyer, PhD, MLS(ASCP), MB(ASCP)
- *Developments in Pharmacogenetics*, Paul Dimaano, CPhT, MB(ASCP)CM, and Katie M. Bennett, PhD, MB(ASCP)CM, NRCC-CC
- *Microbiome and Disease*, Lacey L. Sullivan, MD, and Rodney E. Shackelford, DO, PhD

Upcoming topics for articles scheduled through June 2013 (when the agreement with *ADVANCE* will conclude) include:

KIT Mutations, Use of NGS in Clinical Diagnosis, Attracting and Retaining Molecular Technologists, How to Flunk a CAP Inspection, and Molecular Biomarkers of Lung Cancer.

CAP Today Case Review Articles

Following a conversation with CAP where both AMP and CAP agreed AMP should have a presence in *CAP Today*, AMP offered to prepare case studies. The first study – a test run of sorts, is scheduled for review by the Committee during their meeting this month. Assuming the article is acceptable by AMP and CAP, AMP will develop an editorial calendar allowing authors up to a year if not more lead time. The authors and subspecialties will vary. In addition, if the case studies are included in *CAP Today*, AMP will list subscription to *CAP Today* as a member benefit.

The AMP Case Reviews for *CAP Today* are intended to help pathologists not yet especially familiar with molecular pathology to understand the power and appropriate use of molecular tests. The teaching strategy will be to take them from current routine knowledge, e.g., special stains, to new knowledge in molecular pathology. Authors will have direct access to the *CAP Today* Editor and others who may be of assistance throughout the process of drafting the

Review.

CHAMP 2.0

The topic of CHAMP 2.0 is always on the agenda for the Publications Committee. The immediate focus is to gather informative and actionable data on the use of CHAMP 2.0, the challenges experienced by members, and to provide further instruction and support to those members who need it.

Electronic Media Advisors (EMAs)

The Committee welcomed three new members in an advisory capacity to assist with electronic media issues; particularly CHAMP 2.0. The EMAs came on board in July and have worked to enhance reporting on usage and adoption as well as to develop a brief tutorial on getting started with CHAMP 2.0. The tutorial will be shown on demand at the AMP Booth in the Exhibit Hall. The EMAs intend to develop a brief survey of members regarding CHAMP 2.0 after taking a few more months to allow users to become acclimated.

Test Directory

The *AMP Test Directory* is currently being redesigned. Alexis Carter, MD is heading this effort, and is currently working on the redesign of the database, which is the back-bone of the directory.

AMP Website

The AMP Website received a new format this year resulting in a cleaner, more streamlined look. The Website Editor has met with relevant AMP staff regularly and will continue to on a monthly basis. Current focus includes: overall site organization – is information clearly and easily accessible? Intersection of / compliment between AMP.org and CHAMP 2.0 – how do the two sites relate to one-another? Management of volunteer content providers – ideally, we'll receive regular input from Committee, Working Group, Subdivision Chairs and others on current issues and resources.

AMP Training & Education Committee Report, 2012

A. PUBLICATIONS

A manuscript development group consisting of Alexander C. Mackinnon Jr., Y. Lynn Wang, Amrik Sahota, Cecilia C. Yeung, and Karen E. Weck, finalized and published a report describing the various routes available for certification in molecular diagnostics. Certification in Molecular Pathology in the United States: An Update from the Association for Molecular Pathology Training and Education Committee. *The Journal of Molecular Diagnostics*, Volume 14, Issue 6, November 2012, Pages 541-549.

B. MOLECULAR GENETICS PATHOLOGY PROGRAM DIRECTORS

MGP Program Directors Working Group. Iris Schrijver, Federico Monzon, Vivianna Van Deerlin, Margaret Gulley, Anna Berry. New bylaws establishing a Council of MGP Fellowship Directors were written and approved. As required by the new Bylaws, an election was held for Council Chair and Chair-Elect. Anna Berry was elected 2013 Chair and Federico Monzon 2013 Chair-Elect.

MGP Fellow Training and Curriculum in Genomics Task Force. Chaired by Anna Berry, the task force (established in August 2012) is in its early stages of outlining and developing a suggested molecular pathology and genomics curriculum for fellows. Other members are Michelle Dolan, Kojo Elenitoba-Johnson, Meera Hameed, Mahesh Mansukhani, Federico Monzon, Hanna Rennert, Iris Schrijver, Vivianna Van Deerlin.

C. CURRICULUM DEVELOPMENT TASK FORCES

Molecular Pathology Residency Training. Chaired by Charles Hill, the Task Force (established October 2011) on developing a suggested molecular pathology curriculum for residents continues to meet. Other members are: Ted Schutzbank,(ex officio), Anna Berry, Brian Dawson, George Netto, Randy Hayden, Dara Aisner, Loren Joseph, Steve Schichman and David Zhan.

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 and targeted for directors/managers of Molecular Diagnostics laboratories to provide information about their expectations and needs concerning employee competencies. The survey was launched in September, and the results are currently being analyzed by the task force for its next steps in curriculum development. Other members are: Katie Bennett, Josh Deignan, Ericka Hendrix, Susan Orton, and Shalini Verma

D. CERTIFICATION IN MOLECULAR DIAGNOSTICS

Ted Shutzbank, Melinda Poulter, and Kathy Mangold are leading this effort in assessing the interest for a board certification in Molecular Diagnostics through the American Society for Clinical Pathology (ASCP) Board of Certification. At present, PhD laboratory professionals cannot sign off on cases involving interpretation of molecular diagnostic test results. These individuals also cannot bill Medicare/Medicaid or third party payers for these interpretations. It is curious that MD/DO board certified pathologists, with no molecular pathology/molecular diagnostic training are able to perform both of these activities. It is a critical component of patient care that such interpretations be performed by individuals trained and experienced in molecular diagnostics. PhD level laboratory scientists who can demonstrate the appropriate

training and skills required to make such interpretations should be officially recognized by the medical regulatory bodies, such as CMMS, and granted the same status regarding interpretive results and billing as their MD/DO counterparts. Passing a board certification examination in the specialty field of Molecular Diagnostics, regardless of doctoral degree, will be an important factor in convincing the appropriate regulatory bodies to grant such status. A survey was distributed to the AMP membership to help determine (1) whether or not there is a need for a doctoral certification in Molecular Diagnostics, (2) if so, what range of topics such a certification process should address, and (3) how many people would be interested in obtaining the certification.

E. MEMBERSHIP EDUCATIONAL NEEDS SURVEY

As the AMP Strategic Plan indicates, the educational needs of the membership are to be assessed annually. The online survey was developed in September, and launched in October in preparation for a roundtable discussion during a specialty luncheon at the 2012 Annual Meeting on Genomic Meeting. Kathy Mangold is leading the effort and facilitating the panel and audience discussions. The roundtable panel of T&E Committee members includes Laura Tafe, Annette Kim, and Ted Schutzbank. 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.

F. AWARDS

Young Investigator Awards – 36 poster candidates this year (26 YIA poster candidates in 2011)

Technologist Travel Awards – 23 poster candidates (16 poster candidates in 2011)

G. TRAINEE ACTIVITIES

Annual Trainee Luncheon and Book Drawing - The T&E junior members organized a panel discussion between senior and junior faculty members in Molecular Pathology for the 2012 Trainee Luncheon. Debra Leonard led the senior faculty members and Rachel Sargent led the junior faculty members. Fifteen donated textbooks were given away at the Trainee Luncheon.

H. CO-SPONSORSHIPS AND COLLABORATIONS

Academic Co-sponsorship of webcast productions by Dane Garvin (MedCafe): ASCO Symposium, American Journal of Medicine

ASCP 2012 Workshops presented by AMP. Laura Tafe, Gregory Tsongalis, and Kimberly Lebel are presenting a course for laboratory technologists: "The Omics Era: An Introduction to Molecular Diagnostics." Additionally, Mark Boguski, Richard Haspel, Mark Sobel, and Laura Tafe are presenting an ASIP/AMP/ASCP-sponsored session, "Genomics Testing: What Pathologists Need to Know."

ASCP RISE Question Writers. At the request of ACP, the T&E Committee selected volunteers to write exam questions for the Pathology Resident In-Service Exam (RISE). The selected applicants are: Mahesh Mansukhani, Silvia Spitzer, Rami Mahfouz, Keyur Aptel, Zeba Singh, and Pritish Bhattacharyya.

CAP 2012 Course Presentations. The 2012 courses were: *Molecular Hematopathology in the Era of Personalized Medicine* presented by Drs. Megan Lim, Nathan Bailey and Kojo Elenitoba-Johnson, and *Molecular Testing Guidelines for Selection of Lung Cancer Patients*

for *EGFR* and *ALK* Tyrosine Kinase Inhibitors, presented by Drs. Neal Lindeman and Marc Ladanyi

Society for Laboratory Automation and Screening (SLAS) 2013. The T&E Committee selected AMP speakers as presenters for the Diagnostics track at the SLAS 2013 annual meeting:

- William Wachsman, UC San Diego School of Medicine; Session: Identification of Diagnostic Biomarkers with Novel Clinical Application
- Eric Duncavage, Washington Univ.; Session: Diagnostics Tests and Personalized Medicine

I. EDUCATIONAL PROGRAMS

Molecular Pathology Outreach Course (MPOC 2012). 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 is entitled “Current Applications of Molecular Pathology: Real-Time Updates and Case Studies.” The course includes an overview of applications of molecular pathology by invited speakers (Greg Tsongalis, Iris Schrijver, Christopher Watt, Jennifer Hunt, and Elizabeth Marlowe) followed by case studies presented by T&E members. As of October 10, 2012, there were 104 registrants for the course.

Molecular Genetic Pathology Review Course (MGP 2013). The T&E Committee oversees the implementation and evaluation of the Molecular Genetic Pathology (MGP) Review Course, which takes place every other year (odd years). The MGP 2013 Review Course, directed by Jennifer Hunt, takes place April 4-7, 2013 in Bethesda, MD.

Continuing Education credits (PACE, CME, ACCENT®). AMP continues to apply for PACE credits (AMP Webinars), as well as CME and ACCENT® credits via a joint sponsorship with AACC in 2012 (for the Molecular Pathology Outreach Course and the 2012 Annual Meeting on Genomic Medicine). A new joint sponsorship collaboration has been established with ASCP for educational activities in 2013, including The MGP Review Course (live and online), the MPOC, and the 2013 Annual Meeting.

Webinars

Date	Title	Speakers/Presenters	Attendees	Evaluation Meeting Educational Objectives (5 is high)
April 12	Confused? You are not alone. Molecular CPT Codes in 2012 and Beyond	Jeffrey A. Kant, MD, PhD, Roger D. Klein, MD, JD, Elaine Lyon, PhD, Paul Raslavicus, MD, MHA	274	3.72
May 22	The 2012 Joint ACS/ASCCP/ASCP Guidelines for Cervical Cancer Screening: What you need to know	Mark H. Stoler, MD	156	4.40

July 11	New Mutations and the Genetic Basis of Autism and Intellectual Disability	Evan E. Eichler, PhD	153	4.49
September 25	Bioinformatics for Next Generation Sequencing: Establishing a Pipeline for Candidate Gene Identification in Exome and Genome Sequencing Data	Karl Voelkerding, MD	241	4.42
October 18	HIV Diagnosis: Times They Are A Changing	Richard L. Hodinka, PhD	TBD	TBD
December 11	Genetic Test Registry	Wendy Rubinstein, MD, PhD	TBD	TBD
<i>Co-sponsored series with Asuragen</i>				
April 10	Current Technologies & Advances in CGG Repeat Quantification & Categorization	Sue Richards, PhD, FACMG		
June 20	Reclassification of FMR1 expansion risk: The role of AGG interruptions	Elizabeth Berry-Kravis, MD, PhD		
July 25	FMR1 Methylation PCR: Eliminating the need for Southern Blot testing	Elaine Lyon, PhD		
September 18	FMR1 carrier screening: The how, the why, and the when	Bradford Coffee, PhD		

Submitted by Ted E. Schutzbank, Chair