

INNOVATION & IMPROVED PATIENT CARE



Clinical Practice Committee report, "Relevance, Pathogenesis, and Testing Algorithm for Mismatch Repair-Defective Colorectal Carcinomas" authored by **William Funkhouser** et al. is published in the March issue of *JMD*.

AMP Board approves a manuscript for submission to *JMD*. The report, "Opportunities and Challenges Associated with Clinical Diagnostic Genome Sequencing," is authored by **Iris Schrijver** et al. as part of the Whole Genome Analysis Working Group of the AMP Clinical Practice Committee.

Federico Monzon (Baylor College of Medicine) serves as the AMP co-chair for creating a practice guideline on evaluating molecular markers for colorectal carcinoma testing. Other organizations participating include the American Society for Clinical Pathology (ASCP), the College of American Pathologists (CAP), and the American Society of Clinical Oncology (ASCO).

The practice guideline for lung cancer biomarkers is now in final revisions after a public comment period. **Neal Lindeman** (Harvard Medical School) co-chairs for AMP in the collaboration with the College of American Pathologists (CAP) and the International Association for the Study of Lung Cancer (IASLC).

ADVOCACY



New Molecular Pathology CPT® codes are in the process of being implemented at CMS. The Economic Affairs Committee (EAC) is planning a webinar in early April to explain the background of the new codes and to discuss relevant issues. In March, AMP members will have an opportunity to submit questions and experiences with private payers for inclusion in the webinar content.

The six-member coalition of laboratory professional associations is finishing work with a consultant to "score," or estimate the cost of legislation to **designate doctoral scientists as Qualified Health Care Practitioners**, permitted to bill Medicare for interpretive services for tests in the Molecular Pathology section of the CPT® codebook. The Coalition will soon seek Congressional sponsors for the bill.

2012 is an election year; therefore, there is not likely to be a great deal of activity in Congress other than appropriations and the reauthorizations of the FDA user fee programs. For the latter, **FDA related legislation of interest to AMP** could be added to the bill (such as the Burgess bill on LDTs), and AMP will monitor activity and respond as needed. AMP continues to engage members of Congress in discussions regarding oversight of LDTs and other bills that have the potential to impact AMP members and the field of molecular pathology.

AMP has been in very active conversation with the FDA, members of Congress and with fellow professional associations regarding the **impact of proposed oversight of LDTs and Companion Diagnostics**. FDA agrees with AMP that diagnostics should not be identified by brand name on drug labeling. AMP will continue to engage FDA in dialogue regarding the problems introduced when a single test and testing platform is mandated for any biomarker.

AMP, CAP, and ASCP joined together to file a **formal objection to NIH** regarding the prospective granting of an exclusive license on U.S. Patent Application 61/144,501. AMP's position is that the prospective exclusive license fails to meet the conditions for an exclusive license of a federally-owned invention and that it could clear the market of existing ratio-based quantitative protein assays.

EDUCATION



The International Affairs Working Group (IAWG) is hard at work planning AMP's **participation in several 2012 non-U.S. conferences**. The International Symposium on Molecular Pathology, held January 28-29, 2012 in New Delhi, India, was co-sponsored by AMP and was a great success. For a report on that conference by IAWG member **Bibhu Das**, visit http://www.amp.org/committees/membership_prof_dev/iawg/documents/ISMPReport

Congratulations to Giovanni Insuasti (University of New Mexico) and **Shalini Verman** (MD Anderson Cancer Center), the 2012 Junior Members to the Training & Education Committee. In that role, they will be primarily responsible for bringing trainee issues to the Committee, organizing the Trainee Luncheon at the annual meeting, overseeing the trainee community on CHAMP 2.0, and updating the Molecular Pathology Book List on www.amp.org.

Complimentary 2012 AMP Webinar series coordinated by the Training & Education Committee is in the works. Visit <http://www.amp.org/Webinars/index.cfm> for details.

The **AMP Clinical Practice Committee's Mutation Nomenclature Working Group** presented a webinar on March 1 to explain how to use tools at NCBI to identify the location of sequence variations today. The archived webinar will be available in the members only section at www.amp.org in mid-March.

The Program Committee for the **AMP 2012 Annual Meeting on Genomic Medicine** is busy at work and is shaping up an exciting scientific program that will interest a broad spectrum of genomic medicine professionals as well as AMP members. In addition, several early birds will be targeted to those emerging molecular professionals desiring "starter" courses before the deeper "main course" sessions. The Preliminary Program will be published in late March.

Plan to submit an abstract to the AMP 2012 Annual Meeting on Genomic Medicine! The online submission site opens on April 2 and closes on May 31.

MEMBERSHIP AFFAIRS



The Nominating Committee has almost completed the **slate of candidates for the 2012 elections**. Many thanks to everyone who volunteered themselves or recommended their colleagues for the ballot.

The AMP membership approved bylaws changes February 2 that included governance changes as well as a name change for the Membership and Professional Development Committee to Membership Affairs Committee (MAC). [The MAC continues to pursue their charge with enthusiasm](#). Their recent activities include: junior members and technologists should be appointed to all AMP Committees where appropriate, to provide broader representation and capture the unique perspective of these members; and, they are currently developing an Outstanding Investigator Award to recognize ground-breaking research contributions by an AMP member.

AMP Members Toot Their Own Horn! Have you earned an award lately? Been promoted? Received professional accolade of any kind? Let us know! We'd like to share your good news with AMP members via a special section of this newsletter. Let us know by **April 18** to be included in the next issue!

AMP has joined with fellow pathology associations and has endorsed a bill that would **exclude pathologists from incentive payments and penalties** relating to the meaningful use of electronic health records. The regulations reflect physician office-based practices and do not take into account the practice of pathologists and laboratory medicine.

A provision in the 2011 Patent Reform bill mandates a study by the US Patent and Trade Office (USPTO) on patient access to verification testing for genetic tests. The mandated report to Congress is to address a number of issues relevant to 2nd opinion genetic testing, including:

- The impact that the current lack of independent second opinion testing has had on the ability to provide the highest level of medical care to patients and recipients of genetic diagnostic testing, and on inhibiting innovation to existing testing and diagnoses;
- The effect that providing independent second opinion genetic diagnostic testing would have on the existing patent and license holders of an exclusive genetic test;
- The impact that current exclusive licensing and patents on genetic testing activity has on the practice of medicine, including but not limited to: the interpretation of testing results and performance of testing procedures;
- The role that cost and insurance coverage have on access to and provision of genetic diagnostic tests.

AMP testified at a February 16 hearing at the USPTO. AMP's comments can be found at www.amp.org. Duke University's Center for Public Genomics is gathering information and would like input from all stakeholders, see <http://www.genome.duke.edu/centers/cpg/sec-27-study/> for more details and to learn how to submit information.

Update on *The Association for Molecular Pathology, et al., v. Myriad Genetics, Inc., et al.* (aka the gene patent lawsuit): The ACLU filed a petition to the U.S. Supreme Court on December 7, 2011. We expected the Court to take action on the case on February 21, but it did not, so the petition remains pending. It is speculated that the Court may be delaying until after they issue a decision on [Prometheus v. Mayo](http://www.aclu.org/brca), a case regarding methods patents that has relevance to the gene patent case. An announcement will be sent out on the CHAMP 2.0 Open Forum when the Court issues a decision on the petition. Case documents, background information, and blogs may be found at www.aclu.org/brca.

AMP News is seeking a more interesting name! Enter to win an American Express gift card by submitting your idea or ideas! Email your entries to amp@amp.org by **April 6, 2012**.

AMP News

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