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Association for Molecular Pathology

AMPlifications™

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EDUCATION

• AMP at AACC 2013: AMP is co-sponsoring with AACC a late-breaking session at their upcoming annual meeting in Houston. The session will focus on the recent **U.S. Supreme Court ruling** and its implications for molecular pathology testing. While you're there, be sure to **visit AMP at booth 3525** in the AACC exhibit hall!

• **AMP at the Fifth Annual Next Generation Dx Summit** in Washington, DC: http://www.nextgenerationdx.com/. AMP is a sponsoring organization for the Summit. The Plenary Keynote Discussion, "Perspectives on Evaluating Novel Diagnostics for Reimbursement," will have panelists including **Aaron Bossler**, Co-chair, AMP Economic Affairs Committee.

• AMP at ASCP 2013: **Ted Shutzbank**, **Annette Kim**, and **Kathy Mangold** will be presenting a **Molecular Diagnostics Primer course** at the ASCP 2013 Annual Meeting on September 18 in Chicago, IL. For more information, visit: http://www.ascp.org/2013-Annual-Meeting/index.html. While you're there, be sure to **visit AMP at booth 527** in the ASCP exhibit hall!

• The Training & Education Committee has some exciting webinars coming up! For a full list, visit: http://www.amp.org/Webinars/future_webinars.cfm. These webinars include: June 28, 1pm-2pm (ET): **AMP v. Myriad Genetics, Inc.**, **Roger D. Klein**, Chair of the AMP Professional Relations Committee and Sandra S. Park, Senior Staff Attorney, ACLU and in July, **AMP Variant Nomenclature Database**, **Linda Jeng**, moderated by **Christine Curtis**.

• Congratulations to **Charlie Hill** for his appointment as AMP's MGP representative to the Association for Pathology Chairs **(APC) Fellowship Directors *Ad Hoc* Committee**.

• Congratulations to **Anna Berry** for her appointment as the AMP representative to the Inter-Society Coordinating Committee of the **NIHGRI's Physician Education in Genomics project**. For more information, visit http://www.genome.gov/27552294

INNOVATION & IMPROVED PATIENT CARE

• Congratulations on **recent appointments of AMP members** to the following work groups: **Elaine Lyon** and **Julie Gastier-Foster** to the ACMG Interpretation of Variant Sequences (IVS) Working Group and **Deborah Dillon** to the CAP Cancer Biomarker Reporting Work Group. The **IVS Working Group is planning a public forum** during the AMP 2013 Annual Meeting.

• **Loren Joseph** and **Jan Nowak**, Chair of the Clinical Practice Committee and Co-Chair of the Economic Affairs Committee, respectively, represented AMP at the American Medical Association and the CPT Editorial Panel's Molecular Pathology Advisory Group meeting to discuss the development of **CPT coding to report next generation and whole genome sequencing**. The meeting took place on April 23 in Chicago, IL.

Two AMP Reports have been accepted for **publication in *JMD*** this spring:
1) "**The Role of *MGMT* Testing in Clinical Practice**" was co-authored by **Milena Cankovic**, **Marina Nikiforova**, **Matija Snuderl**, **Adekunle Adesina**, **Neal Lindeman**, **Patrick Wen**, and **Eudocia Lee**, with contributions from **Iris Schrijver** and **Ken Aldape**. The review summarizes the existing data that support the rationale for *MGMT* promoter methylation testing and possibly other molecular testing in gliomas Additionally, the paper encourages pathologists and oncologists to understand the clinical utility of molecular testing and its impact on the application of targeted treatment regimens.

Registration for the AMP 2013 Annual Meeting is now open!
Visit www.amp.org/2013 for details.

ADVOCACY

• **Reimbursement for molecular pathology tests** is AMP's primary advocacy issue. AMP is working independently, as well as within a coalition of other professional associations and is supportive of the work of a company coalition. The EAC has collected data from member laboratories on test costs and will submit comments to CMS by July 8 and encourages all AMP members to comment as well. Send all comments directly to CMS at MoPathGapfillInquiries@cms.hhs.gov.

• For physicians using the **CMS G0452 CPT code** to provide a report and interpretation, CMS requires that the -26 modifier be used. AMP recommends usage of this code according to the regulations by CMS so that the claims information gathered by CMS this year accurately reflects the necessity of interpretation. AMP continues to advocate regarding the critical role of a professional interpretation in molecular diagnostics tests.

• The CMS will hold its annual **Lab Fee Schedule meeting on July 10**; AMP will have crosswalk recommendations.

• The Supreme Court of the U.S. handed down a unanimous decision favoring the plaintiffs in the **AMP v. Myriad** case on June 13.The decision helps to lay the foundation for continued research and application of diagnosis and treatment of diseases at the molecular level. **Roger D. Klein**, Chair of the AMP Professional Relations Committee and **Mary S. Williams**, AMP Executive Director (pictured on right), were on-hand at the Supreme Court in April to hear the arguments. View the AMP Press Release online at http://www.amp.org/documents/20131306_SCOTUSAMPvMYRIAD.pdf.

• AMP continues to **advise CMS on Medically Unlikely Edits** (MUEs); the most recent comments were submitted by AMP in April of this year.

• The CPT codes for genomic or multi-gene sequencing procedures are being discussed by the AMA; **Elaine Lyon**, **Vicky Pratt**, **Aaron Bossler**, **Roger Klein**, **Maria Bettinotti** and **David Wilkinson** are all serving on the AMA Molecular Pathology Advisory Group.

• *The Wall Street Journal* reported on June 11 that **Medicare** could have saved $910 million in 2011 if it had paid the lowest rate negotiated by private insurers for lab tests. The study examined 20 tests, **none of them molecular pathology tests**. CMS is exploring whether they have the authority under current statute to revise payments for lab tests on the CLFS. It has also been noted that Medicare beneficiaries do not pay co-pays or deductibles for lab tests on the CLFS, whereas the contracts of many private payers do have co-pays and this may be another mechanism for Medicare to cut costs.

• The CMS Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) met May 1 to discuss **evidence for (1) DNA- or RNA- based tests** to predict the likely tissue of origin in patients presenting with a cancer of unknown primary site ('CUP' tests); **and (2) Fluorescence in situ hybridization**

2) "**Laboratory Practice Guidelines for Detecting and Reporting *JAK2* and *MPL* Mutations in Myeloproliferative Neoplasms**" was co-authored by **Jerry Gong**, **James Cook**, **Timothy Greiner**, **Cyrus Hedvat**, **Charles Hill**, **Megan Lim**, **Janina Longtine**, **Daniel Sabath**, and **Y. Lynn Wang**. The article summarizes results from a nationwide laboratory survey, and provides recommendations for laboratory practice for the detection of mutations in *JAK2* and *MPL* genes based on current practice and published literature. For information about submiting a manuscript to *JMD*, visit: http://www.journals.elsevierhealth.com/periodicals/jmdi/authorinfo.

AMP AT WORK FOR YOU

• The International Affairs Working Group (IAWG) welcomes its new chair, **Chris Wong** and thanks the outgoing Chair, **Patrik Vitazka**. The IAWG has worked diligently to expand access to AMP overseas and is delighted to announce the first International Affiliate - the **Hong Kong Society for Molecular Diagnostic Sciences** (HKSMDS). Visit http://www.hksmds.org/main.php for more information about the HKSMDS.

• The Membership Affairs Committee thanks you for your input and comments via the recent **membership survey**. Look for a summary of survey results in the next issue of *AMPlifications*.

• Nominating Committee chair, **Iris Schrijver** announced **Jan Nowak** as the recipient of the **2013 Leadership Award**. For more information on the Leadership Award visit: http://www.amp.org/awards_grants_honors/amp_leadership_award.cfm

• The new slate of **AMP leadership has been announced**. Many thanks to everyone for volunteering and casting their votes! A full list of the newly elected 2014 AMP leadership follows:

BOARD OF DIRECTORS
President-Elect: **Janina A. Longtine**, MD
Program Committee Chair-Elect: **Ted E. Schutzbank**, PhD
Secretary-Treasurer: **Vivianna Van Deerlin**, MD, PhD
Membership Affairs Committee Chair: **Nirali M. Patel**, MD
Publication and Communication Committee Chair: **Min Fang**, MD, PhD
Training & Education Committee Chair: **Laura J. Tafe**, MD

Technical Topics Representative to the Program Committee: **John P. Gibson**, MS, SV(ASCP), CLSp(MB), CLAS-MDx

GENETICS SUBDIVISION
Genetics Clinical Practice Committee Representative: **Carolyn Sue Richards**, PhD
Genetics Nominating Committee Representative: **Cindy L. Vnencak-Jones**, PhD
Genetics Program Committee Representative: **D. Brian Dawson**, PhD
Genetics Training & Education Committee Representative: **Jill M. Hagenkord**, MD

HEMATOPATHOLOGY SUBDIVISION
Hematopathology Subdivision Chair: **Lynne V. Abruzzo**, MD, PhD
Hematopathology Clinical Practice Committee Representative: **Annette S. Kim**, MD, PhD
Hematopathology Nominating Committee Representative: **Karen Mann**, MD, PhD
Hematopathology Program Committee Representative: **Rachel L. Sargent**, MD
Hematopathology Training & Education Committee Representative: **Christopher D. Watt**, MD, PhD

INFECTIOUS DISEASES SUBDIVISION
Infectious Diseases Clinical Practice Committee Representative: **Melissa B. Miller**, PhD
Infectious Diseases Nominating Committee Representative: **Richard L. Hodinka**, PhD
Infectious Diseases Program Committee Representative: **Marie Louise Landry**, MD
Infectious Diseases Training & Education Committee Representative: **Benjamin Pinsky**, MD, PhD

SOLID TUMORS SUBDIVISION
Solid Tumors Subdivision Chair: **Shuji Ogino**, MD, PhD
Solid Tumors Clinical Practice Committee Representative: **Mary Lowery Nordberg**, PhD

('FISH') tests for cancer/pre-cancer in patients with atypical squamous cells of unknown significance (ASCUS) or low-grade squamous intraepithelial lesions (LSIL) in cytological specimens from the uterine cervix. Panelists gave scores ranging from 1 (low) to 5 (high) regarding their level of confidence that the existing evidence is sufficient to confirm the clinical validity of the tests. Panelists gave an average score of 2.5 for the FISH test, so no further discussion was held on that test. Discussions regarding the CUP test did go beyond this first question. In the end, most panelists felt the test will prove to be valid and useful, but more evidence is needed.

• **FDA Commissioner Margaret Hamburg** alluded to future FDA regulation of "high risk" LDTs at the 2013 ASCO Annual Meeting, citing LabCorp's OvaSure as a specific example of a "flawed" test. Her comments on LDTs were juxtaposed next to a discussion of recently approved companion diagnostics, raising concern that some or all LDTs for "companion analytes" could potentially fall within the scope of a future FDA guidance regulating high risk tests. **AMP has been working with FDA to educate officials** about clinical laboratory practices and operations, and has emphasized the infeasibility of mandating the use of specific assays with particular drugs because of the multiplicity of potential drugs and assays platforms. Additionally, LDTs offer important benefits to patients through the rapid introduction of assays in response to new medical discoveries, enhanced flexibility in performance due to the ability to continually modify assays, and increased innovation stemming from the relative ease in incorporating new test methods and knowledge. AMP will continue to work diligently with FDA on this issue in order to achieve the best outcomes for our patients.

Additionally, LDTs offer an important benefit to patients by rapid assay introduction following discovery of a medically important variant-drug relationship, *e.g.* KRAS, as well as through their greater flexibility in performance, and the innovation they drive. AMP will continue to work diligently with FDA on this issue in order to achieve the best outcomes for our patients.

• The **LDT Working Group** has completed its white paper that addressed the complexities involved with oversight of LDTs and submitted it to *JMD* for peer review and possible publication.
• AMP will submit comments on the **FDA Draft Guidance on Molecular Diagnostic Instruments with Combined Functions** (due July 8). AMP believes this is a step forward in that FDA is formalizing the use of open channels on instruments. The PRC gratefully acknowledges the assistance of the new Industry Member Task Force: **Roberta Madej** (Chair & PRC liaison); **Wendy Benson**; **Bryan Cobb**; **Steve Day** (PRC liaison); **David Ellis**; **Renee Howell**; Jennifer Leib (AMP government relations consultant); **Roger Klein** (ex officio - PRC Chair); **Lynne Rainen**; **Jennifer Skeen**; and **Anita Suresh**.

• AMP continues to monitor **federal restrictions on employee travel**, and advocate for AMP members who work in federal agencies both on Capitol Hill (see below) and within respective agencies as appropriate.

• AMP is studying an **evidence guidance document produced by the Center for Medical Technology Policy** entitled, "Evaluation of Clinical Validity and Clinical Utility of Actionable Molecular Diagnostic Tests in Adult Oncology," with intent to provide comments.

• AMP continues to participate in **policy discussions with other professional societies**, laboratory groups, as well as coalition groups such as the Personalized Medicine Coalition.

• AMP is joining 70 other organizations in support of the creation of an international alliance that will enable **responsible sharing of genomic and clinical data**.

• AMP's **recent Hill visits** addressed the following topics: Reimbursement of the new molecular pathology codes; Federal employee travel restrictions; and the Health IT Reform Act: this bill has been reintroduced; we delivered AMP's renewed endorsement.

Solid Tumors Nominating Committee Representative: **Karen Weck**, MD
Solid Tumors Program Committee Representative: **Catherine Dumur**, PhD
Solid Tumors Training & Education Committee Representative: **Maria E. Arcila**, MD

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