



## AMP 2022 Committee and Subdivision Annual Reports

### Board of Directors

President	Daniel E. Sabath, MD, PhD
President-Elect; Awards and Strategic Opportunities Committee Chair	Laura J. Tafe, MD
Past President and Nominating Committee Chair	Antonia R. Sepulveda, MD, PhD
Secretary-Treasurer and Finance Committee Chair	Alexis B. Carter, MD
Clinical Practice Committee Chair	Jane Gibson, PhD
Economic Affairs Committee Chair	Samuel K. Caughron, MD
International Affairs Committee	Rami Mahfouz, MD, MPH
Membership Affairs Committee Chair	Shelby Melton, MD
Professional Relations Committee Chair	Eric Konnick, MD, MS
Program Committee Chair	Nirali Patel, MD
Publication & Communication Committee Chair	Patricia Tsang, MD
Training & Education Committee Chair	Alanna Church, MD
Genetics Subdivision Chair	Avni Santani, BS, PhD
Hematopathology Subdivision Chair	Eric Duncavage, MD
Infectious Diseases Subdivision Chair	Donna M. Wolk, PhD, D(ABMM)
Informatics Subdivision Chair	Jason D. Merker, MD, PhD
Solid Tumors Subdivision Chair	Anna Yemelyanova, MD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

## AMP Awards Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Laura J. Tafe, MD
Member	Megan S. Lim, MD, PhD
Member	Ronald M. Przygodzki, MD
Member	Lynette Sholl, MD
Member	Yaolin Zhou, MD

### PURPOSE SUMMARY:

The Awards Committee consists of 5 members (4 appointed) who oversee 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.

The President-Elect serves as the Chair of the Awards Committee. The remaining 4 committee members are appointed by the Board and serve staggered two-year terms. The annual selection of 2 incoming committee members is conducted by the committee and the candidates' names are brought forward for Board approval and appointment.

### 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, if any

### Selected Award Recipients

- 2022 Jeffrey A. Kant Leadership Award: Karen E. Weck, MD
- 2022 Meritorious Service Award: Samuel K. Caughron, MD
- 2025 Award for Excellence in Molecular Diagnostics: To be announced in Spring 2025

## AMP Clinical Practice Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Jane Gibson, PhD
Genetics Subdivision Representative	Diana Mandelker, MD, PhD
Genetics Subdivision Representative	Steven M. Sperber, PhD
Hematopathology Subdivision Representative	Michael J. Kluk, MD, PhD
Hematopathology Subdivision Representative	Rena Xian, MD
Infectious Diseases Subdivision Representative	Blake W. Buchan, PhD
Infectious Diseases Subdivision Representative	Karissa Culbreath, PhD
Informatics Subdivision Representative	Elaine Gee, PhD
Informatics Subdivision Representative	Sabah Kadri, PhD
Solid Tumors Subdivision Representative	David A. Eberhard, MD, PhD
Solid Tumors Subdivision Representative	Navid Sadri, MD, PhD
Junior Member	Lauren J. Miller, MD
Junior Member	Jack Tung, MD, PhD

### 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. The AMP Clinical Practice Guidelines Program is comprised of multiple AMP-led working groups that 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. The majority of these projects include representation from other professional organizations and groups. AMP's External Representatives Program additionally fosters collaboration by providing AMP subject matter experts to clinical practice projects led by other professional organizations and groups.

### Publications

- Recommendations for the Use of *In silico* Approaches for Next Generation Sequencing Bioinformatic Pipeline Validation: A Joint Report of the Association for Molecular Pathology, Association for Pathology Informatics, and College of American Pathologists, in press, *Journal of Molecular Diagnostics*. Eric Duncavage & Justin Zook (Co-chairs), Mark Routbort, Joshua Coleman, Annette Meredith, Carlos Jose Suarez, Sabah Kadri, Somak Roy (CAP representative), Monica de Baca (API representative), and Chad Vanderbilt.
- *TPMT* and *NUDT15* Genotyping Recommendations: A Joint Consensus Recommendation of the Association for Molecular Pathology, Clinical Pharmacogenetics Implementation Consortium, College of American Pathologists, Dutch Pharmacogenetics Working Group of the Royal Dutch Pharmacists Association, European Society for Pharmacogenomics and Personalized Therapy, and Pharmacogenomics Knowledgebase, published August 2022 issue of the *Journal of Molecular Diagnostics*. Victoria Pratt & Karen Weck (Co-chairs), Larisa Cavallari, Lisa Kalman, Houda Hachad, Yuan Ji, Stuart Scott, Andrea Gaedigk, Reynold Ly, Ann Moyer (CAP representative), Michelle Whirl-Carrillo (CPIC representative), Ron van Schaik (DPWG), and Makenzie Fulmer. DOI: <https://doi.org/10.1016/j.jmoldx.2022.06.007>
- An Educational Assessment of Evidence used for Variant Classification: A Report of the Association for Molecular Pathology. Published in the June 2022 issue of the *Journal of*

*Molecular Diagnostics*. Elaine Lyon, (Chair), Madhuri Hegde, Julie Gastier-Foster, Carolyn Sue Richards, Robyn Temple-Smolkin, and Glenn Palomaki; DOI: <https://doi.org/10.1016/j.jmoldx.2021.12.014>. This project was supported by an unrestricted educational grant support from QIAGEN, Inc.

**Additional Accomplishments**

- Multiple CPC and Scientific Subdivision members hosting or presenting in AMP Webinar events.
- Multiple AMP working group projects are underway.
- CPC members actively brainstormed new project ideas. Several of these project ideas are awaiting launch next year.
- Assisted AMP Advocacy and the various Subdivisions with input for their various initiatives where applicable.
- Multiple early career AMP members working on CPC working groups as Junior members.

**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.
- Suggestions from AMP members for new CPC initiatives are always welcome! Visit <https://www.amp.org/clinical-practice/clinical-practice-overview/> for more details or email [ampclinicalpractice@amp.org](mailto:ampclinicalpractice@amp.org).

**AMP Clinical Practice Guidelines Program**

<b>Working Group / Task Force</b>	<b>Members</b>
Standardization of Clinically Relevant Pharmacogenetic Alleles (PGx) <i>TPMT / NUDT15</i>	Victoria Pratt (Chair), Karen Weck (Co-Chair), Larisa Cavallari, Makenzie Fulmer (Junior Member), Andrea Gaedigk (PharmVar representative), Houda Hachad, Yuan Ji, Lisa Kalman, Reynold Ly, Ann Moyer (CAP representative), Stuart Scott, R.H.N. (Ron) van Schaik (DPWG representative), and Michelle Whirl-Carrillo
Guidance/Standards for NGS Germline Variant Confirmation	Kristy Crooks (Chair), Avni Santani, Diana Mandelker, Steve Lincoln, Kelly Hagman (NSGC representative), and Ryan Schmidt
NGS Utility for Assessment of T/B-cell Clonality	David Viswanatha (Chair), Keyur Patel, Maria Arcila, Timothy Greiner, Joseph Houry (CAP representative), David Wu, Devon Chabot-Richards (SH representative), and Habibe Kurt
Variant Interpretation Test Across Labs (VITAL) Inherited Conditions*	Elaine Lyon, (Chair), Madhuri Hegde, Julie Gastier-Foster, Carolyn Sue Richards, Sherri Bale and Glenn Palomaki; unrestricted educational grant support from QIAGEN, Inc.
Guidance for Non-standard or Emerging Applications: Liquid Biopsy	Christina Lockwood (Chair), Laetitia Borsu, Christopher Gocke, Milena Cankovic, Kandelaria Rumilla, Meera Hameed, Laura Tafe (CAP representative), Apostolia Tsimberidou (ASCO representative), Jonathan Earle, Jean Lopategui, Jacquelyn Reuther and Panieh Terraf

New Frontiers in Infectious Diseases Multiplex Testing*	Michael Lewinski (Chair), Susan Butler-Wu, Kevin Alby, Jennifer Dien Bard, Alex Greninger, Esther Babady (PASCV representative), Duane Newton (ASM representative), and Kimberly Hanson (IDSA representative)
Guidance/Standards for Tumor Mutational Burden Testing by Molecular Methods	Larissa Furtado (Chair), Jeffrey Gregg, Benjamin Kipp, Jonathan Nowak, Susan Hsiao, Antonia Sepulveda, Ahmet Zehir, Jeremy Segal, Lauren Ritterhouse, Carlo Bifulco (SITC representative), Neal Lindeman (CAP representative), Solange Peters (ASCO representative), and Daniel Dolderer
Implementation of AMP/ASCO/CAP Reporting and Interpretation of Somatic Sequence Variants Recommendations in Clinical Practice (VITAL Somatic)*	Marilyn Li (Chair), Somak Roy, Cindy Vnencak-Jones, Catherine Cottrell, Kai Wang, and Scott Turner
Molecular MRD Monitoring in Acute Myeloid Leukemia	Keyur Patel (Chair), Noah Brown, Marian Harris, Rashmi Goswami, Duane Hassane, Todd Druley, Brian Parkin, Annette Kim, Christopher Watt (CAP representative), Aaron Shaver (ASH representative), David Wu (SH representative), Hong Fang, Nikhil Patkar, Dale Bixby, and Harrison Tsai
Guidance/Standards for the Use of <i>In Silico</i> Approaches for Validation of NGS Bioinformatics Pipelines*	Eric Duncavage & Justin Zook (Co-chairs), Mark Routbort, Joshua Coleman, Annette Meredith, Carlos Jose Suarez, Sabah Kadri, Somak Roy (CAP representative), Monica de Baca (API representative) and Chad Vanderbilt
Clinical Whole Exome Sequencing for Inherited Conditions as a First Line Test: Spectrum of applications and standards	Rong Mao (Chair), Birgit Funke, Pinar Bayrak-Toydemir, Jianling Ji, Megan Wachsmann, Celeste Eno, Avni Santani (CAP representative), Karen Wain (NSGC representative), and Jeffrey SoRelle
Homologous recombination deficiency (HRD) assessment using next generation sequencing (NGS)	Susan Hsiao (Chair), Lawrence Jennings, Diana Mandelker, Vera Paulson, Michelle Shiller, Tracy Stockley, Eric Vail, Anna Yemelyanova, Destin Black (ACCC representative), Ian Hagemann (CAP representative), Praveen Vikas (ASCO representative), and Kelly Devereaux
CAP/IASLC/AMP Molecular Testing Guideline for Selection of Lung Cancer Patients for <i>EGFR</i> and <i>ALK</i> Tyrosine Kinase Inhibitors – Revision	Neal Lindeman (AMP Co-Chair), Maria Arcila, David Kwiatowski, Lynette Sholl, and Dhananjay Chitale
Validation of Next-Generation Sequencing Panels for Gene Fusion and Splice Variant Detection	Laura J. Tafe (Chair), Alanna Church (Co-Chair), Eduardo Castro-Echeverry, Marjorie P. David, Sabah Kadri, Suneel Kamath (ASCO representative), Michael J. Kluk, Ravindra Kolhe (CAP representative), Christian Kunder, Andres G. Madrigal, Fatimah Nahhas, Valentina Nardi, and Jack Tung (Junior Member)
Update of “Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint	Marilyn M. Li (Chair), Cindy Vnencak-Jones (Co-Chair), Amir Behdad, Ozge Ceyhan-Birsoy (ACMG representative), Catherine E. Cottrell, Eric J. Duncavage,

Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists”	Melissa Gildenberg (Junior Member), Obi Griffith (CGC representative), Annette S. Kim, Shashikant Kulkarni (ClinGen Cancer Variant Interpretation representative), Christine Lovly (ASCO representative), Jason N. Rosenbaum, Somak Roy, Eytan Stein (ASH representative), Lea F. Surrey (CAP representative), Scott A. Turner, and Kai Wang
Oncologist-friendly Biomarker Reporting	Jane Gibson (Chair), Dana Altenburger (CAP representative), Noah Brown, Amy Clark (ASCO representative), Joshua Coleman, Hanadi El Achi (CAP representative), Rajyasree Emmadi (Ex-Officio), Meera Hameed, Jennifer Laudadio, Anthony Provenzano (ASCO representative), Christopher Suci (Junior Member)
Patient-friendly Biomarker Reporting	Rajyasree Emmadi (Chair), Allison Cushman-Vokoun, Jane Gibson, Julie Woolworth Hirschhorn, Jennifer Morrisette, Irene Newsham, Sinchita Roy Chowdhuri, Eric Vail
Standardization of Clinically Relevant Pharmacogenetic Alleles (PGx) <i>CYP3A5 / CYP3A4</i>	Victoria Pratt (Chair), Karen Weck (Co-Chair), Larisa Cavallari, Makenzie Fulmer (Junior Member), Andrea Gaedigk (PharmVar representative), Houda Hachad, Yuan Ji, Lisa Kalman, Reynold Ly, Ann Moyer (CAP representative), Stuart Scott, R.H.N. (Ron) van Schaik (DPWG representative), and Michelle Whirl-Carrillo

\* Manuscript submitted to *The Journal of Molecular Diagnostics*

#### **AMP External Representatives Program**

<b>AMP Representative</b>	<b>Collaborating Organization(s)</b>	<b>Workgroup / Committee</b>
Daniel Farkas	College of American Pathologists	Molecular Oncology Committee
Scott Topper	American College of Medical Genetics and Genomics, ClinGen, College of American Pathologists	Interpretation of Sequence Variants Update Workgroup
Monica Basehore	National Institute of Standards and Technology	Genome in a Bottle Steering Committee
Carolyn Sue Richards	American College of Medical Genetics and Genomics	Incidental Findings in Inherited Diseases Update Workgroup
Lauren Ritterhouse Ahmet Zehir	College of American Pathologists, American Society of Clinical Oncology	PD-L1 Testing in Lung Cancer Workgroup
Federico Monzon	American Society of Clinical Oncology	CancerLinQ Oncology Leadership Council
Marilyn Li	American College of Medical Genetics and Genomics, ClinGen	Somatic Cancer Clinical Domain Workgroup
Maria Bettinotti	Foundation for the National Institutes of Health	Biomarkers Consortium Steering Committee for Inflammation and Immunity
Snehal Patel	Foundation for the National Institutes of Health	Biomarkers Consortium Steering Committee for Cancer

Sinchita Roy-Chowdhuri	American Society of Cytopathology	Organizational liaison
Benjamin Pinsky	American Society for Microbiology	Next Generation Sequencing Coalition
Pranil Chandra	College of American Pathologists	Personalized Healthcare Committee Incidental Findings in the Context of Tumor Genomic Evaluations Project Workgroup
Nikoletta Sidiropoulos Jane Gibson	College of American Pathologists	Cytopathology Committee/Personalized Healthcare Committee Pre-analytcs for Precision Medicine Cytology Preparations for Molecular Testing Project Team
Ryan Schmidt	College of American Pathologists	Genomic Medicine Resource Committee
Avni Santani	Clinical Laboratory Standards Institute	Nucleic Acid Sequencing Methods in Diagnostic Laboratory Medicine, 2nd Edition (MM09) Working Group
Yaolin Zhou Joshua Deignan	Test Renaming for Understanding and Utilization (TRUU-Lab) coalition	Steering Committee
Peter Canoll Dolores Lopez-Terrada Meera Hameed	College of American Pathologists, American Association of Neuropathologists, American Society of Clinical Oncology, Society for Neuro-Oncology	Diagnostic Testing for Diffuse Gliomas Workgroup
Antonia Sepulveda	College of American Pathologists, American Society of Clinical Oncology	Checkpoint Inhibitor Testing in Body Sites Other Than Lung
Eric Duncavage	Association of Community Cancer Centers	Advisory Committee
Daniel Jones	Clinical Laboratory Improvement Advisory Committee	Next Generation Sequencing Best Practices Forum
Christina Lockwood	BloodPAC	Advisory Committee, Analytical Validation Workgroup, and Minimal Data Elements Workgroup
Sanja Dacic	Cancer Support Community	Lung Biomarker Digital Tool Advisory Board
Frederick Nolte	Coronavirus Standards Working Group	The Joint Initiative for Metrology in Biology
Dara Aisner Sinchita Roy-Chowdhuri	Association of Community Cancer Centers	Operational Pathways in Lung Cancer
Antonia Sepulveda	World Health Organization International Agency for Research on Cancer	International Collaboration for Cancer Classification and Research (IC3R)

Somak Roy	Clinical Laboratory Standards Institute	MM25 Document Development Committee on Bioinformatics "Sequencing Bioinformatics for Human Genetics and Oncology" work group
Mehdi Nassiri	Food and Drug Administration	SHIELD Consortium - Standardization of Lab Data to Enhance Patient-Centered Outcomes Research and Value-Based Care
Sinchita Roy-Chowdhuri	LUNGeivity	"How to Read Your Biomarker Testing Results Report" patient pamphlet
Michelle Shiller	Association of Community Cancer Centers	Cancer Diagnostics Advisory Committee
Rena Xian	American Society of Clinical Oncology	Cell-free DNA Testing Guideline Expert Panel
Dara Aisner	American Society of Clinical Oncology	Multi-Site Guideline Advisory Group
Antonia Sepulveda	World Health Organization	Classification of Tumours 5th Series Editorial Board
Mehdi Nassiri	Centers for Disease Control and Prevention	Forum on Adoption of Standards for Laboratory Data Exchange and Interoperability



## AMP Economic Affairs Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Samuel K. Caughron, MD
Vice Chair, New Codes & Pricing	Jay L. Patel, MD
Vice Chair, Coverage	Pranil Chandra, DO
Member ( <i>Ad-Hoc</i> – Hemepath Subdivision Rep.)	Maria E. Arcila, MD
Member	Jay Brock, PhD
Member	Maude Champagne, MBA
Member	Rajyasree Emmadi, MD
Member	Jeffrey Gagan, MD, PhD
Member	Tanner Hagelstrom, PhD, MBA
Member	Mathew Hiemenz, MD
Member (Solid Tumor Subdivision Rep.)	Susan Hsaio, MD, PhD
Member	Loren Joseph, MD
Member ( <i>Ex Officio</i> – PRC Chair)	Eric Konnick, MD, MS
Member	Federico Monzon, MD
Member	Keyur Patel, MD, PhD
Member (Genetics Subdivision Rep.)	Victoria Pratt, PhD
Member	Salvatore Priore, MD, PhD
Member	Aparna Rajadhyaksha, MD
Member	Oana C. Rosca, MD
Member ( <i>Ex Officio</i> President)	Daniel Sabath, MD, PHD
Member	Navid Sadri, MD, PhD
Member	Jennifer Sanmann, PhD
Member	Ester Stein, MBA
Member ( <i>Ex officio</i> President Elect)	Laura Tafe, MD
Member	Patricia Tsang, MD
Member	Eric Vail, MD
Member (Infectious Disease Subdivision Rep.)	Joseph Yao, MD
Junior Member	Nicholas Bevins, PhD
Committee Advisor	Aaron D. Bossler, MD, PhD
Committee Advisor	Jan A. Nowak, MD, PhD

### PURPOSE SUMMARY:

The Economic Affairs Committee (EAC) addresses, advises, and educates the AMP Board of Directors, membership, payors, 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 availability to patients of high quality molecular pathology services. The Committee's scope encompasses short and long-term issues associated with the coding for molecular procedures, utilization of and coverage for molecular pathology, the determination of test pricing, and the potential economic impact of public policy decisions on molecular pathology practice. The Committee interacts with the American Medical Association and other interested organizations in order to achieve common goals.

### 2022 ACTIVITIES:

CMS, who has oversight of Medicare, has increasingly either denied coverage or reduced payment for many medically necessary molecular pathology tests. The increasing restrictions create a challenging environment for clinical practice and for innovators to translate new genomic discoveries into clinical applications. AMP's government relations consultants, Erika Miller, Stefanie Reinhart, and Michaela Hollis of Cavarocchi, Ruscio,

Dennis Associates (CRD) provide advice regarding advocacy strategies and help to guide AMP's relationships at key federal agencies and on Capitol Hill. Beyond CRD, the EAC is supported by AMP Director of Public Policy and Advocacy, Sarah Thibault-Sennett, AMP Policy Analyst, Monika Franco, and AMP Policy Fellow, Samantha Pettersen. AMP continues to work with the broader professional community to address policy challenges and opportunities, and engage and inform payors who aim to achieve rightful reimbursements for appropriate patient care services.

### **Economics of Testing During a Public Health Emergency: Lessons learned from two years of COVID-19**

In April, the EAC released a comprehensive white-paper that reflects on the first two years of the COVID-19 pandemic and the unique economic challenges faced by laboratories, particularly at the onset. Policies on coding, coverage, and pricing enacted to respond to the COVID-19 pandemic for SARS-CoV-2 molecular diagnostic tests are examined, and recommendations for how the challenges laboratories faced can be prevented (or at least mitigated) in the future are provided. The white-paper asserts that during a public health emergency, changes must be made to coding, coverage, and pricing processes for tests and must be considered in the context of the overall financial impact to both the providers of testing and those who pay for it. While careful consideration is needed, the traditional time-consuming methods are challenged to meet the needs for an effective pandemic response where rapid, even daily, adjustments may be needed. The white-paper was developed by a selection of members of the 2021 EAC: **Drs. Samuel Caughron, Jennifer Dien Bard, Pranil Chandra, Susan Hsiao, Jay Patel, Navid Sadri, Ester Stein, Katherine Tynan, and Eric Vail.**

### **Molecular Pathology Economics Summit**

On July 15<sup>th</sup> AMP held its second Annual Molecular Pathology Economics Summit (the Summit). Though it was delayed for two years due to COVID-19 related issues, this event was a follow up of the first Summit held in 2019. This one-day event brought together 67 attendees ranging from patient advocacy groups, pharmaceutical companies, clinical laboratories, as well as trade and professional associations. The goal of the second Summit was to further expand upon the discussion that was held in 2019, while adding new topics to explore.

During the Summit, a series of roundtable discussions were held, each focused on a specific issue: impact of COVID-19 on laboratories, Coding, Pricing, and Coverage. Interactive candid discussions between stakeholders explored the unique challenges they face and barriers to patient access, as well potential solutions and/or novel approaches to overcoming these barriers, with the goal of identifying shared policy agendas for the participating stakeholders. Furthermore, AMP held its first ever Innovation Lab series, where stakeholders were given the opportunity to present their work on expanding patient access to molecular diagnostics as well as potential action items the organization could take in the future. This year Cancer Support Community (CSC), FORCE: Facing Our Risk of Cancer Empowered, Illumina, and Loxo@Lily participated in the Innovation Lab.

The 2022 Summit Planning Committee included: **Drs. Samuel Caughron, Pranil Chandra, Jay Patel, Anthony Sireci, Nicholas Bevins, Tanner Hagelstrom, Victoria Pratt, and Salvatore Priore.** With the success of our 2019 Summit and the enthusiastic reception of the 2022 Summit, AMP plans to make this an annual event moving forward.

### **"Value of Molecular Diagnostics" Congressional Education Campaign**

In response to concerning use of the term "high cost" laboratory tests in legislation proposed this year regarding telehealth services and a recent Medical Payment Advisory Commission report, the EAC launched a campaign to provide key congressional offices with education on the value of molecular testing. In May, twelve EAC members (plus one member of the AMP Professional Relations Committee) met with 20 Congressional offices on relevant committees or who have previously engaged on topics touching molecular diagnostics. AMP recommended that instead of focusing on the cost of tests in isolation, Congress should evaluate the full value that molecular diagnostic tests have on patient care and outcomes. Our members expressed concern that policies developed by only considering the test price will negatively affect the access, utilization, and reimbursement of these tests.

The meetings went very well and those on Capitol Hill were appreciative to hear about how molecular diagnostic tests impact patient care and the overall costs associated with a course of disease.

### **Payer Engagement**

In 2016 and 2017, the EAC undertook a significant initiative to bring together molecular pathology experts and payers to discuss how traditional routes for establishing coding, coverage policy and pricing apply to molecular procedures. In 2021, AMP decided to build upon these previous engagement and education efforts by hosting a payer engagement virtual meeting focused on hepatobiliary cancer testing. AMP decided to expand these efforts into 2022 due to the tremendous value in these meetings, as the conversations are an important opportunity for dialogue on critical issues and offer payers a chance to provide input and feedback to AMP's efforts at improving the economic landscape for molecular testing. This year, AMP organized three different payer engagement events. The first event was held in April of 2022 and focused on key subject matter areas: payer concerns of fraud, the need for payer education, issues with coding, and evidence development. AMP held an event in June to follow up this discussion and dive deeper into these issues. The last payer event will occur in late November and will focus on identifying ways that AMP could assist payers to develop appropriate coverage policies for molecular diagnostics. These efforts are directed by an EAC workgroup, led by **Dr. Sam Caughron**.

### **Protecting Access to Medicare Act (PAMA)**

The Protecting Access to Medicare Act of 2014 (PAMA) required laboratories that perform clinical diagnostic laboratory tests to report the amounts they are paid by private insurers for said tests to the Centers for Medicare and Medicaid Services (CMS). CMS then sets the Medicare payment rates for laboratory tests paid under the Clinical Laboratory Fee Schedule (CLFS) based on the weighted median of the private payor data. Since 2014, AMP has continued to express significant concerns to CMS and Congress on various occasions about issues with the first PAMA exercise and how rates were established (e.g., data entity and reporting entities).

In early 2020, the Laboratory Access for Beneficiaries (LAB) Act was passed by Congress. The LAB Act was supported by AMP and addressed some of AMP's and other stakeholders' concerns with PAMA. It delayed the next round of data reporting until 2021 and delayed the timing for payment reductions under PAMA. Additionally, the LAB Act authorizes MedPAC (Medicare Payment Advisory Committee) to study the methodology CMS used to rate-set through PAMA.

Since the passage of the LAB Act, two additional pieces of legislation were passed: the CARES Act (to address the COVID-19 public health crisis) included an additional one-year delay to PAMA and the Protecting Medicare and American Farmers from Sequester Cuts Act, which was passed in December 2021, also included an additional one-year delay to PAMA. Following these actions, the next PAMA reporting cycle will begin in 2023, with the new rates effective on January 1, 2024.

Following these delays, AMP is engaging with other stakeholders to advocate for a permanent fix to PAMA. In September, AMP signed on with twenty-five other organizations calling for Congress to enact the Saving Access to Laboratory Services Act (SALSA/H.R. 8188/S.4449) by January 2023. SALSA would give CMS new authority to collect private market data through statistically valid sampling from all laboratory segments for the widely available test services where previous data collection was inadequate. AMP is hopeful that if enacted, SALSA would greatly reduce the burden on members to comply with PAMA. Additionally, the joint EAC and Professional Relations Committee PAMA task force received a grant to conduct a survey to better understand the impacts that PAMA has had on clinical laboratories, hospital systems, and physicians and the downstream effects on patient access. The PAMA task force anticipates releasing the results of this survey and incorporating the data into AMP's advocacy strategies by 2023.

### **Clinical Lab Fee Schedule for Calendar Year 2023**

During the summer, AMP provided written and oral comments to CMS on the Calendar Year 2023 Clinical Lab Fee Schedule (CY2023 CLFS). **Dr. Jay Patel** represented AMP at the annual CLFS meeting at CMS on June 23, 2022. He presented crosswalk recommendations for the new and reconsidered CY2023 CLFS molecular pathology, genomic sequencing, and microbiology procedures.

Additionally, the Advisory Panel on Clinical Diagnostic Tests (The Advisory Panel) reviewed stakeholder recommendations presented to CMS in July and voted on the best approach to pricing new and reconsidered codes. The Panel was established by the Protecting Access to Medicare Act (PAMA) and advises CMS on various issues under PAMA including payment rates for new tests, including whether to use the crosswalk or gapfill methodology for initial price determination. Several AMP members are members of The Panel, with **Drs. Aaron Bossler, Elaine Lyon, and Pranil Chandra** nominated by AMP to serve.

In late September, CMS released the CY2023 CLFS Preliminary Determinations for the new and reconsidered services. While some of the preliminary CMS determinations align with AMP and other laboratory organizations' recommendations, some of the preliminary recommendations provided by CMS differ vastly from both the Advisory Panel recommendations and stakeholder input and, in many cases, do not represent the best options for crosswalks. AMP provided detailed comments to CMS on the preliminary determinations at the end of October. Pricing determinations will be finalized later this year.

### **Medicare and Private Payer Coverage Policies**

Monitoring emerging policies continued to be a major focus of the Coverage subcommittee and was led by **Dr. Pranil Chandra**. AMP continues to advocate with CMS regarding coverage policy actions taken by Medicare Administrative Contractors (MACs). Thus far in 2022, AMP has provided responses to various MACs for approximately eight draft local coverage determinations (LCDs). Frequently, AMP and the College of American Pathologists (CAP) collaborated to draft joint responses. The EAC is very thankful to the AMP members who volunteered their time and subject matter expertise to assist in responding to the diverse coverage policy issues. Additionally, earlier in 2022, AMP responded to a private payer coverage policy on next generation sequencing for cancer and inherited conditions, where AMP identified problematic parameters for these services and aims to work with the payer to update the policy to better reflect the utility of these services.

### **CPT Codes**

The EAC New Codes and Pricing Subcommittee, led by **Dr. Jay Patel**, advises and reviews new CPT code applications submitted to the Pathology Coding Caucus (PCC) and the Molecular Pathology Advisory Group (MPAG). Throughout the year, the Subcommittee may submit new CPT code change proposals to AMA based on member need and input. Additionally, in 2022, the subcommittee provided input to the AMA Tumor Genomics Testing (TGT) Workgroup, which is charged with creating CPT coding solution(s) for extended/comprehensive genomic testing in tumor/neoplastic conditions, including whole genome sequencing. The workgroup is chaired by **Dr. Aaron Bossler** and includes multiple AMP members, including **Dr. Jay Patel** who serves as AMP's representative. The subcommittee also provided input to CMS' National Correct Coding Initiative (NCCI) to help ensure national correct coding methodologies of procedure to procedure (PTP) and medically unlikely edits (MUEs) for molecular procedures and is working with a broad group of stakeholders to address issues with updates to the NCCI manual.

### **Outside Organization Involvement**

- **Dr. Aaron Bossler** serves on the CPT Editorial Panel
- **Drs. Victoria Pratt, Jay Patel, Joseph Yao, Aaron Bossler** serve on the AMA Proprietary Laboratory Analyses Technical Advisory Group (PLA-TAG)
- **Dr. Jay Patel** serves on the PCC, with **Dr. Anthony Sireci** serving as the technical advisor.
- The AMA Molecular Pathology Advisory Group (MPAG) includes AMP members **Drs. Anthony Sireci, Aaron Bossler, Ann Moyer, Madhuri Hegde, Jeremy Segal, Larry Jennings, and Victoria Pratt**.

## AMP Finance Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Alexis B. Carter, MD
President	Daniel E. Sabath, MD, PhD
President-Elect	Laura J. Tafe, MD
Past President	Antonia R. Sepulveda, MD, PhD
Member	Sharathkumar Bhagavathi, MD
Member	Steven A. Schichman, MD, PhD
Member	Xiao-Ming Yin, MD, PhD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

The Finance Committee oversees AMP's financial affairs, including reviewing revenue & expense reports and recommending to the Board for approval an annual operating budget and the investment policy for the Association's assets.

## AMP International Affairs Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair and Membership Affairs Liaison (Middle East)	Rami Mahfouz, MD
Member (Africa)	Adewunmi Oluseye Adeoye, MD
Member and Professional Relations Liaison (Europe)	David E. Barton, PhD
Member (Latin America)	Renata A. Coudry, MD, PhD
Member and India Affiliate Liaison (South Asia)	Bibhu R. Das, PhD
Member (Australia)	Andrew P. Fellowes, PhD
Member and Korea Affiliate Liaison (East Asia)	Jin Kyung Lee, MD, PhD
Member (Southeast Asia)	Kenneth Chang, MBCHB
Member and Training & Educ Liaison (Latin America)	Roberta Sitnik, PhD
Member and Hong Kong Affiliate Liaison (East Asia)	Lei Po (Chris) Wong, PhD
Member (Africa)	Denis Francis York, PhD
German Affiliate Coordinator	Silke Lassmann, PhD
Italy Affiliate Coordinator	Massimiliano (Max) M. Corsi Romanelli, MD, PhD
Advisor	Helen Fernandes, PhD
Advisor	Jin-Yeong Han, MD, PhD

### PURPOSE SUMMARY:

The International Affairs Committee (IAC):

- Enhances AMP as an international organization
- Promotes AMP's vision and mission internationally
- Facilitates international presence and participation in AMP groups and programs
- Expands excellence in education and advocacy on behalf of patients, clinicians, and lab professionals to an international audience
- Enables the interaction of scientists and molecular pathologists in the various parts of the world

### 2022 ACTIVITIES:

- Selected a new Southeast Asia IAC Member
- Planned and held the Global Networking Session – “The Impact of COVID Pandemic on Molecular Pathology Practice: The Experience of the International Community” in January 2022
- AMP 2022 Annual Meeting Events:
  - Joined with Membership Affairs Committee to welcome first time AMP attendees during the First Timer's Lunch
- Designed and released survey to collect data on International Technologists Training and Certification
  - This data will be presented via webinar in January 2023
- Selected International Trainee Travel Awardees from India and Cyprus.
- Awarded International Membership Grants to molecular professionals from India, Egypt, Brazil, and the Philippines.
- IAC Committee represented by its Chair is assisting in the planning, organization, and launching of the AMP Europe 2023 in Milan, Italy.
- Supported AMP speakers at international (non-U.S.) conferences:
  - Shelby Melton, MD at the International Academy of Pathology Arab Division (IAPAD) Molecular Pathology Preconference Workshop. Organizing Committee AMP Member: Rami Mahfouz, MD
  - Support for the Brazilian Society of Clinical Pathology 54<sup>th</sup> Congress (Florianopolis, Brazil). Organizing Committee AMP Member: Roberta Sitnik, PhD

## AMP Membership Affairs Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Shelby Melton, MD
Member	Kevin E. Fisher, MD, PhD
Member	Lisa M. Haley, MS
Member	Jin-Yeong Han, MD, PhD
Member	Talent Theparee, MD
Member, Representative to Training & Education	Yang Cao, PhD
Member	Jennifer Morrissette, PhD
Member	Irene Newsham, PhD
Member	Nikoletta Sidiropoulos, MD
Member	Jessica Thomas, MD
Member	Bijal Parikh, MD, PhD
Member	Ying Wang, PhD
Member	Shi Yang, MD
Member	Tejus Bale, MD, PhD
Member	Lisa Lansdon, PhD
Junior Member	Eitan Halper-Stromberg, MD
International Affairs Liaison	Rami Mahfouz, MD

### 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.

### Ongoing Responsibilities Include:

- 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
- Updated and released 2022 Membership Surveys
- Selected
  - AMP 2022 Technologist Travel Awards recipients
  - AMP 2022 Underrepresented in Medicine Travel Award recipients
- Planned and hosted
  - 2022 AMP Annual Meeting First Timer's Lunch
  - Speed Networking at the AMP 2022 Annual Meeting
- Planned and hosted a Committee Meet & Greet in AMP Central at the AMP 2022 Annual Meeting
- Presented weighted scoring model to Board of Directors for possible implementation organization wide

- Analyzed the Regular, Associate, and Technologist Member Satisfaction Surveys to identify ways AMP and the MAC can best serve members, and recruit new members to join
- Developed committee member-driven projects to increase recruitment, retention, and member satisfaction. These ongoing projects include:
  - Using graphic design to better convey the value of membership
  - Working with the Program Committee to enhance technologist specific content at the Annual Meeting
  - Maximizing networking events at the Annual Meeting, including Speed Networking
  - Fostering membership opportunities for trainees in low-income countries
  - Creating a comprehensive suite of projects to inform and recruit trainees as part of the new free Associate Membership program
  - Executing a review of demographic options available for new members to self-select when creating a member profile with AMP, making our member profiles more inclusive
  - Expanding AMP's microvolunteer program so that everyone who wants to share their time and expertise with AMP has an opportunity to do so.
  - Developing projects include an AMP Journal Club and an in-depth look at AMP Committees and How they Work
- Worked closely with the International Affairs and Training & Education Committees to ensure that membership needs are met around the globe and through educational offerings.



## AMP Nominating Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Antonia R. Sepulveda, MD, PhD
Genetics Subdivision Representative	Jennelle C. Hodge, PhD
Genetics Subdivision Representative	Birgit Funke, PhD
Hematopathology Subdivision Representative	Marian H. Harris, MD, PhD
Hematopathology Subdivision Representative	Noah A. Brown, MD
Infectious Diseases Subdivision Representative	Ted E. Schutzbank, PhD
Infectious Diseases Subdivision Representative	Sanchita Das, MD
Informatics Subdivision Representative	Julie Woolworth Hirschhorn, PhD, HCLD
Informatics Subdivision Representative	Jason Young Park, MD, PhD
Solid Tumors Subdivision Representative	Allison Cushman-Vokoun, MD, PhD
Solid Tumors Subdivision Representative	Eric Vail, MD
President	Daniel E. Sabath, MD, PhD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

### 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 or June each year.

### 2022 ACTIVITIES:

The Nominating Committee nominated Officers and Committee Representatives for the 2022 annual elections.

## AMP Professional Relations Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Eric Q. Konnick, MD
Member	Esther Babady, PhD
Member	Linnea M. Baudhuin, PhD
Member	Heather Blakenship, PhD
Member	David Bosler, MD
Member	Emilia Calvaresi, MD, PhD
Member ( <i>Ex officio</i> – EAC Chair)	Samuel Caughron, MD
Member (Hemepath Subdivision Rep.)	Betty Chung, DO, MPH, MA
Member	Jennifer Dien Bard, PhD
Member (Genetics Subdivision Rep.)	Andria Del Tredici, PhD
Member	Andrea Ferreira-Gonzalez, PhD
Member	Jill Hagenkord, MD
Member	Amy Lo, MD
Member	Jill Murrell, PhD
Member	George J. Netto, MD
Member ( <i>Ad-Hoc</i> – ID Subdivision Rep.)	Frederick Nolte, PhD
Member	Nirali M. Patel, MD
Member (Inofrmatics Subdivision Rep.)	Jason Rosenbaum, MD
Member ( <i>Ex officio</i> – President)	Daniel Sabath, MD, PhD
Member ( <i>Ex officio</i> – President-Elect)	Laura Tafe, MD
Member	David Viswanatha, MD
Member	Karen Weck, MD
Member	Barbara Zehnbauer, PhD
Junior Member	Xiaoli Du, PhD
Junior Member	Bryan Iorgulescu, MD
International Affairs Committee Liaison ( <i>Ex Officio</i> )	David E. Barton, PhD
AMP Rep. to FASEB Science Policy Committee ( <i>Ex Officio</i> )	Betsy A. Bove, PhD
Committee Advisor	Roger Klein, MD, JD
Committee Advisor	Jordan Laser, MD
Committee Advisor	Elaine Lyon, PhD

### 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.

## 2022 ACTIVITIES:

The PRC continues to monitor the activities of, and in some cases work with, federal agencies such as FDA and CMS as well as policy committees such as the Roundtable on Genomics and Precision Health at the National Academies of Sciences, Engineering, and Medicine. After extensive discussion, the committee drafts AMP's policy positions and comments to federal agencies and members of Congress. AMP's government relations consultants, Jennifer Leib and Megan Anderson Brooks of Innovation Policy Solutions, LLC (IPS), keep the Committee informed of all policy and legislative activity, assist in drafting policy positions, provide advice regarding advocacy strategies, and guide AMP's presence on Capitol Hill. IPS along with AMP Director of Public Policy and Advocacy, Sarah Thibault-Sennett, AMP Policy Analyst, Monika Franco, AMP Policy Fellow, Samantha Pettersen, 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 Testing Procedures (LDPs)**

A major advocacy issue of 2022 continued to be regulatory oversight of laboratory developed testing procedures (LDPs), also known as laboratory developed tests (LDTs). Since its introduction, the Verifying Accurate Leading-edge IVCT (In Vitro Clinical Test) Development Act of 2021 (VALID Act) has become the center of legislative activity on this issue. The VALID Act is a large piece of legislation that would create a single regulatory pathway at the FDA for both LDPs and in vitro diagnostic tests (IVDs). The VALID Act proposes dramatic modifications to current oversight mechanisms and thus has the potential to significantly impact many clinical testing laboratories, healthcare providers, and patients throughout the US. AMP submitted comments in 2019 and 2020 on the VALID Act, in addition to participating in multiple roundtable discussions and meetings with the bill sponsors' offices to discuss our concerns.

Discussions regarding VALID took on a new urgency this year, as proponents looked to include VALID in the Medical Device User Fee Agreement (MDUFA) V legislative process. The MDUFA legislative process determines the fees that medical device companies pay to FDA when they register their establishments and list their devices within the agency. The current process, MDUFA V, was considered "must-pass" in 2022 as this significant source of funding for FDA was set to expire on September 30<sup>th</sup>.

On February 24<sup>th</sup>, **Dr. Dara Aisner** represented AMP at a Senate Committee on Health, Education, Labor and Pensions (HELP) Briefing on Diagnostic Regulatory Reform. AMP was invited to participate along with representatives from the Pew Charitable Trusts, AdvaMedDx, the Diagnostic Test Working Group (DTWG), and the American Clinical Laboratory Association (ACLA). Dr. Aisner provided an overview of molecular diagnostic laboratory medicine and its role in patient care, in addition to explaining how the VALID Act would hinder her ability to practice medicine and care for her patients.

On April 4<sup>th</sup>, AMP, along with the American Association for Clinical Chemistry (AACC), the American College of Medical Genetics and Genomics (ACMG), and the Association of Pathology Chairs (APC) hosted an in-person Congressional briefing on "COVID-19, LDTs, VALID, and MDUFA – What These Acronyms Mean for Patient Care." **Dr. Eric Konnick**, Chair of the AMP Professional Relations Committee, spoke on behalf of AMP. Following the briefing, AMP led joint stakeholder meetings with key congressional leadership offices to express our concerns regarding inclusion of VALID in the MDUFA legislative process. AMP was joined in these meetings by AACC, ACMG, APC, the American Society for Histocompatibility and Immunogenetics (ASHI), the American Society for Microbiology (ASM), and the National Independent Laboratory Association (NILA). The joint meetings were extremely productive and gave our united organizations a strong platform to express solidarity on this issue.

On May 17<sup>th</sup>, Senate HELP introduced a new version of the VALID Act in the discussion draft of the Food and Drug Administration Safety and Landmark Advancements Act (FDASLA), Senate HELP's version of legislation that would reauthorize the FDA user fee programs. Following this announcement, AMP quickly took action. Approximately 500 letters were sent through AMP's grassroots system requesting that VALID not be included with the user fee agreement. Additionally, on May 22<sup>nd</sup> AMP sent an extensive response to the Senate HELP Committee highlighting the harm VALID would do to the field of molecular diagnostics if it were passed in the FDASLA. AMP also championed a sign-on letter that was delivered to the Hill on July 6<sup>th</sup>, with over 125 signatures from other institutions and stakeholders, including many academic medical centers. Finally, on July, 27<sup>th</sup> 45 AMP members and staff took their concerns directly to the Hill and held 90 meetings with the offices of their elected officials during the 2022 AMP Virtual Advocacy Day.

On October 4<sup>th</sup>, Congress passed a continuing resolution (CR) to extend government funding through December 16<sup>th</sup>. This CR also included a clean reauthorization of the user fee programs for five years that did not include VALID. This is a very large victory for AMP and could not have been possible without strong and continued engagement of the AMP membership on this topic.

Looking forward, the bill sponsors are now focused on including VALID as a policy rider in the large omnibus appropriations bill that needs to be passed in mid-December. Over the next few months, AMP will continue to work with other stakeholders to keep up the fight against VALID through additional Congressional meetings, action alerts, and other advocacy strategies.

### **Capitol Hill**

AMP continues to nurture existing and grow new relationships on Capitol Hill. Between the two Virtual Advocacy Days held in December 2021 and July 2022, AMP members participated in over 200 meetings on Capitol Hill to express concern about the VALID Act and support CLIA modernization. AMP members also asked members of Congress to sponsor the Verified Innovative Testing in American Laboratories (VITAL) Act of 2021. The VITAL Act, which has been strongly supported by AMP, clarifies that LDPs are regulated under CLIA and kickstarts the process to update the CLIA regulations. Beyond the two successful Virtual Advocacy Days, AMP also met with over 20 key Congressional offices to strongly advocate against a speedy passage of VALID.

### **Gene Patents**

AMP continues to strongly advocate against efforts on Capitol Hill to revise Section 101 of the Patent Act, which defines what is and is not patent eligible. Throughout 2022, AMP has remained heavily engaged with other stakeholders and the sponsors' offices to express opposition to legislation that would abrogate Supreme Court precedent and expand patent-eligible subject matter to encompass "abstract ideas", "laws of nature", or "natural phenomena". In August, Senator Tillis (R-NC) released the text of the Patent Eligibility Restoration Act (S.4734) and as drafted, the bill would allow for the patenting of genetic sequences and other biomarkers and their association with a health condition.

Just prior to the bills introduction, AMP met with Kathi Vidal, the Director of the United States Patent and Trademark Office (USPTO), along with the American Civil Liberties Union (ACLU) and Invitae. During the meeting, AMP highlighted how the molecular diagnostics field, and especially our members' ability to respond to the COVID-19 pandemic, would be hampered by proposed updates to patent eligibility. In September, AMP submitted detailed comments to USPTO in response to their patent eligibility jurisprudence study, which sought to evaluate "how the current jurisprudence has impacted investment and innovation." AMP's comments focused on case studies and highlighted the growth of molecular pathology as a practice and the positive impact on the U.S. economy, which would both have been impossible with patents on genes. Additionally, we expressed concern that this type of legislation would have a negative impact on patient access and diagnostic testing innovation if enacted. AMP reiterated our stance that we oppose any type of patenting on naturally occurring genetic sequences, and their associations with disease and health conditions.

Additionally, in October, AMP held a Congressional briefing, in collaboration with ACLU, Invitae Corporation, and FORCE: Facing Our Risk of Cancer Empowered, to express concern and state opposition to any legislative or regulatory proposals that would revisit Section 101 and overturn years of court precedent. **Dr. Karen Weck** represented AMP and discussed the negative impact of this legislation would have on the field of molecular diagnostics. AMP anticipates that this topic will continue to be a major focus of the PRC in 2023 and AMP plans to continue engaging with a large group of diverse stakeholders, including patient advocates, on this issue.

### **Patient Advocacy Group Engagement**

Since 2016, AMP has held “Lunch and Learn” events with patient groups, with the objective of identifying and establishing relationships with relevant patient groups in oncology, inherited conditions, and infectious diseases. AMP aims to understand the goals and needs of the patient groups, identify ways we can work together, and effectively communicate that patient care is central to AMP members’ practice. The events have been incredibly well-received with both the representatives from patient groups and AMP members excited by the conversations.

So far in 2022, AMP held two virtual Lunch and Learns. In February, AMP hosted an event on “Non-invasive Prenatal Testing: A Powerful (but Misunderstood) Screening Tool”. The Lunch and Learn featured **Dr. Jill Murrell**, the Chair of the PRC Patient Engagement Subcommittee, along with speakers from My Gene Counsel, Invitae, and Society for Women’s Health Research. The topic was of great interest and over 130 attendees participated from patient advocacy groups, health care professional organizations, a variety of healthcare settings, academic centers and training programs, in vitro diagnostic manufacturing companies, and others. In October, **Drs. Jill Murrell and Karen Weck**, along with a representative from FORCE, spoke with patient advocates about potential legislative revisions to the Section 101 of the Patent Act (discussed in detail above), patient experiences with molecular diagnostic testing before and after the 2013 Supreme Court decision, and opportunities for AMP to work with the patient community to ensure continued access to molecular testing.

Additionally, the Patient Engagement Subcommittee plans to further expand the AMP patient-facing outreach website with the launch of a new section focused on inherited disorders by 2023. This project grows upon the two previously launched sections of the website: cancer-specific resources (launched in 2019) and COVID-19 resources (launched in 2021). The most recent addition aims to answer questions patients or lay audience may have regarding inherited disorders, including but not limited to what is an inherited disorder, variants of uncertain significance, and the different types of screening and diagnostics tests that they could receive. In 2022, the Patient Engagement Subcommittee also released a Spanish translation of their graphic “Inside a Molecular Diagnostic Laboratory,” with the goal to increase access to the patient-facing materials produced.

### **Public Health Emergency Response**

#### *COVID-19*

Throughout 2022, AMP has continued to keep the AMP membership and general public informed on key issues impacting molecular professionals on the front lines of the COVID-19 pandemic. The AMP “Testing Resources for COVID-19” webpage continues to be updated with new resources enabling members to stay up to date on the most recent advances in COVID-19 diagnostic testing, including changes to regulatory policy and clinical practice announcements.

AMP continued to leverage the data and laboratory experiences from the first two years of the COVID-19 pandemic to highlight the role that molecular diagnostics laboratories perform during a public health emergency and the unique issues that they face. In 2022, AMP continued to express support for the Tracking Pathogens Act, which would significantly boost U.S. genetic surveillance and viral sequencing for infectious diseases. In February, AMP submitted extensive comments on the Prepare for and Respond to Existing Viruses, Emerging New Threats, and Pandemics (PREVENT Pandemics) Act, which seeks to apply the lessons learned from the COVID-19 pandemic in the hope of better preparing the United States for responding to future infectious disease outbreaks. Also in February, AMP met with the White House Office of Science and Technology Policy (OSTP) to discuss our members’ experiences and recommendations. In April, AMP joined patient advocacy and

professional organizations to urge congressional leadership to approve additional resources for the nation's COVID-19 response. Finally, in August, AMP submitted comments that highlighted our members' experiences and concerns following both the release of the Government Accountability Office (GAO) report on "COVID-19: FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed" and the conclusion of the National Academy of Sciences' (NAS) workshop "Lessons from COVID-19 for the Public Health Emergency Enterprise: What Happened to the Plans".

### *Monkeypox*

On August 4<sup>th</sup>, 2022, Health and Human Services (HHS) Secretary Xavier Becerra declared monkeypox a national public health emergency (PHE). Just prior to the PHE declaration, on July 25<sup>th</sup>, AMP held a follow-up conversation with the White House OSTP to relay our members' experiences launching Monkeypox diagnostic tests and expressing concerns that we were seeing similarities with the early days of the COVID-19 pandemic. On September 8<sup>th</sup>, 2022 the HHS issued a declaration under section 654 of the Federal, Food, Drug, and Cosmetic Act which allows the FDA to issue emergency use authorizations (EUAs) for in vitro diagnostic tests for monkeypox. AMP worked quickly and efficiently to make sure membership was receiving all incoming information on a timely manner. After the FDA issued their final guidance on September 13<sup>th</sup> regarding their requirements for monkeypox laboratory developed tests (LDPS), AMP issued an Alert with pertinent information. AMP has compiled a "Monkeypox Resources Website" that has all the information needed for clinical laboratories. This resource continues to be updated as new information becomes available.

### **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 **Drs. Roger Klein, and Amy Lo**), National Academies of Sciences, Engineering, and Medicine Roundtable on Genomics and Precision Health (AMP representative **Dr. Vicky Pratt**), Federation of American Societies for Experimental Biology (FASEB) (AMP representative **Dr. Betsy Bove**), and the Cancer Leadership Council.

## AMP Program Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Nirali M. Patel, MD
Chair-Elect	Yasmine M.N. Akkari, PhD
Genetics Representative	Pinar Bayrak-Toydemir, MD, PhD
Genetics Representative	Jialing (Jenny) Ji, MD, MS
Hematopathology Representative	Valentina Nardi, MD
Hematopathology Representative	Nathan Montgomery, MD, PhD
Infectious Diseases Representative	Erin Graf
Infectious Diseases Representative	Rangaraj Selvarangan, PhD
Informatics Representative	Annette Leon, PhD, FACMG
Informatics Representative	Mark Routbort, MD, PhD
Solid Tumors Representative	Sinchita Roy Chowdhuri, MD, PhD
Solid Tumors Representative	Lauren L. Ritterhouse, MD, PhD
Technical Topics Representative	Ashley Elizabeth Shean, BS, MS
Technical Topics Representative	Barbara A. Anderson, MS

### 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.

### 2022 ACTIVITIES:

Planned and moderated the sessions for the 2022 Annual Meeting & from November 1-5, 2022, along with the recorded content that will be available in January 2023.

## AMP Publications Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Patricia Tsang, MD, MBA
JMD Editor-in-Chief	Ronald M. Przygodzki, MD
Member	Fei Dong, MD
Member	Annacarolina Fabiana Lucia da Silva, MD
Member	Juehua Gao, MD, PhD
Member	Midhat S. Farooqi, MD, PhD
Member	Arivarasan Karunamurthy, MBBS, MD
Junior Member	Marie Smithgall, MD
Member	Thuy L. Phung, MD, PhD
Member	Madhu M Ouseph, MD, PhD
Member	Paul G. Rothberg, PhD
Member	Barbara A. Zehnbauer, PhD
JMD Managing Editor	Emily Essex
JMD Scientific Editor	Chhavi Chauhan, PhD

**PURPOSE SUMMARY:** Members of the Publications Committee are appointed by the Board to serve up to six (6) two-year, renewable terms, and a junior member to serve a two-year term.

- The Publications Committee has certain responsibilities for AMP's official journal, *The Journal of Molecular Diagnostics (JMD)*, which is co-owned by the American Society for Investigative Pathology (ASIP), including advisory to AMP's Board and ASIP's Council regarding *JMD* policy issues; scope statement; business success; publisher Request for Proposal and selection; selection of Editors and Editorial Board members; performance expectations for Editors.
- The Publications Committee does not oversee *JMD*'s production or editorial functions; however, it may request or receive information and make recommendations to the Editor-in-Chief and Managing Editor.
- The Committee reviews AMP member submissions of Case Reports for potential publication in *CAP Today*.
- The Committee meets monthly by conference call, face-to-face before the annual meeting, and by electronic communication.

### 2022 ACTIVITIES:

- Solicited and reviewed AMP Case Reports submissions for potential publication in *CAP Today*.
- Solicited volunteer applications across all subdivisions for subject matter experts and a junior member.
- Devised a plan for enhancing the readability of *JMD* based on AMP members' feedback, such as adding a highlights section and graphical summary to the original articles.
- Developed potential topics for *JMD* review articles, guest editorial and spotlight page.
- Established a task force to update AMP's Wikipedia webpage.



## AMP Strategic Opportunities Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Laura J. Tafe, MD
Member	Alexis Carter, MD
Member	Michael Hadjisavas, PhD
Member	Jordan Laser, MD
Member	Robert L. Nussbaum, MD
Member	Nirali Patel, MD
Member	Jill Hagenkord, MD
Member	Anthony N. Sireci, MD, MS
President	Daniel E. Sabath, MD, PhD
Executive Director	Mary Steele Williams, MNA, MT(ASCP)SM, CAE

### 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.

### 2022 ACTIVITIES:

- Identified and assessed the opportunities and challenges in the molecular pathology profession and other environments that affect AMP interests, including:
  - external threats that could prevent AMP from attaining its goals
  - external opportunities that can help AMP attain its goals
  - organizations for potential relationships that can help AMP attain its goals
- Provided relevant recommendations to the Board of Directors

## AMP Training & Education Committee Annual Report, 2022

### COMMITTEE MEMBERS:

Chair	Alanna Church, MD
Genetics Subdivision Representative	Ying Zou, MD, PhD
Genetics Subdivision Representative	Shashi Shetty, PhD
Hematopathology Subdivision Representative	Amir Behdad, MD, MBA
Hematopathology Subdivision Representative	Jennifer Bynum, MD
Infectious Diseases Subdivision Representative	Allen Bateman, PhD, MPH
Infectious Diseases Subdivision Representative	Paige M.K. Larkin, PhD, D(ABMM), M(ASCP)CM
Informatics Subdivision Representative	Eduardo Castro-Echeverry, MD, MPH
Informatics Subdivision Representative	Thomas D. Lee, MD, PhD
Solid Tumors Subdivision Representative	Marjorie Parker David, MD, MS
Solid Tumors Subdivision Representative	Ying-Chun Lo, MD, PhD
Junior Member	Jeffrey Kleinberger, MD, PhD
Junior Member	Adam Fisch, MD, PhD
Medical Technologist Member	Timothy Daniels, MLS(ASCP)CM, MBCM, QLSCM
Medical Technologist Member	Michelle Mah, MSc, MLT
Membership Affairs Committee Liaison	Yang Cao, PhD, FACMG
International Affairs Committee Liaison	Roberta Sitnik, PhD

### PURPOSE SUMMARY:

The Training and Education (T&E) Committee is comprised of representatives from each of AMP's subdivisions: genetics, hematopathology, infectious diseases, informatics, and solid tumors as well as technologist representatives, junior members, and liaisons from the International Affairs and Membership Affairs Committees (IAC and MAC). It oversees important issues such as education and certification in molecular pathology and mentoring of trainees, as well as developing educational programs for different audiences.

### *Educational Programs*

#### **2022 GetAMPed! Updates and Case Studies in Molecular Pathology:**

The T&E Committee planned an in-person course for the AMP 2022 Annual Meeting & Expo on November 2<sup>nd</sup>. The program was geared towards individuals with basic knowledge of molecular techniques and included current molecular hot topics, preanalytical variables, workflow considerations that impact molecular testing, and an overview of current molecular technology. This was then followed by immersive interactive case studies. The course reached a peak capacity of 80 participants.

**Early Bird Sessions at the Annual Meeting & Expo - Case Studies Presented by Trainees or Technologists:**

The T&E Committee hosted an opportunity for fellows, residents, postdocs, graduate students, or technologists to present an interesting and/or challenging case study for the AMP 2022 Annual Meeting and Expo. Trainee/technologist presenters in 2022 are listed below:

Case Studies in Genetics	Next Generation Sequencing changing a preliminary diagnosis of lung lesion, case series.	Tarneem Darwish, MD	Case Western Reserve University, University Hospitals of Cleveland
	Case Study of a Patient with Multiple Vascular Malformations and Three Variants in the TEK Gene	Fernando Zazueta Leon-Quintero, MD	Washington University in Saint Louis
	CMA pattern in recognition of derived inversion - a lesson learned from a fetal demise potentially caused by parental chromosomal inversion	Reza Ghasemi, PhD	Washington University in Saint Louis
Case Studies in Hematopathology	The Dangers of Single Modality Testing in a Case of Undifferentiated Pleomorphic Sarcoma with Low Level Involvement by Chronic Lymphocytic Leukemia/Small Cell Lymphoma	Kelly Craven, MD, PhD	Memorial Sloan Kettering Cancer Center
	AML Relapse After Stem Cell Transplant from a Presumed Carrier of MyD88 Deficiency	Cansu Karakas, MD	University of Rochester Medical Center
	Relapsed Post-transplant Acute Myeloid Leukemia with Testicular Involvement and Concurrent Bone Marrow Donor-derived Pathogenic Variants	Dorottya Laczko, MD, PhD	Hospital of the University of Pennsylvania
	Vexed by VEXAS Syndrome: UBA1 mutation- Agent for autoinflammatory marrow destruction or driver for myelodysplasia?	Lisa Robinson, MD	University of Nebraska Medical Center
Case Studies in Infectious Diseases	Deceptively Bland: Viral Meningitis Associate with Normal CSF Findings	Patricia Hernandez, MD	Washington University in Saint Louis
Case Studies in Solid Tumors	Incidental IDH2 Variant in Low Grade Glioneuronal Tumor: A Tale of a Hematopoietic Clone	Fei Chen, MD, PhD	NYU Langone Health
	PTCHing together a diagnosis: molecular resolution of a challenging case	Amy Guimaraes-Young, MD, PhD	University of Colorado Anschutz Medical Campus
	Molecular lineage tracing reveals cancer diagnosis	David Basta, MD, PhD	Brigham and Women's Hospital
	Novel BRAF activating mutation in a case of hyalinizing trabecular tumor of the thyroid	Christopher Zarbock, MD	University of Minnesota
	Pelvic mass with unique FGFR1-TACC fusion	Jack Reid, MD	University of California Irvine Medical Center
	SHH-activated medulloblastoma with or without TP53 mutation? Tumor Heterogeneity Causes a Diagnostic Dilemma with Profound Clinical Implications.	Vanessa Smith, MD	Duke University Medical Center
	Homozygous SMARCA4 Deletion in SMARCA4 Deficient Undifferentiated Tumor	Kenneth Ofori, MD, MHS	Columbia University Irving Medical center
	Origin of a Cancer of Unknown Primary Traced to Donor Kidney by Short Tandem Repeat Testing	Bryan Iorgulescu, MD, MPH	MD Anderson Cancer Center

**2022 Webcasts and Recorded Online Content (ROCs):**

Date	Title	Speaker/T&E Moderator	NOTES (Registrants/Attendees)
<b>Major Initiative:</b> <a href="#">Emerging and Evolving Biomarkers: Recent Findings, Laboratory Considerations, and Clinical Implications</a>			
January 25	Methylation Profiling	Brent Orr	271/552
April 7	IgG Rearrangements/T-cell Receptors	Rena Xian	185/446
May 3	Mutational Signatures in Cancer	Fei Dong	281/568
September 22	Molecular Diagnostic and Clinical Perspectives on Microsatellite Instability Testing for Cancer	Sameet Roychowdhury	155/472
December 6	EGFR Exon 20	Eric Vail	TBD
<b>Major Initiative:</b> <a href="#">Utility of Cell-free DNA in the Clinic: Current State and Future Directions</a>			
January 6	Cell free (cf)DNA-based Prenatal Screening: Lessons Learned and Future Strategies – includes a microlearning module	Glenn Palomaki	184/395
March 24	Unique Challenges, and Possible Solutions, Encountered in Clinical ctDNA Testing	Keyur Patel	256/582
August 9	Cell-free DNA: predictive tissue injury maps in COVID-19	Sean Agbor-Enoh	94/190
December 13	Utility of Clinical Metagenomic Next-Generation Sequencing for Diagnosis of Infections	Charles Chiu	TBD
February 23, 2023	cfDNA Applications in Cancer Early Detection (tentative title)	Trevor Pugh	TBD
<b>Webinar Series: Horizons</b>			
February 8	AMP Horizons: Mechanistic basis for structural and numerical chromosome abnormalities in cancer	David Pellman	337/552
June 7	Somatic variant curation using OncoKB, an FDA-recognized precision oncology knowledge base	Debyani Chakravarty	295/599
July 26	Variant Interpretation Testing Among Laboratories (VITAL) Project: Outcomes and Lessons Learned	Sue Richards and Julie Gastier-Foster	323/633
August 30	TPMT and NUDT15 Genotyping Recommendations	MacKenzie L. Fulmer, PhD	185/362
September 15	Optical genome mapping: about its potential in routine human genetic diagnostics	Paul Dremsek	145/404

## 2022 Education Initiatives

- **Continuing Education credits (CME and CMLE):**

AMP offers Continuing Education credits for most educational activities. Accredited activities include the MGP Review Course (live and online), live and enduring webinars and Recorded Online Content (ROC) lectures. Currently, there are nearly 200 hours of CME and CMLE credit available on the learning management system. In addition, most of the live programming is available for continuing education credit.

- **Online Education - AMPED™:**

The T&E Committee and staff have designed and developed additional educational materials for populating [educate.amp.org](https://educate.amp.org). The LMS has attracted over 3,600 active users in 2022 (January 2022-October 17, 2022). It has 133 educational products, 66 On-Demand Courses, 51 Microlearning Modules, 6 certificate programs, 4 Self-Study + Review Courses 4 Flashcards on different topics.

- **Course Bundles/AMP Certificate Programs:** Courses are live programs that were recorded and translated to a self-paced online course. Certificate programs are self-paced on-demand content designed to provide a deep dive on specific areas of interest. New courses and certificate programs launched in 2022 include:
  - AMP Certificate Program: [Pharmacogenomics: Genes, Drugs, and Genotyping: AMP Pharmacogenomics Guidelines](#)
  - [2021 GetAMPed! Course recordings](#)
  - [JMD 2022 CME Program](#)
- **AMP Flashcards:** A new card set has been created for medical technologists. This 40+ card set can help clinical technologists and laboratory managers with laboratory operations challenges, including standard lab practices, QA/QC, safety issues, contamination prevention, and laboratory regulations. The cards can also be used as study aids for ASCP certification exams. In addition, there are three more sets available: a 40+ card set on [multiple myeloma](#) and a 20+ card set on [colorectal cancer](#) and a 50+ set on [acute myeloid leukemia](#).
- **FISE Question Bank:** This is the fifth year of a continuing collaboration with the MGP-PD Council to provide fellows with a Fellowship In-Service Examination (FISE) at the beginning and at the end of their fellowship year. Additional FISE exam questions were written by MGP faculty and reviewed by the T&E. The bank currently consists of >350 questions and learners are presented with 45 randomly selected questions for their examination. AMP staff provides non-attributed results to participating institutions at the beginning of the fellowship year (in October) and at the end of the year (in May/June).
- **Molecular in a Minute:** Since its initiation in 2021, the T&E Committee completed 10 microlearning modules called Molecular in a Minute. This features 5-15 minute videos on a variety of molecular pathology competency topics including Biomarkers for Immunotherapy, Germline / Somatic Variants, Lymphoid Clonality Testing, Fluorescence *in Situ* Hybridization (FISH): Methodology and Clinical Utility, Quantitative PCR, PCR and Sanger Sequencing and Detection of a Cryptic Gene Fusion in a B-ALL.

- **Molecular-in-My-Pocket™ cards:** The T&E Committee continued expanding the Molecular-in-My-Pocket™ reference card collection. Two new cards were created. One on Pharmacogenetic testing (available [here](#)) and one on plasma cell neoplasm (available soon). The T&E has also made substantial edits to many of the cards and the webpage has been re-organized to create a more intuitive interface. There are now 25 cards, total. Cards are reviewed annually by T&E Committee members for accuracy and for any required updates. There have been more than 2,000 site visits to the MIMP card homepage in the past 6 months.
- **Member Spotlights:** The T&E committee continues this collaboration with the Membership Affairs Committee by identifying and interviewing AMP members for the Member Spotlights page on the AMP website. Interviews and profiles highlight the training and career paths of various molecular professionals.

#### ***AMP 2022 Annual Meeting & Expo Activities:***

- **The Molecular Genetic Pathology Fellowship Program Directors (MGP PD) Council**  
The MGP Program Directors (MGP PD) Council consists of Rena Xian (Chair), Mark Ewalt (Chair-Elect), and Rizwan Naeem (Past-Chair). Amir Behdad acts as the T&E committee representative to this group. The MGP PD Council facilitates the discussions of the MGP Program Directors Working Group and responds to the ABP and ACGME on matters related to MGP Fellowship programs. The Council works with the T&E Committee to continue to offer the in-service practice exam question bank for MGP Fellows (FISE; see above). At the Annual Meeting & Expo this year, the working group will be proposing a unified timeline for the MGP Program Directors to vote on. The unified timeline was developed to help streamline the process of fellow application to MGP Programs nationwide.
- **The Education Community of Practice (EdCoP) Group**  
The AMP Education Community of Practice Group is led by Marjorie David, MD, MS with working group members Alanna Church, MD; Cynthia Jackson, PhD; Eduardo Castro-Echeverry, MD, MPH and Thomas Lee, MD, PhD. During 2022, the group held two webinars that are available on AMPED™; [Education via Social Media in Pathology](#) and [Teaching Tips for Virtual Platforms](#). The EdCoP group will be hosting a meeting at the Annual Meeting and Expo focusing on interactive learning techniques.
- **Innovation Stages**  
The T&E Committee will be hosting two Innovation Stages. Hot off the Press! New Training & Education Resources Innovation Stage will introduce the most relevant and useful educational content. Highlights will include the AMP certificate programs, the AMP Horizons Series and other initiatives. Alternate Career Pathways in Laboratory Medicine will focus on the progressively changing field of laboratory medicine and explore the role of a Laboratory Technical Director.
- **Trainee Networking Luncheon**  
Trainees, students, and junior faculty are invited to an opportunity to network with faculty and other trainees in molecular pathology, while learning about career opportunities in their field. In addition to lunch, there will be a free textbook raffle.
- **Technologist Networking Luncheon - Conversations About Career Development**  
The luncheon will be a social opportunity to share working and learning experiences with others in the field of laboratory technology.

### ***Curriculum and Educational Manuscript Development Task Forces***

- **Genomics Education for Primary Care Residents:** This Task Force was led by Laura Tafe. They developed a modified basic genomics curriculum for primary care residents, *i.e.*, internal medicine, family practice, and pediatrics. Other working group members were Yasmine Akkari, Maria Arcila, Devon Chabot-Richards, Preeti Pancholi, and Anthony Snow. This manuscript has been published and a webcast is available [here](#).
- **Molecular Genetic Pathology (MGP) Curriculum Update (MGP-CUP):** This task force was led by Karen Kaul and includes working group members Rashmi Goswami, Allison Cushman-Vokoun, Mark Ewalt, Harriet Feilotter, Julie Gastier-Foster, Jennifer Laudadio, Randy Olsen, Lauren Ritterhouse, Jason Rosenbaum and Priya Velu. The goal of this project was to prepare a set of recommendations and guidelines by which MGP training programs can develop curricula for MGP fellowship trainees. It was published [here](#).
- **Emerging and Evolving Biomarker Manuscripts:** These practice advances, led by Kurtis Davies, Lauren Ritterhouse, and Anthony Snow, features the science, laboratory considerations, and clinical implications of the individual biomarkers presented in the Emerging and Evolving Biomarker webinar series. Featured biomarkers included [NTRK](#) (written by Lynette Sholl), [Metex14](#) (written by Nikoletta Sidiropoulos), and [ERBB2\(Her2\)](#) (written by Sinchita Roy-Chowdhuri).

### ***Co-Sponsorships, Companion Meetings, and/or Collaborations***

- **United States and Canadian Academy of Pathology (USCAP) March 2022 – Los Angeles, CA**  
***The AMP 2022 Companion Society Symposium,***  
“Update on Molecular Diagnostics for Soft Tissue Tumors”, was co-moderated by Alanna Church, MD and Honey Reddi, PhD, FACMG Speakers were:
  - Adrián Mariño Enríquez
  - Larissa V. Furtado
  - Alanna J. Church
- **College of American Pathologists (CAP) October 2022 – New Orleans, LA**  
***CAP 2022 Course Presentation***  
“Understanding NGS and Interpreting Reports for Oncologic Pathology” was presented by Cecilia Yeung, MD
- **Cambridge Health Institute (CHI) Conferences**
  - **Next Generation Dx Summit, August 2022**  
*Technical Validation Considerations in Clinical ctDNA Tests. Christina Lockwood, PhD, DABCC, DABMGG*

## AMP Subdivision Leadership Annual Report, 2022

### SUBDIVISION LEADERSHIP

	Genetics	Hematopathology	Infectious Diseases	Informatics	Solid Tumors
<b>Chair</b>	Avni Santani	Eric Duncavage	Donna Wolk	Jason Merker	Anna Yemelyanova
<b>Clinical Practice Committee</b>	Steven Sperber	Michael Kluk	Blake Buchan	Elaine Gee	David Eberhard
	Diana Mandelker	Rena Xian	Karissa Culbreath	Sabah Kadri	Navid Sadri
<b>Economic Affairs Committee</b>	Victoria Pratt	Maria Arcila	Joseph Yao	Jeffrey Gagan	Susan Hsiao
<b>Nominating Committee</b>	Jennelle Hodge	Marian Harris	Ted Schutzbank	Julie Hirschhorn	Allison Cushman-Vokoun
	Birgit Funke	Noah Brown	Sanchita Das	Jason Park	Eric Vail
<b>Professional Relations Committee</b>	Andria Del Tredici	Betty Chung	Frederick Nolte	Jason Rosenbaum	Amy Lo
<b>Program Committee</b>	Pinar Bayrak-Toydemir	Valentina Nardi	Erin Graf	Annette Leon	Sinchita Roy-Chowdhuri
	Jianling Ji	Nathan Montgomery	Rangaraj Selvarangan	Mark Routbort	Lauren Ritterhouse
<b>Training &amp; Education Committee</b>	Ying Zou	Amir Behdad	Allen Bateman	Eduardo Castro-Echeverry	Marjorie Parker David
	Shashirekha Shetty	Jennifer Bynum	Paige MK Larkin	Thomas Lee	Ying-Chun Lo

#### PURPOSE SUMMARY:

The Subdivision Leadership consists of a Chair, representatives to the Clinical Practice, Economic Affairs, Nominating, Program, Professional Relations, Training & Education Committees, and *ad hoc* representatives to the Subdivision Leadership groups from the Professional Relations and Economic Affairs Committees. Subdivision Chairs are responsible for the successful operation and development of the subdivision that they lead.

Each Subdivision Leadership group meets quarterly and functions in an AMP advisory panel of discipline-specific subject matter experts convened to address issues of importance to their Subdivision. They carry out their subdivision leadership responsibilities by:

- Identifying and ascertaining the needs of the Subdivision membership and of the discipline itself
- Providing feedback regarding projects to the Clinical Practice Committee, Training and Education Committee, or other relevant committees
- Providing input and suggestions regarding content for the Annual Meeting and other educational events
- Assisting to identify and recommend future AMP volunteers and leaders
- Resource for advocacy-related initiatives



## 2022 ACTIVITIES:

All Subdivision Leadership groups contribute to biannual Subdivision Spotlight email digests that highlights AMP activities and *JMD* articles related to Subdivision member's interests.

**Genetics** - Addressed current issues and topics related to genetics, including variant interpretation and classification, next-generation sequencing, pharmacogenomics, whole genome and exome sequencing standards, forensics, and diversity in genomic databases. Participated and contributed to projects related to the different AMP Committees. Subdivision Leadership members also assisted the Professional Relations Committee (PRC) taskforce by providing input on their response to the NASEM Study on Use of Race, Ethnicity, and Ancestry. Supported AMP Advocacy efforts opposing the VALID Act inclusion in FDASLA Act.

**Hematopathology** - Addressed current issues and topics in molecular hematopathology, including advances in translational research related to myelomas, MRD monitoring in hematologic malignancies, next-generation sequencing, and immunology. Participated and contributed to projects related to the different AMP Committees. Supported AMP Advocacy efforts opposing the VALID Act inclusion in FDASLA Act. Curated and provided a "Must Reads" list of hematopathology-relevant literature to the Subdivision membership.

**Infectious Diseases** - Served as AMP's internal advisory board for Infectious Diseases to develop initiatives related to clinical practice, advocacy, and education. Addressed current issues and topics related to the clinical molecular diagnostics laboratory, including related to SARS-CoV-2 and Monkeypox. Participated and provided subject matter expertise at the Corporate Advisory Council (CAC) Infectious Diseases Roundtable to discuss the challenges facing ID labs now and in the immediate future. Participated and contributed to projects related to the different AMP Committees. Supported AMP Advocacy efforts opposing the VALID Act inclusion in FDASLA Act. Contributed to AMP Monkeypox Resource website.

**Informatics** - Served as AMP's internal advisory board for informatics to develop initiatives related to clinical practice, advocacy, and education. Participated and contributed to projects related to the different AMP Committees. Addressed current issues and topics related to development of bioinformatics pipelines for clinical next-generation sequencing, informatics tools in metagenomics, electronic health record (EHR) interoperability for clinical genomics data, and body of knowledge (BoK) for Clinical Genomics Bioinformaticist. Supported publication of *Electronic Health Records and Genomics: Perspectives from the Association for Molecular Pathology Electronic Health Record (EHR) Interoperability for Clinical Genomics Data Working Group* published January 2022 issue of the *Journal of Molecular Diagnostics*. Alexis Carter & Somak Roy (Co-chairs), Lynne V. Abruzzo, Julie Hirschhorn, Dan Jones, Danielle Jordan, Mehdi Nassiri, Shuji Ogino, Nimesh Patel, Christopher Suci, Robyn Temple-Smolkin, and Ahmet Zehir. DOI: <https://doi.org/10.1016/j.jmoldx.2021.09.009>. Assisted the Professional Relations Committee (PRC) taskforce by providing input on their response to The Federal Trade Commission (FTC) advanced notice of proposed rulemaking (ANPR) on Commercial Surveillance and Data Security. Supported AMP Advocacy efforts opposing the VALID Act inclusion in FDASLA Act.

**Solid Tumors** - Served as AMP's internal advisory board for solid tumors to develop initiatives related to clinical practice, advocacy, and education. Addressed various current issues and topics related to clinical applications of circulating tumor cells, gene fusions, homologous recombination deficiency (HRD), liquid biopsies, tumor mutational burden, and other factors related to clinical practice of cancer. Participated and contributed to projects related to the different AMP Committees. Supported AMP Advocacy efforts opposing the VALID Act inclusion in FDASLA Act.

### **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.