AMP 2023 Committee and Subdivision Annual Reports

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AMP Awards Committee Annual Report, 2023

COMMITTEE MEMBERS:

Chair	Maria E. Arcila, MD
Member	Margaret Gulley, MD
Member	Shelby Melton, 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 for a two-year, renewable term, up to a maximum of six years. 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

- 2023 Jeffrey A. Kant Leadership Award: Victoria M. Pratt, PhD, FACMG
- 2023 Meritorious Service Award: Jordan Laser, MD
- 2025 Award for Excellence in Molecular Diagnostics: To be announced in Spring 2025

AMP Clinical Practice Committee Annual Report, 2023

COMMITTEE MEMBERS:

Chair	Susan Hsiao, MD, PhD
Genetics Subdivision Representative	Diana Mandelker, MD, PhD
Genetics Subdivision Representative	Ann Moyer, MD, PhD
Hematopathology Subdivision Representative	Rena Xian, MD
Hematopathology Subdivision Representative	Pawel Mroz, MD, PhD
Infectious Diseases Subdivision Representative	Donna M. Wolk, PhD
Infectious Diseases Subdivision Representative	Erin Graf, PhD
Informatics Subdivision Representative	Weiwei Zhang, PhD
Informatics Subdivision Representative	Andrea Sboner, PhD
Solid Tumors Subdivision Representative	Navid Sadri, MD, PhD
Solid Tumors Subdivision Representative	Katherine Geiersbach, MD
Junior Member	Lauren Miller, MD, MJ
Junior Member	Samuel Harvey, 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 Cell-free Tumor DNA Assay Validations: A Joint Consensus Recommendation of the Association for Molecular Pathology and College of American Pathologists*, in press, *Journal of Molecular Diagnostics*. Christina Lockwood (Chair), Laetitia Borsu, Milena Cankovic, Jonathan Earle, Christopher Gocke, Meera Hameed, Danielle Jordan, Jean Lopategui, Mrudula Pullambhatla, Jacquelyn Reuther, Kandelaria Rumilla, Laura Tafe (CAP representative), Robyn Temple-Smolkin, Panieh Terraf, and Apostolia Tsimberidou (ASCO representative).
- *Exploring the Utility of Multiplex Infectious Disease Panel Testing for Diagnosis of Infection in Different Body Sites: A Joint Report of the Association for Molecular Pathology, American Society for Microbiology, Infectious Diseases Society of America, and Pan American Society for Clinical Virology*, in press, *Journal of Molecular Diagnostics*. Michael Lewinski (Chair), Kevin Alby, Esther Babady (PASCV representative), Susan Butler-Wu, Jennifer Dien Bard, Alex Greninger, Kimberly Hanson (IDSA representative), Samia Naccache, Duane Newton (ASM representative), Robyn Temple-Smolkin, and Frederick Nolte. DOI: https://doi.org/10.1016/j.jmoldx.2023.08.005.
- *CYP3A4 and CYP3A5 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 in the September 2023 issue of the *Journal of Molecular Diagnostics*. Victoria Pratt (Chair), Karen Weck (Co-Chair), Larisa Cavallari, Makenzie Fulmer, Andrea Gaedigk (PharmVar

representative), Houda Hachad, Yuan Ji, Lisa Kalman, Reynold Ly, Ann Moyer (CAP representative), Stuart Scott, Ron van Schaik (DPWG and ESPT representative), and Michelle Whirl-Carrillo (CPIC and PharmGKB representative). DOI: https://doi.org/10.1016/j.jmoldx.2023.06.008.

- *Recommendations for Next-Generation Sequencing Germline Variant Confirmation: A Joint Report of the Association for Molecular Pathology and National Society of Genetic Counselors*. Published in the July 2023 issue of the *Journal of Molecular Diagnostics*. Kristy Crooks (Chair), Kelly Hagman (NSGC representative), Diana Mandelker, Avni Santani, Ryan Schmidt, Robyn Temple-Smolkin, and Stephen Lincoln. DOI: https://doi.org/10.1016/j.jmoldx.2023.03.012.
- *Assessments of Somatic Variant Classification Using the Association for Molecular Pathology/American Society of Clinical Oncology/College of American Pathologists Guidelines: A Report from the Association for Molecular Pathology*. Published in the February 2023 issue of the *Journal of Molecular Diagnostics*. Marilyn Li (Chair), Catherine Cottrell, Mrudula Pullambhatla, Somak Roy, Robyn Temple-Smolkin, Scott Turner, Kai Wang, Yunyun Zhou, and Cindy Vnencak-Jones. DOI: https://doi.org/10.1016/j.jmoldx.2022.11.002.
- *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*. Published in the January 2023 issue of the *Journal of Molecular Diagnostics*. Eric Duncavage & Justin Zook (Co-Chairs), Joshua Coleman, Monica de Baca (API representative), Sabah Kadri, Annette Leon, Mark Routbort, Somak Roy (CAP representative), Carlos Suarez, and Chad Vanderbilt. DOI: https://doi.org/10.1016/j.jmoldx.2022.09.007.

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.

AMP Clinical Practice Guidelines Program

Working Group / Task Force	Members
Guidance/Standards for NGS Germline Variant Confirmation	Kristy Crooks (Chair), Avni Santani, Diana Mandelker, Stephen 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 Khoury (CAP representative), David Wu, Devon Chabot-Richards (SH representative), and Habibe Kurt
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, Samia Naccache, Frederick Nolte, 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, Annette Kim, Rena Xian (CAP representative), David Wu (SH representative), Hong Fang, Nikhil Patkar, Dale Bixby, and Harrison Tsai
Guidance/Standards for the Use of *In Silico* Approaches for Validation of NGS Bioinformatics Pipelines	Eric Duncavage & Justin Zook (Co-Chairs), Mark Routbort, Joshua Coleman, Annette Leon, Carlos 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 *EGFR* and *ALK* Tyrosine Kinase Inhibitors – Revision	Neal Lindeman (AMP Co-Chair), Maria Arcila, David Kwiatkowski, Lynette Sholl, Laura Tafe, and Dhananjay Chitale
Validation of Next-Generation Sequencing Panels for Gene Fusion and Splice Variant Detection	Laura Tafe (Chair), Alanna Church (Co-Chair), Eduardo Castro-Echeverry, Marjorie David, Suneel Kamath (ASCO representative), Michael Kluk, Ravindra Kolhe (CAP representative), Christian Kunder, Andres Madrigal, Fatimah Nahhas, Valentina Nardi, and Jack Tung
Update of "Standards and Guidelines for the Interpretation and Reporting of Sequence Variants in Cancer: A Joint Consensus Recommendation of the Association for Molecular Pathology, American Society of Clinical Oncology, and College of American Pathologists"	Marilyn Li (Chair), Cindy Vnencak-Jones (Co-Chair), Amir Behdad, Ozge Ceyhan-Birsoy (ACMG representative), Catherine Cottrell, Eric Duncavage, Melissa Gildenberg, Obi Griffith (CGC representative), Annette Kim (SH representative), Shashikant Kulkarni (ClinGen Cancer Variant Interpretation representative), Christine Lovly (ASCO representative), Jason Rosenbaum, Somak Roy,

	Eytan Stein (ASH representative), Lea Surrey (CAP representative), Scott 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), and Christopher Suciu
Patient-friendly Biomarker Reporting	Rajyasree Emmadi (Chair), Allison Cushman-Vokoun, Jane Gibson, Julie Hirschhorn, Jennifer Morrissette, Irene Newsham, Sinchita Roy Chowdhuri, and Eric Vail
Standardization of Clinically Relevant Pharmacogenetic Alleles (PGx) *CYP3A5* / *CYP3A4*	Victoria Pratt (Chair), Karen Weck (Co-Chair), Larisa Cavallari, Makenzie Fulmer, Andrea Gaedigk (PharmVar representative), Houda Hachad, Yuan Ji, Lisa Kalman, Reynold Ly, Ann Moyer (CAP representative), Stuart Scott, Ron van Schaik (DPWG and ESPT representative), and Michelle Whirl-Carrillo (CPIC and PharmGKB representative)
Standardization of Clinically Relevant Pharmacogenetic Alleles (PGx) *DPYD*	Karen Weck (Chair), Victoria Pratt (Co-Chair), Larisa Cavallari, Makenzie Fulmer, Andrea Gaedigk (PharmVar representative), Houda Hachad, Yuan Ji, Lisa Kalman, Reynold Ly, Ann Moyer (CAP representative), Stuart Scott, Amy Turner, Ron van Schaik (DPWG and ESPT representative), and Michelle Whirl-Carrillo (CPIC and PharmGKB representative)
ICC-WHO Classifications Hematopathology Subdivision Leadership Task Force	Eric Duncavage (Chair), Rena Xian (Co-Chair), Noah Brown, Valentina Nardi, Mark Ewalt, Amir Behdad, Pawel Mroz, Joanna Conant, and Jennifer Bynum
Clinical Validation of cfDNA and ctDNA Assays	Panieh Terraf (Chair), Christina Lockwood (Co-Chair), Navid Sadri, Rena Xian, Jack Tung, Katherine Geiersbach, Shamini Selvarajah, Pawel Mroz, and Samuel Harvey

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

AMP External Representatives Program

AMP Representative	Collaborating Organization(s)	Workgroup / Committee
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
Carolyn Sue Richards	American College of Medical Genetics and Genomics	Incidental Findings in Inherited Diseases Update Workgroup
Lauren Ritterhouse (Expert Panel) Ahmet Zehir	College of American Pathologists, American Society of Clinical Oncology	PD-L1 Testing of Patients with Lung Cancer for Selection of Immune Checkpoint Inhibitor Therapies 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 Heath	Biomarkers Consortium Steering Committee for Inflammation and Immunity
Snehal Patel	Foundation for the National Institutes of Heath	Biomarkers Consortium Steering Committee for Cancer
Sinchita Roy-Chowdhuri	American Society of Cytopathology	Organizational liaison
Ryan Schmidt	College of American Pathologists	Genomic Medicine Resource Committee; Clinical Grade HGVS Workgroup
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
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
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	LUNGevity	"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
Betsy Bove	College of American Pathologists, American College of Medical Genetics and Genomics	Pharmacogenomics (PGx) Sub-committee of the Biochemical and Molecular Genetics Committee (BMGC) Workgroup
Somak Roy Fei Dong	American College of Medical Genetics and Genomics, College of American Pathologists, and HUGO Gene Nomenclature Committee with representation from EMQN and Association for Clinical Genomic Science	Workgroup to establish journal technical standards for reporting variant nomenclature
Christina Lockwood	Clinical Laboratory Standards Institute	Document Development Committee on Liquid Biopsy Methods for Oncology (MM28)
Shashirekha Shetty	American College of Medical Genetics and Genomics, ClinGen, College of American Pathologists	2020 ACMG/ClinGen Technical Standards for Interpretation and Reporting of Constitutional Copy Number Variants (CNVs) Workgroup
Valentina Nardi	Variant Interpretation for Cancer Consortium	Gene Fusion Oncogenicity Work Group
Panieh Terraf	Variant Interpretation for Cancer Consortium	Gene Fusion Curation Working Group
Mary Beth Beasley	LUNGevity	Reflex testing in NSCLC Workgroup

AMP Economic Affairs Committee Annual Report, 2023

COMMITTEE MEMBERS:

Chair	Samuel K. Caughron, MD
Co Chair	Jay L. Patel, MD
Senior Vice Chair, Coverage	Pranil Chandra, DO
Vice Chair, Coverage- Genetics and Oncology	Eric Vail, MD
Vice Chair, Coverage- Infectious Disease	Erin Graf, PhD
Vice Chair, New Codes & Pricing (Genetics Subdivision Rep.)	Victoria Pratt, PhD
Member	Betsy Bove, PhD
Member	Jay Brock, PhD
Member	Maude Champagne, MBA
Member	Rajyasree Emmadi, MD
Member	Jeffrey Gagan, MD, PhD
Member	Tanner Hagelstrom, PhD, MBA
Member (Solid Tumor Subdivision Rep.)	Susan Hsaio, MD, PhD
Member	Lloyd Hutchinson, MD
Member	Loren Joseph, MD
Member	Rina Kansal, MD
Member	Federico Monzon, MD
Member	Keyur Patel, MD, PhD
Member	Salvatore Priore, MD, PhD
Member	Oana C. Rosca, MD
Member	Navid Sadri, MD, PhD
Member	Jennifer Sanmann, PhD
Member	Ester Stein, MBA
Member (Hemepath Subdivision Rep.)	Patricia Tsang, MD
Member	Heather Williams, 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
Member (*Ex Officio*- President)	Laura Tafe, MD
Member (*Ex Offcio*- President Elect)	Maria E. Arcila, MD
Member (*Ex Officio* – PRC Chair)	Eric Konnick, MD, MS
Member (*Ex Officio* Past President)	Daniel Sabath, 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.

2023 ACTIVITIES:

The Centers for Medicare and Medicaid Services (CMS) have increasingly denied coverage and/or reduced payment for many medically necessary molecular pathology tests. These restrictions create a challenging environment for clinical practice and for innovators to translate new genomic discoveries into clinical applications. AMP employs government relations consultants, Erika Miller, Stefanie Reinhart, and Michaela Hollis of Cavarocchi, Ruscio, Dennis Associates (CRD) to advise the EAC on advocacy strategies and assist with fostering relationships between AMP, key federal agencies and Congressional offices. Additionally, the EAC is supported by AMP Associate Director of Public Policy and Advocacy, Annie Scrimenti, AMP Senior Policy Analyst, Monika Franco, and AMP Policy Analyst, Samantha Pettersen. AMP continues to work with the broader professional community to address policy challenges and opportunities to engage and inform payors who aim to achieve rightful reimbursements for appropriate patient care services.

Leadership

In 2023, the Economic Affairs Committee responded to several leadership changes including the following promotions:

Jay Patel, MD, Co-Chair of the Economic Affairs Committee
Pranil Chandra, DO, Senior Vice Chair of the Coverage Subcommittee,
Eric Vail, MD, Vice Chair of the Coverage Subcommittee, Oncology and Genetics,
Erin Graf, PhD, Vice Chair of the Coverage Subcommittee, Infectious Disease, and
Victoria Pratt, PhD, Vice Chair of the New Codes and Pricing Subcommittee.

AMP Molecular Pathology Economics Summit

On September 13th, AMP held its third Annual Molecular Pathology Economics Summit (the Summit). This event was a continuation of the 2022 Summit and brought together 56 attendees from patient advocacy groups, pharmaceutical companies, clinical laboratories, as well as trade and professional associations.

This year, a series of roundtable discussions focused on the impacts of Coding, Pricing, and Coverage has on various stakeholder groups including Clinical Laboratory Community, Patients and Providers, Manufacturers, and Pharmaceutical companies. Stakeholders explored unique challenges and barriers to patient access as well as potential solutions and/or novel approaches to overcoming these barriers, with the shared goal of identifying policy action items within each sector. Furthermore, AMP held in-depth breakout sessions that targeted coding, coverage and reimbursement issues and possible solutions. The last session outlined the largest threats to the economic landscape of molecular pathology. Overall, stakeholders committed to collaborate moving forward and the day concluded positively.

The 2023 Summit Planning Committee included: **Samuel Caughron, Pranil Chandra, Jay Patel, Erin Graf, Keyur Patel, Victoria Pratt, Ester Stein, Eric Vail, and Heather Williams.** The 2023 summit was incredibly successful and highly regarded by the participants. Due to this response, AMP intends to continue this on an annual basis.

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 set 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 Medicare Payment Advisory Committee (MedPAC) to study the methodology CMS used to rate-set through PAMA.

Since the passage of the LAB Act, three 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. The Consolidated Appropriations Act of 2023 was passed in December 2022. This revised the phase-in of payment reductions under the Medicare private payor rate-based CLFS. Statutory phase-in of payment reductions is extended through calendar year (CY) 2026. This created a 0.0 percent reduction for CY 2023 and determined that payment may not be reduced by more than 15 percent for CYs 2024 through 2026. Following these actions, the next PAMA reporting cycle will begin in 2024.

On March 15th, 2023, AMP released the results of the Protecting Access to Medicare Act (PAMA) Impact Survey. The Protecting Access to Medicare Act (PAMA) of 2014 has resulted in inappropriately priced tests due to a flawed data reporting system. PAMA led to steep cuts to pricing such that reimbursement no longer reflects the effort or expertise required to perform the procedure. Through this survey, AMP sought to gain more insight into the financial and logistical impacts of this legislation. AMP used these survey results to support its advocacy for appropriate payment rates and effective PAMA reform. The results of this assessment are critical to inform discussions with payers, federal agencies, and members of Congress. AMP will continue to actively work with many professional organizations as part of its ongoing commitment to support public policies that ensure fair and reasonable reimbursement solutions. AMP continues to support SALSA, signing on to multiple letters championed by ACLA. In June, AMP staff met with Majority and Minority Staff from the U.S House of Representatives Ways and Means Committee as well as the U.S. Senate Finance Committee Staff to discuss the possible passage of SALSA. AMP participated in the SALSA Day of Action on September21, sending letters of support to the co-sponsors of the bill and urging them to discuss the bill with their peers.

Finn Sawyer Access to Cancer Testing Act

The Finn Sawyer Access to Cancer Testing Act was introduced this congress by Senators Roger Wicker (R-MS) and Amy Klobuchar (D-MN) in the U.S. Senate and by Representatives Doris Matsui (D-CA) and Gus Bilirakis (R-FL) in the U.S. House of Representatives. Formally known as the Cancer Patient Equity Act and championed by retired Congressman G.K. Butterfield (D-NC), AMP continues to educate legislators to clarify existing bill language that would conflate the work of a genetic counselor with that of a molecular pathologist. AMP met with the offices of Sens. Wicker and Klobuchar along with Rep. Matsui to discuss details of this bill. collaborating with Congressional staffers and providing redline edits to the bill.

Clinical Lab Fee Schedule for Calendar Year 2023

During the summer, AMP provided written and oral comments to CMS on the Calendar Year (CY) 2024 Clinical Lab Fee Schedule (CLFS). **Dr. Jay Patel** represented AMP at the annual CLFS meeting on June 22, 2023. He presented crosswalk recommendations for the new and reconsidered CY2024 CLFS molecular pathology, genomic sequencing, and microbiology procedures.

Additionally, the Advisory Panel on Clinical Laboratory 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,** and **Pranil Chandra** nominated by AMP to serve.

In late September, CMS released the CY2024 CLFS Preliminary Determinations for the new and reconsidered services. While some of the preliminary CMS determinations align with AMP and other laboratory organizations' recommendations, the majority of the preliminary recommendations provided by CMS vastly differ from both the Advisory Panel and AMP recommendations, along with stakeholder input and, in many cases, do not represent the best options for crosswalks. 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 led by **Dr. Pranil Chandra.** AMP continues to advocate with CMS regarding coverage policy actions taken by Medicare Administrative Contractors (MACs). As of October 4, 2023, AMP has provided responses to various MACs for approximately six draft local coverage determinations (dLCDs). Frequently, AMP and the College of American Pathologists (CAP) collaborated and drafted 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 2023, AMP responded to two private payer coverage policies: Elevance (formally known as Anthem) Circulating Tumor DNA Panel Testing (Liquid Biopsy) and Blue Cross Blue Shield Kansas Comprehensive Genomic Profiling Policy.

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). In September 2023, AMP nominated **Dr. Keyur Patel** for the MPAG. Throughout the year, the Subcommittee may submit new CPT code change proposals to AMA based on member need and input. 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. Keyur Patel** 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, 2023

COMMITTEE MEMBERS:

Chair	Alexis B. Carter, MD
President	Laura J. Tafe, MD
President-Elect	Maria E. Arcila, MD
Past President	Daniel E. Sabath, MD, PhD
Member	Benjamin Liu, MD, PhD
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, 2023

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 and Korea Affiliate Liaison (East Asia)	Jieun Kim, 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	Nicole Pfarr
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
- Enhances AMP's international membership.

2023 ACTIVITIES:

- Selected a new East Asia IAC Member
- Planning for changing IAC roster and kick-off with new members starting 2024
- Planned and held the Global Networking Webinar Session – "Molecular Pathology Certification for Technologists: Where are we today? Survey Data and Expert Opinion" in February 2023
- AMP 2023 Annual Meeting Events:
  - Joined with Membership Affairs Committee to participate in the Networking Session: How to Get Involved with AMP
- Designed and released survey to collect data on Evolution of Molecular Pathology in the Era of AI
  - This data will be presented at the International Affairs Global Networking Lunch on Saturday November 18th as well as during a companion webinar to be held in January or February 2024.
- Selected International Trainee Travel Awardees from India, Poland, and Egypt.
- Awarded International Membership Grants to molecular professionals from India, Egypt, and Syria.
- IAC Committee represented by its Chair assisted in the planning, organization, and launching of the AMP Europe 2023 in Milan, Italy.
- Selected:
  - AMP Europe 2023 Young Investigator Travel Award and AMP Europe 2023 IMPACT recipients
- Supported AMP speakers at international (non-U.S.) conferences:
- Support for the 10th Annual Conference of the Molecular Pathology Association of India (MPAI) (Lucknow, India). Organizing Committee AMP Member: Bibhu Das, PhD

AMP Membership Affairs Committee Annual Report, 2023

COMMITTEE MEMBERS:

Chair	Yaolin Zhou, MD
Member	Barbara Anderson, MS
Member	Tejus Bale, MD, PhD
Member, Representative to Training & Education	Yang Cao, PhD
Member	Timothy Daniels, BS
Member	Kevin E. Fisher, MD, PhD
Member	Lisa Lansdon, PhD
Member	Mariana Macedo, MD, PhD
Member	Jennifer Morrissette, PhD
Member	Bijal Parikh, MD, PhD
Member	Jacquelyn Reuther, PhD
Member	Sherin Shaaban, MD, PhD
Member	Jessica Thomas, MD
Member	Ying Wang, PhD
Member	Shi Yang, MD
Junior Member	Eitan Halper-Stromberg, MD
Junior Member	Rand Abou Shaar, MD
International Affairs Liaison	Rami Mahfouz, MD

PURPOSE SUMMARY:

The AMP Membership Affairs Committee (MAC) provides recommendations to the 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:

- 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

2022-2023 Accomplishments

- Selected:
    - 9 recipients AMP 2023 Technologist Travel Awards recipients.
    - 3 AMP 2023 Underrepresented in Medicine Travel Award.
- Planned and hosted:
    - 2023 AMP Annual Meeting First Timer's Lunch with a focus on understanding the needs of first-time attendees (in addition to providing information about AMP and the AMP Annual Meeting)

    - Networking Session: How to Get Involved with AMP at the AMP 2023 Annual Meeting. Invited representatives from five committees to attend and share about their committee responsibilities and how to become more involved; obtained corporate sponsorship to cover the cost of snacks for this networking session.
- Developed committee member-driven projects to increase recruitment, retention, and member satisfaction. These ongoing projects include:
    - Followed up with 96 first-time lunch attendees from 2022 Annual Meeting (Yaolin Zhou, Kevin Fisher, Ying Wang, Shi Yang, Bijal Parikh, Jessica Thomas, Tejus Bale, Yang Cao, Rand Abou Shaar, Jacqueline Reuther, Lisa Lansdon, Barbara Anderson, and Eitan Halper Stromberg)
    - Created a "Salt Lake City at-a-Glance" cheat sheet for first time meeting attendees (Sherin Shaaban and Lisa Lansdon)
    - Designed AMP First Timer's Lunch pens (Yaolin Zhou)
    - Created a flow chart for AMP Committees that was distributed during the MAC Networking Session (Ying Wang, Jennifer Morrisette, and Yaolin Zhou)
    - Using graphic design to better convey the value of membership. (Jennifer Morrisette)
    - Working with the Program Committee to enhance technologist specific content at the Annual Meeting (Barbara Anderson)
    - Maximizing networking events at the Annual Meeting, including the Networking Session (Shi Yang & Jennifer Morrisette, with entire committee input)
    - Fostering membership opportunities for trainees in low-income countries (Tejus Bale)
    - Creating a comprehensive suite of projects to inform and recruit trainees as part of the new free Associate Membership program (Kevin Fisher, Eitan Halper-Stromberg, and Jessica Thomas)
    - Expanding AMP's micro-volunteer program so that everyone who wants to share their time and expertise with AMP has an opportunity to do so. (Lisa Lansdon)
    - Co-Chaired the Training & Early Career Leadership Development Task Force (Eitan Halper-Stromberg)
    - Creating an AMP Ambassador Pilot Program to inform and recruit trainees by word of mouth from fellow trainees. (Rand Abou Shaar)
    - Continuing the Member Spotlights project that the Training & Education Committee started. (Jacqueline Reuther, Bijal Parikh, Yang Cao, Kevin Fisher, and Marina Macedo)
- Worked closely with the International Affairs and Training & Education Committees to ensure that membership needs are met around the globe and through educational offerings.

Diversity, Equity, and Inclusion (DEI) Working Group Activities

- Member engagement: In collaboration with the International Organizing Committee, planned a session at AMP Europe -"DEI in Pathology: From Education to Clinical Practice." These engagement events are developed from feedback received from our members and are designed to inspire conversation and change, both in AMP members' workplaces and training programs.
- Member outreach: Conducted a survey to track progress on AMP's diversity, equity, and inclusion (DEI) Action Plan and better appreciate our members' perception of and experience with AMP in this regard.
- Projects: Convened a project group to identify the current challenges of genomic test reporting for transgender individuals and suggest possible solutions for improvement.

AMP Nominating Committee Annual Report, 2023

COMMITTEE MEMBERS:

Chair	Daniel E. Sabath, MD, PhD
Genetics Subdivision Representative	Birgit Funke, PhD
Genetics Subdivision Representative	Tina Hambuch Hawks, PhD
Hematopathology Subdivision Representative	Noah A. Brown, MD
Hematopathology Subdivision Representative	Mark D. Ewalt, MD
Infectious Diseases Subdivision Representative	Sanchita Das, MD
Infectious Diseases Subdivision Representative	Ana María Cárdenas, PhD
Informatics Subdivision Representative	Jason Y. Park, MD, PhD
Informatics Subdivision Representative	Ahmet Zehir, PhD
Solid Tumors Subdivision Representative	Eric Vail, MD
Solid Tumors Subdivision Representative	Nikoletta Sidiropoulos, MD
President	Laura J. Tafe, MD
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.

2023 ACTIVITIES:

The Nominating Committee nominated Officers and Committee Representatives for the 2023 annual elections.

AMP Professional Relations Committee Annual Report, 2023

COMMITTEE MEMBERS:

Chair	Eric Q. Konnick, MD
Co-Chair	Karen Weck, MD
Member (*Ex officio* – President-Elect)	Maria E. Arcila, MD
Member	Esther Babady, PhD
Member (Infectious Disease Subdivision Rep.)	Heather Blakenship, PhD
Member	David Bosler, MD
Member (AMP Rep. to FASEB Science Policy Committee)	Emilia Calvaresi, MD, PhD
Member (*Ex officio* – EAC Chair)	Samuel Caughron, MD
Member (Hemepath Subdivision Rep.)	Betty Chung, DO, MPH, MA
Member	Jennifer Dien Bard, PhD
Member (Genetics Subdivision Rep.)	Xiaoli Du, PhD
Member	Rajyasree Emmadi, MD
Member	Andrea Ferreira-Gonzalez, PhD
Member	Amy Lo, MD
Member *(Ex officio* – Patient Engagement Chair)	Jill Murrell, PhD
Member	George J. Netto, MD
Member	Thủy Phùng, MD, PhD
Member (Informatics Subdivision Rep.)	Jason Rosenbaum, MD
Member	Elizabeth Spiteri, PhD
Member (*Ex officio* – President)	Laura Tafe, MD
Member	Andria Del Tredici, PhD
Member	Thao Truong, PhD, D(ABMM), M(ASCP)CM
Member	Oana Vele, MD
Member	David Viswanatha, MD
Member	Barbara Zehnbauer, PhD
Junior Member (Solid Tumor Subdivision Rep.)	Bryan Iorgulescu, MD
Junior Member	Rosalie Sterner, MD, PhD
Committee Advisor	Roger Klein, MD, JD
Committee Advisor	Jordan Laser, MD
Past President	Daniel E. Sabath, MD, 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.

2023 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, Megan Anderson Brooks, and Lindsey Trischler of Innovation Policy Solutions, LLC (iPolicy), inform the Committee of all policy and legislative activity, assist in drafting policy positions, provide advice regarding advocacy strategies, and guide AMP's presence on Capitol Hill. iPolicy along with AMP Associate Director of Public Policy and Advocacy, Annie Scrimenti, AMP Senior Policy Analyst, Monika Franco, AMP Policy Analyst, 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)

Verifying Accurate Leading-edge IVCT Development Act of 2021

A major advocacy issue of 2023 continued to be regulatory oversight of laboratory developed testing procedures (LDPs), also known as laboratory developed testing procedures (LDPs). The Verifying Accurate Leading-edge IVCT (In Vitro Clinical Test) Development Act of 2021 (VALID Act) was at the center of legislative activity on this issue last year. The VALID Act would have created a single regulatory pathway through the U.S. Food and Drug Administration (FDA) for both LDPs and in vitro diagnostic tests (IVDs). Currently, the Centers for Medicare and Medicaid Services (CMS) have authority to regulate LDPs. The VALID Act proposed dramatic modifications to the oversight mechanisms in place and thus had the potential to significantly impact many clinical testing laboratories, healthcare providers, and patients throughout the U.S.

In December of 2022, the co-sponsors of VALID updated the bill to include a very narrow academic medical center exemption. At this time, there was increased support in both the House and Senate as a viable option to include in the FY 2023 omnibus spending legislation. AMP did not deem this exemption palatable and led tremendous advocacy efforts with partner organizations in the final weeks of the year. AMP was instrumental in educating Congressional offices on the potential ramifications of VALID, namely that the FDA-centric framework would significantly impact the ability of our members to practice medicine. AMP organized nearly 20 hill meetings in two weeks for 12 organizations. Notably, our members sent approximately 800 emails in December to their elected officials in Congress expressing their concerns over the legislation. In total, AMP members have sent 1,547 letters to Congress expressing their concerns about VALID over the years. AMP was crucial for cultivating stakeholder support and sending the message that VALID was harmful to the field of molecular pathology.

On December 23, 2022, President Biden signed the long-awaited $1.7 trillion FY 2023 omnibus spending legislation. Despite a last-minute push for the VALID Act, the bill was not included in the final legislative package. Representatives Diana DeGette (D-CO) and Larry Bucshon (R-IN) reintroduced the bill on March 29, 2023. However, there is no Senate companion bill, and Senator Bennett has been unable to find a Republican co-sponsor this year. Additionally, there are not broad endorsements from stakeholders that previously supported the legislation. The House Energy and Commerce Committee plans to have a hearing on the bill which we expect in the last quarter of 2023, there is no other legislative activity anticipated. Overall, the VALID Act has not moved forward this Congress.

FDA Initiates Rulemaking to Regulate Laboratory Developed Testing Procedures (LDPs) as Medical Devices

In June 2023, President Biden's unified regulatory agenda was released and indicated that the FDA was aiming to release a draft Rule in August in relation to Regulation of Laboratory Developed Tests as Medical Devices. Under the regulatory rulemaking process, before the Notice of Proposed Rulemaking (NPRM) is published in the Federal Register for public comment, the President may take the opportunity to review the rule through the White House Office of Information and Regulatory Affairs (OIRA). OIRA analyzes draft proposed rules when they are "significant" due to economic effects or because they raise important policy issues. AMP met with OIRA on August 10th to voice our concerns the LDT Proposed Rule. **Dr. Eric Konnick** spoke to the impacts FDA regulation would have on "laboratory developed testing *procedures*" including barriers for patient access to critical testing and stifling precision medicine innovations. AMP asked prior to issuing an NPRM, that a Request For Information (RFI) be issued to collect data and better understand the impact of rulemaking on academic medical center laboratories and other clinical laboratories offering localized care. After the meeting, AMP shared additional supporting materials and sent draft RFI as requested from the Office of Management and Budget staff. On October 3rd FDA published a proposed rule on Laboratory Developed Tests (LDTs) in the Federal Register. The agency will accept comments until December 4th, 2023. AMP is tracking this closely and encourages members to submit individual comments. AMP will request an extension for the comment period in order to delay the rulemaking process to increase the likelihood it will not become final.

CLIA Modernization

AMP maintains the position that Laboratory Developed Testing Procedures (LDPs) should remain under the authority of the Centers for Medicare and Medicaid Services (CMS), Clinical Laboratory Improvement Amendments (CLIA). This oversight will preserve a flexible system that fosters innovation and is the most streamlined, cost-effective approach to addressing clinical and analytic validity and establishing enhanced transparency.

In 2015, a PRC working group developed a proposal to modernize the CLIA regulations and maintain oversight of LDPs under those regulations. The proposal consisted of a tiered, risk-based structure to avoid duplication of activities between federal agencies. AMP reconvened in 2018 and reinstated the CLIA modernization workgroup to review the proposal and determine if any updates are warranted.

This year, AMP created the Regulatory Reform Task Force to update the CLIA Modernization Proposal that was last drafted in 2018. The Task Force is reviewing broad stakeholder input and finalizing the proposal, which encompasses the highest standards of practice in the field of Molecular Pathology, and would definitively remove FDA involvement from regulating LDPs. The most current version does not include a risk classification system, but instead focuses on enhancing transparency with the goal to ensure quality without the need for a premarket review process. At the time this was written, the Proposal is in the late stages of finalization.
In light of the recent FDA proposed rule on LDTs, AMP is dedicated to working with stakeholders and Congressional offices that continue to move this initiative forward.

Gene Patent Law

Throughout 2023, AMP strongly advocated against The Patent Eligibility and Restoration Act, 2023 (S. 4734) which is an attempt to permit patents of genes, laws of nature and abstract ideas. This bill was introduced by Senator Coons (D-DE) and Tom Tillis (R-NC) and would revise Section 101 of the Patent Act, which defines patent eligibility. It would also reverse the Supreme Court decision, *AMP v. Myriad*. AMP was heavily engaged with stakeholders including the American Civil Liberties Union (ACLU), Invitae, American College of Medical Genetics and Genomics (ACMG), and Facing Our Risk of Cancer Empowered (FORCE). On June 7th, 2023, AMP and these organizations met with congressional offices to express opposition to this proposed legislation, which, as currently drafted, would allow genetic sequences and other biomarkers and their associations with a health condition to be patented. Congress did not prioritize this bill, and it has not gained traction this year.

June 13th, 2023 marked the 10th year anniversary of the U.S. Supreme Court ruling*, AMP v. Myriad,* that forever changed the ability to conduct genetic testing and enabled practitioners to accurately diagnose and inform treatments for numerous patient conditions. In celebration with advocates for Precision Medicine, AMP created a new webpage under Advocacy to highlight the history of the case. Dr. Eric Konnick authored a blog post and AMP published a press release and posted on social media in coordination with other stakeholders. Furthermore, AMP honored HHS Secretary Xavier Becerra with a Champion of Innovation Award for his 30 years of leadership in efforts to protect patient access to critical medical testing procedures.

This year, AMP's Virtual Advocacy Day, on July 27th, centered on the potentially devastating impacts the Patent Eligibility Restoration Act would have on patient care and innovation. AMP members and staff held 70 congressional meetings, including 7 direct meetings with Members of Congress.

In August, Senators Tillis and Coons expressed interest in holding a hearing on the bill as well as convening stakeholder roundtable discussions, similarly to those in prior years. AMP continues to monitor legislative activities that threaten gene patent laws.

Capitol Hill Happenings

AMP continues to foster existing partnerships on Capitol Hill. AMP Advocacy participated in over 120 congressional meetings in 2023 that focused on gene patent law, laboratory diagnostics legislation and regulation, and the Protecting Access to Medicare Act (PAMA)/Saving Access to Laboratory Services Act (SALSA). Of note, at the end of 2022, AMP led the charge against the Verifying Leading-edge IVCT Development (VALID) Act which ultimately did not pass as part of a larger legislative package.

Patient Advocacy Group Engagement

AMP has had several Patient Advocacy initiatives in 2023. The Patient Engagement Subcommittee along with the formation of a new Working group released multiple patient-facing materials this year.

In 2020, AMP created a website that included free infographics, descriptions of testing types, and answers to frequently asked questions, to inform patients and advocates of the role diagnostic testing plays in patient care. There are regularly updated educational resources on cancer, COVID-19 testing, and inherited disorders. The latter was launched on April 17th, 2023 and is AMP's most comprehensive patient-centered online resource to date, and provides answers for patients and the general population.

Additionally, the Patient Engagement Subcommittee released a Screening vs Diagnostic Infographic Series which explains the differences between screening and diagnostic tests to a lay audience. The three-part series includes Newborn Screening, Breast Cancer Screening, infectious disease screening and diagnostic testing.

AMP also continued to host "Lunch and Learn" events this year to identify and establish relationships with relevant patient groups in oncology, inherited conditions, and infectious diseases. AMP seeks to collaborate with patent groups to understand their specific needs, and to convey the fundamental importance of patient care to AMP members. These events have been incredibly well-received by both patient groups and AMP members.

In June 2023, AMP hosted a virtual Lunch and Learn event entitled: "Patient Resources Where We Are Now, and Where We are Going". This was hosted by **Dr. Jill Murrell**, the Chair of the PRC Patient Engagement Subcommittee, and **Maria Alejandra Diaz-Miranda, PhD** and focused on AMP's new patient-facing materials Dr. Maria Alejandra Diaz-Miranda was integral in the release of our first Spanish translated graphic "Inside a Molecular Diagnostic Laboratory/Una Mirada a Un Laboratorio Clinico de Diagnostico Molecular" in 2022. This event had 10 attendees from various patient advocate groups who are all invested in the molecular pathology

space. Dr. Jill Murrel spoke to the various projects of the Patient Engagement Subcommittee and the event concluded with a well-received Q&A Session.

Furthermore, in 2023, AMP began a new endeavor: 90-second, animated, educational videos that will cover the following topics:

- "A Look Inside A Clinical Molecular Diagnostic Laboratory"
- "An Introduction to Molecular In The Patient's Pocket"
- "Understanding the difference between screening and diagnostic tests"

The platform will allow for feedback to ensure the videos address patient concerns. These videos will be available in both English and Spanish. The first video will be released by the end of the year.

Public Health Emergency Response

Throughout 2023, 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. The public health emergency ended on May 11th; AMP released information to our membership on how this would impact their workflow and the practice of molecular diagnostics. Though the PHE ended, AMP continues to express support for the Emerging Pathogen Task Force, previously known as the COVID-19 Response Task Force. The Task Force has been maintained to implement AMP's policy around emerging infectious diseases including pandemic preparedness and response efforts.

On March 23rd **Dr. Eric Konnick** presented comments on behalf of AMP to the National Academies of Sciences, Engineering, and Medicine Forum on Medical and Public Health Preparedness for Disasters and Emergencies in-person workshop titled "Future of the Nation's Laboratory Systems for Health Emergency Response".

This summer, the Pandemic and All Hazards Preparedness Act (PAHPA) reauthorization, which occurs every 5 years, gained traction on the hill. The Task Force submitted comments which included several pandemic preparedness recommendations. In June, the Task Force submitted a Letter to the U.S. House Energy and Commerce Committee Leadership that contained updated policy recommendations that addressed challenges experienced by our members during the pandemic. The Task Force requested the following recommendations:

- Ensure strategies are in place for the rapid development and availability of diagnostics
- Increase clinical and diagnostic laboratory testing capacity during a public health emergency.
- Require the Department of Health and Human Services (HHS) to develop a testing strategy to allow for
    - Redistribution of supply allocations based on clinical testing needs; and
    - Real-time coordination amongst laboratories to leverage moments of excess capacity.

Furthermore, many of our members experienced barriers to accessing control samples during the emergency due to Institutional Review Board (IRB) procedures. AMP urged the Office of Human Protections to issue guidance that clarifies that during future public health emergencies, the use of HIPAA de-identified samples from a hospital's clinical population for the purpose of validating a diagnostic test for the pathogen for which the public health emergency has been declared is considered to be an action taken for public health under 45 CFR part 46 and thus, does not necessitate IRB review.

In August, AMP provided verbal comments to the National Biodefense Science Board (NBSB). NBSB provides expert advice and guidance to the Secretary of HHS and the Assistant Secretary for Preparedness and Response (ASPR) on scientific, technical, and other matters related to public health emergency preparedness and response. The Board held a public meeting based on lessons learned from the COVID-19 pandemic to improve the operational public health and health system data for disaster response. The second recommendation focused on diagnostics and the draft language narrowly called for authorization to adapt tests developed by the WHO or other internationally recognized organizations if domestic tests are not available. We requested edits to this recommendation based on the PRC's previously developed position and the Board recommendations now include the phrase "laboratory developed testing procedures" and call for the avoidance of duplicative

regulatory requirements. Once finalized, this report will be made publicly available, and presented to the leadership of HHS to inform responses to future emergencies.

Collaborations

AMP continues to participate in a variety of policy discussions with other professional societies, laboratory groups, such as the Personalized Medicine Coalition (AMP representatives **Drs. Roger Klein** and **Amy Lo**), the National Academies of Sciences, Engineering, and Medicine (NASEM) Roundtable on Genomics and Precision Health (AMP representative **Dr. Vicky Pratt**), Federation of American Societies for Experimental Biology (FASEB) (AMP representative **Dr. Emilia Calvaresi**), and the Cancer Leadership Council.

AMP Program Committee Annual Report, 2023

COMMITTEE MEMBERS:

Chair	Yassmine M.N. Akkari, PhD
Chair-Elect	Jonathan Nowak, PhD
Genetics Representative	Jialing (Jenny) Ji, MD, MS
Genetics Representative	Honey Reddi, PhD
Hematopathlogy Representative	Nathan Montgomery, MD, PhD
Hematopathlogy Representative	Craig Soderquist, MD
Infectious Diseases Representative	Rangaraj Selvarangan, PhD
Infectious Diseases Representative	Heba Mostafa, MD, PhD
Informatics Representative	Mark Routbort, MD, PhD
Informatics Representative	Julie Hirschhorn, PhD
Solid Tumors Representative	Lauren L. Ritterhouse, MD, PhD
Solid Tumors Representative	Deepika Sirohi, MD
Technical Topics Representative	Barbara A. Anderson, PhD
Technical Topics Representative	Tracy McMillen, 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.

2023 ACTIVITIES:

Planned and moderated the sessions for the 2023 Annual Meeting & from November 14-18, 2023, along with the recorded content that will be available in January 2024.

AMP Publications Committee Annual Report, 2023

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
Member	Daniel Sabath, MD, PhD
Member	Yogesh Chander, PhD
Member	Zheng Jin Tu, 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 holds a virtual meeting monthly, meets face-to-face before the annual meeting, and communicates electronically throughout the year.

2023 ACTIVITIES:

- Solicited and reviewed AMP Case Reports submissions for potential publication in *CAP Today*.
- Solicited volunteer applications for a junior member.
- Welcomed 2 new members with expertise in informatics and microbiology, respectively.
- Recommended approval of two Associate Editors for *JMD's* Editorial Board to the AMP Board of Directors and ASIP Council.
- Provided requested feedback to *JMD* for an update to the author instructions (including definitions on gender and sex, and use of artificial intelligence), DEI statement, and article type documents and website information.
- Updated the AMP Wikipedia page.

- Developed a potential topics and authors list for *JMD* review articles, guest editorials, spotlight pages, and Silver Anniversary Edition.
- Recommended addition of a *JMD* subtitle to help improve awareness of the journal's scope to the AMP Board of Directors and ASIP Council.
- Conducted a review of AMP Case Reports in CAP Today program to identify potential improvements.

Requests from the Publications Committee

- We encourage AMP members to serve as a reviewer for the *Journal of Molecular Diagnostics.* Please register an account on the JMDI Editorial Manager platform and enter applicable expertise terms/keywords to your profile. AMP membership is not required.
- We encourage AMP members to submit Case Reports for potential publication in *CAP Today*. More information about the program and online submission portal is available on our website.

AMP Strategic Opportunities Committee Annual Report, 2023

COMMITTEE MEMBERS:

Chair	Maria Arcila, MD
Member	Alexis Carter, MD
Member	Michael Hadjisavas, PhD
Member	Jill Hagenkord, MD
Member	Jordan Laser, MD
Member	Robert L. Nussbaum, MD
Member	Anthony N. Sireci, MD, MS
President	Laura J. Tafe, MD
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.

2023 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, 2023

COMMITTEE MEMBERS:

Chair	Alanna Church, MD
Genetics Subdivision Representative	Shashi Shetty, PhD
Genetics Subdivision Representative	Eli Williams, PhD
Hematopathology Subdivision Representative	Jennifer Bynum, MD
Hematopathology Subdivision Representative	Joanna Conant, MD
Infectious Diseases Subdivision Representative	Cecilia Thompson, PhD
Infectious Diseases Subdivision Representative	Rebecca Yee, PhD
Informatics Subdivision Representative	Thomas D. Lee, MD, PhD
Informatics Subdivision Representative	Jamal Benhamida, MD
Solid Tumors Subdivision Representative	Ying-Chun Lo, MD, PhD
Solid Tumors Subdivision Representative	Anna Matynia, MD
Junior Member	Adam Fisch, MD, PhD
Junior Member	Kenneth Ofori, MBCHB
Medical Technologist Member	Michelle Mah, MSc, MLT
Medical Technologist Member	Margaret Cameron, MS
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

2023 GetAMPed! Updates and Case Studies in Molecular Pathology:

The T&E Committee planned and taught an in-person course for the AMP 2023 Annual Meeting & Expo on November 15th. This year, the course was taught twice as 3.5-hour long sessions focused on NGS, including an overview of the assay selection, validation considerations, informatics, and troubleshooting. The course included four interactive case study break-out sessions which enabled participants to apply what they learned to NGS cases in infectious diseases, solid tumors, hematopathology, and genetics.

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 2023 Annual Meeting and Expo. Trainee/technologist presenters in 2023 are listed below:

Case Studies in Genetics	Male or female? Integrated molecular and cytogenetic testing resolves discordant prenatal results	Ting Wen	University of Utah School of Medicine/ARUP Laboratories
	Siblings with familial hemophagocytic lymphohistiocytosis and compound heterozygous PRF1 variants.	Chinwe Madubata	Columbia University Irving Medical Center
	Rare patient with an interstitial 13q deletion derived from a paternal chromosome 13 paracentric inversion	Divya Vinjamur	Virginia Commonwealth University Health System
	Rapid whole exome sequencing detects novel homozygous deletion in a newborn with refractory seizures	Lauren Wainman	Dartmouth Health
	A mysterious sex chromosome puzzle solved by comprehensive cytogenetic evaluations.	Hamed Rahi	Washington University
	DNA Purity as Determinants of False Negative Genetic Testing Results	Joyce Nicola	West Virginia University Hospital

Case Studies in Hematopathology	Challenges in Diagnosing Germline Predisposition in Hematologic Malignancies-A Case with DDX41 Mutation	Anjanaa Vijayanarayanan	MD Anderson Cancer Center
	RNA sequencing detects novel fusion partner for PDGFRA rearranged myeloid/lymphoid neoplasm with eosinophilia	Ravi Tej Bommu	University of Minnesota
	Variant t(2;11)/IGK::CCND1 rearrangement detected by optical genomic mapping in a CD5 negative low-grade B-cell lymphoma	Okechukwu Nwogbo	MD Anderson Cancer Center
	Cytogenetic and molecular characterization of a complex three-way translocation in acute promyelocytic leukemia	Katherine Morgan	Perelman School of Medicine at the University of Pennsylvania
	Molecular evidence of differentiation syndrome following menin inhibitor treatment in a patient with relapsed acute myeloid leukemia	Christopher Zarbock	Washington University School of Medicine in St. Louis
	UNCOMMON CYTOGENETIC ABNORMALITIES IN MYELOID MALIGNANCIES	Zeeshan Ansar Ahmed	Aga Khan University Hospital, Karachi, Pakistan
Case Studies in Solid Tumors	CDKN2A deletion in oropharyngeal squamous cell carcinoma: a potential pitfall of relying on p16 immunohistochemistry as a surrogate marker for HPV involvement	Trevor Teich	University of Toronto
	BRAF internal deletion in a case of pilocytic astrocytoma	Darren Brow	University of Chicago
	A Pediatric Ultra-Hypermutated Glioma Mimicking CMMRD in a Patient with Lynch Syndrome	Mary Clay Bailey	Baylor College of Medicine
	Identification of a spliced, exonic templated sequence insertion in a BRCA1-deficient high-grade serous carcinoma with a therapy-related BRCA1 reversion mutation - evidence of RNA-templated double-strand break repair?	Alexander Neil	Brigham and Women's Hospital
	A case of HPV-associated combined adenocarcinoma and neuroendocrine carcinoma of the cervix with a targetable FGFR2::TACC2 fusion	Audrey Roy	Memorial Sloan Kettering Cancer Center
	Unveiling concurrent lung adenocarcinoma through a rare germline variant in a patient with invasive breast carcinoma	David Basta	Massachusetts General Hospital
	An even greater masquerader: uveal melanoma identified with molecular profiling of liver metastasis	Ellie Hong	University of Colorado
	Rare COL1A1-PDGFB fusion in uterine tumor	Anamaria Munteanu	University of California, Los Angeles

2023 Live Webinars and Recorded Online Content (ROCs):

Date	Title	Speaker/T&E Moderator	NOTES (Registrants/Attendees)
Major Initiative: Breast Cancer Molecular Testing: Catching Up to Increased Complexity			
August 23	A Practical Guide to Understanding Breast Multi-Gene Assays	Mara Rendi	346/158
September 21	Predictive Tests for Therapeutic Options in Breast Cancer: Indications, Utility, and Interpretation	Kimberly Allison	405/129
Major Initiative: Emerging and Evolving Biomarkers: Recent Findings, Laboratory Considerations, and Clinical Implications			
April 12	Being eNRGy Conscious: Understanding NRG1 Fusions	Stephen Liu	346/158
September 28	FLT3 mutations and AML: Recent findings, laboratory considerations, and clinical implications	Mark Levis	205/126
Major Initiative: Utility of Cell-free DNA in the Clinic: Current State and Future Directions			
February 2	Hereditary Cancer Surveillance Using Cell-free DNA Sequencing	Trevor Pugh	536/240
Webinar Series: Horizons			
January 23	Rapid Genotyping for Therapy Selection in Patients with Lung Cancer	Jochen K. Lennerz & Ibiayi Dagogo-Jack	441/170
July 18	Artificial Intelligence and Molecular Pathology: An Introduction to Principles, Techniques and Applications	Jamal Benhamida	829/351
August 3	Molecular Subtypes of Diffuse Large B-cell Lymphoma	David W Scott	575/245
Webinar Series: Horizons; Clinical Practice Webinars			
February 16	Assessments of Somatic Variant Classification Using the AMP/ASCO/CAP Guidelines	Marilyn M. Li	961/532
July 27	AMP/NSGC Recommendations for Next-Generation Sequencing Germline Variant Confirmation	Kristy Crooks	940/429
September 19	CYP3A4 and CYP3A5 Genotyping Recommendations	Yuan Ji	547/270
Webinar Series: Trainee and Early Career Series			
April 25	Tips for Board Preparation in Molecular Genetic Pathology	Annie Garcia, Alessia Buglioni, & Melissa Krystel-Whittemore,	300/183
August 9	Embarking on a Job Search	Esther Baranov, Annie Garcia, & Drew Williamson	182/57
September 27	Excelling in Molecular Pathology and Laboratory Genetics Job Opportunities: Insights on Interview Preparation, Job Talk, and Negotiation	Cinthya J. Zepeda Mendoza, Zehra Ordulu Sahin, & Ying-Chun Lo, MD, PhD	281/106

2023 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) and live and enduring webinars. Currently, there are nearly 270 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 - AMP*ED*™:**

The T&E Committee and staff have designed and developed educational materials for populating educate.amp.org. The LMS has attracted over 4,400 active users in 2022 (January 2022-December 31, 2022). It has 174 educational products, 79 On-Demand Courses, 63 Microloearning Modules, 4 certificate programs, 6 Self-Study + Review Courses, and 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 2023 include:

    - Bundle: Utility of Cell-free DNA in the Clinic: Current State and Future Directions
    - Ovarian Cancer Virtual Education Series
    - AMP 2023 Molecular Genetic Pathology Review Course (self-paced ondemand)

  - **AMP Flashcards:** Another card set has been created for medical technologists. This 30+ card set will help clinical technologists gain or review their knowledge of molecular techniques including nucleic acid isolation, manipulation of RNA/DNA, separation and detection and nucleic acid amplification. The cards can also be used as study aids for ASCP certification exams. In addition, there are four more sets available: 1) multiple myeloma, 2) colorectal cancer 3) acute myeloid leukemia, and 4) Technologist in Molecular Biology: Laboratory Operations

  - **FISE Question Bank:** This is the sixth 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 >500 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 15 microlearning modules called Molecular in a Minute. Five new topics were added in 2023 focused on NGS testing.

  - **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 Ovarian Cancer and the other on Breast Cancer (available soon). The T&E has also made substantial edits to many of the cards. Cards are reviewed annually by T&E Committee members for accuracy and for any required updates. There have been more than 2,000 user visits to the MIMP card homepage in the past 6 months.

- **Molecular Genetic Pathology Review Course:**

In May 2023, the Molecular Genetic Pathology Review course was held as a 4-day virtual-live course. With 15 molecular genetic pathology expert faculty speaking on topics ranging from molecular technologies, test validations and statistics, molecular oncology, infectious diseases and more, the course was designed to assist attendees in preparing for the MGP subspecialty certification exam as well as other exams in molecular pathology. A total of 79 people, 16 (20%) of which were from outside of the United States, enrolled in the course and at any one point there were between 40 to 55 unique attendees.

AMP 2023 Annual Meeting & Expo Activities:

- **The Molecular Genetic Pathology Fellowship Program Directors (MGP PD) Council**
  The MGP Program Directors (MGP PD) Council consists of Mark Ewalt (Chair), Noah Brown (Chair-Elect), and Rena Xian (Past-Chair). Anna Matynia 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. This year, they successfully launching the unified timeline. A total of 31 MGP Programs participated. The MGP program directors will meet at the AMP 2023 Annual Meeting & Expo, to discuss lessons learned regarding the unified timeline.

- **The Education Community of Practice (EdCoP) Group**
  The AMP Education Community of Practice Group is lead by Thomas Lee with working group members Cynthia Jackson and Yang Cao. In 2023, the working group began the task of mapping educational resources to core competencies identified in molecular pathology curriculum manuscripts. The EdCoP group also hosted a meeting at the AMP Annual Meeting and Expo focusing on the utility of large language model machine learning technologies for use in molecular pathology education.

- **Innovation Stages**
  The T&E Committee will be hosting one Innovation Stage on the trainee and early career webinar series and discuss solicit feedback on future directions.

- **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**
  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

- **Emerging and Evolving Biomarker Manuscripts:** These special articles, led by Kurtis Davies, Rena Xian, and Anthony Snow, features the science, laboratory considerations, and clinical implications of the individual biomarkers presented in the Emerging and Evolving Biomarker webinar series. Mutational Signatures (written by Fei Dong) was published in August 2023. Other 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 2023 – New Orleans, LA**

  The AMP 2023 Companion Society Symposium,

  "Bridging Histology and Molecular Pathology with Computational Pathology:", was co-moderated by Honey Reddi, PhD, FACMG and Rashmi Kanagal-Shamanna, MD Speakers were:

  Toby C. Cornish, MD, PhD

  Jason D. Hipp, MD, PhD

  Nefize Sertac Kip, MD, PhD

- **College of American Pathologists (CAP) October 2023 – Chicago, IL**

  CAP 2023 Course Presentation

  "Neoplasms with Germline Predisposition in Clinical Practice" was presented by Yang Cao, PhD and Thomas Lee MD, PhD, FCAP

- **Cambridge Health Institute (CHI) Conferences – Washington, DC**

  Next Generation Dx Summit, August 2023

  "Collaborating to Lay the Groundwork for Molecular Residual Disease as an Early Endpoint in Solid Tumors" presented by Christina Lockwood, PhD, DABCC, DABMGG

- **Medscape – online education**

  EGFR Exon 20 Insertion Mutations in NSCLC: Underscoring the Value of Detection and Subsequent Care - Released August 2023

- **PRIME Education – online education**

  Employing Tools in Clinical Practice to Accelerate Prompt, Accurate Diagnosis and Risk Assessment in MDS – Released May 2023

AMP Subdivision Leadership Annual Report, 2023

SUBDIVISION LEADERSHIP

	Genetics	Hematopathology	Infectious Diseases	Informatics	Solid Tumors
Chair	Matt Lebo	Eric Duncavage	Kirsten St. George	Annette Leon	Anna Yemelyanova
Clinical Practice Committee	Ann Moyer	Pawel Mroz	Donna Wolk	Elaine Gee	Katherine Geiersbach
	Diana Mandelker	Rena Xian	Erin Graf	Andrea Sboner	Navid Sadri
Economic Affairs Committee	Victoria Pratt	Patricia Tsang	Joseph Yao	Jeffrey Gagan	Susan Hsiao
Nominating Committee	Tina Hambuch	Mark Ewalt	Ana Maria Cárdenas	Ahmet Zehir	Nikoletta Sidiropoulos
	Birgit Funke	Noah Brown	Sanchita Das	Jason Park	Eric Vail
Professional Relations Committee	Xiaoli Du	Betty Chung	Heather Blankenship	Jason Rosenbaum	Bryan Iorgulescu
Program Committee	Honey Reddi	Craig Soderquist	Heba Mostafa	Julie Woolworth Hirschhorn	Deepika Sirohi
	Jianling Ji	Nathan Montgomery	Rangaraj Selvarangan	Mark Routbort	Lauren Ritterhouse
Training & Education Committee	Eli Williams	Joanna Conant	Cecilia Thompson	Jamal Benhamida	Anna Matynia
	Shashirekha Shetty	Jennifer Bynum	Rebecca Yee	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

2023 ACTIVITIES:

All Subdivision Leadership groups contribute to biannual Subdivision Spotlight email digests that highlight 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. Discussed National Academy of Medicine's *Use of Race Ethnicity and Ancestry as Population Descriptors in Genomics Research* report and potential impacts on clinical care. Discussed ways to attract cytogeneticists to AMP and increase collaboration with other cytogenetics groups. Provided feedback to *JMD* Editor in Chief related to increasing and improving genomic medicine related articles and highlighting AMP Genetics Subdivision activities in the journal. Participated and contributed to projects related to the different AMP Committees.

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. Curated and provided a "Must Reads" list of hematopathology-relevant literature to the Subdivision membership. Established a task force to create a perspective article addressing clinical molecular testing using the 2022 ICC and WHO classifications for myeloid neoplasms. Provided feedback to *JMD* Editor in Chief related to increasing and improving hematopathology related articles and highlighting AMP Hematopathology Subdivision activities in the journal. Participated and contributed to projects related to the different AMP Committees.

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 next generation sequencing, artificial intelligence and machine learning, antimicrobial resistance, SARS-CoV-2, Mpox, and microbiome. Reviewed AMP resources related to SARS-CoV-2 and Mpox. Provided feedback to *JMD* Editor in Chief related to increasing and improving infectious disease related articles and highlighting AMP ID Subdivision activities in the journal. Participated and contributed to projects related to the different AMP Committees.

Informatics - Served as AMP's internal advisory board for informatics to develop initiatives related to clinical practice, advocacy, and education. 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. Assisted the Clinical Practice Committee (CPC) with topics involving artificial intelligence and machine learning. Provided feedback to *JMD* Editor in Chief related to increasing and improving informatics related articles and highlighting AMP Informatics Subdivision activities in the journal. Participated and contributed to projects related to the different AMP Committees.

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. Provided feedback to *JMD* Editor in Chief related to increasing and improving oncology related articles and highlighting AMP Solid Tumor Subdivision activities in the journal. Discussed oncology-related clinical practice areas in need of additional expert guidance. Participated and contributed to projects related to the different AMP Committees.

Requests from the Subdivision Leadership

- We encourage all AMP members to alert their Subdivision Chair or Representatives to 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.
- We encourage AMP members to serve as a reviewer for the *Journal of Molecular Diagnostics.* Please register an account on the JMDI Editorial Manager platform and enter applicable expertise terms/keywords to your profile. AMP membership is not required.