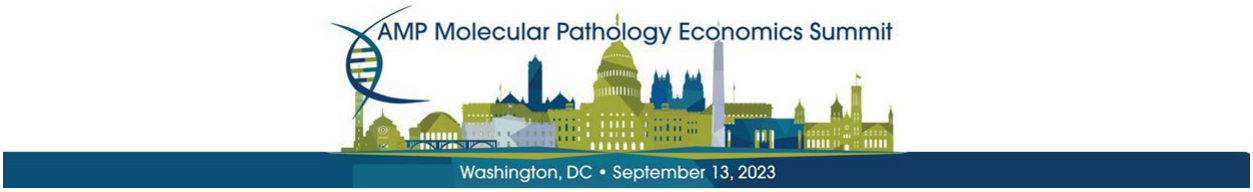
AMP

Association for Molecular Pathology

Molecular Pathology Economics Summit

September 13, 2023

Washington, D.C



Agenda at a Glance

Wednesday, September 13, 2023 – Omni Shoreham Hotel, Empire Room, Washington, D.C.

7:30 am	Registration and Breakfast *(Empire Foyer)*
8:00 am	Welcome and Opening Remarks
8:15 am	Real World Perspectives Roundtable: Clinical Laboratories
9:00 am	Real World Perspectives Roundtable: Patient Advocacy Community
9:45 am	Coffee Break *(Empire Foyer)*
10:15 am	Real World Perspectives Roundtable: Manufacturer Community
11:00 am	Real World Perspectives Roundtable: Pharmaceutical Community
11:45 am	Lunch *(Empire Foyer)*
12:30 pm	Introductions to Afternoon Session/Activity
12:45 pm	Navigating the Future Economic Challenges of Precision Medicine
1:30 pm	Coffee Break *(Empire Foyer)*
2:00 pm	Facilitated Discussion: Identifying Solutions and Action Items
2:45 pm	Facilitated Discussion: Looking into the Future
3:15 pm	Closing Remarks and Next Steps
3:30 pm	Departure

Main Program

Wednesday, September 13, 2023

7:30 am — **Registration and Breakfast**

Omni Shoreham Hotel, Empire Room
2500 Calvert Street NW, Washington
District of Columbia 20008

8:00 am — **Welcome and Opening Remarks**

Empire Room

Speaker: **Samuel Caughron**, MD, Chair, AMP Economic Affairs Committee, *MAWD Pathology Group, P.A.*

8:15am-11:45am — **Real World Perspectives Roundtable – *Session Overview***

Stakeholders from different industries are affected by the economic challenges plaguing clinical molecular diagnostics. Each industry and stakeholder is uniquely impacted, but there is a common alignment around improving the overall economics for diagnostic testing.
Advances in diagnostic testing and closely related therapies are driving precision medicine, while simultaneously challenging current paradigms for molecular diagnostic coding, coverage, and reimbursement procedures/processes. During the morning session, a series of roundtable discussions will be held, each focused on a specific stakeholder perspective including clinical laboratories, pharmaceutical companies, in vitro diagnostic manufacturers, and patient advocacy groups. Interactive candid discussions will explore the unique challenges confronting each of these stakeholder groups, with the ultimate goal of achieving mutual understanding and identifying common areas that require resources in order to improve the economics to reach the highest level/quality of patient care.

Details regarding individual morning sessions on next page.

8:15 am	**Real World Perspectives Roundtable: Clinical Laboratories** Facilitator: Clifford Goodman, PhD The facilitator will lead a discussion with interested panel members and summit attendees representing the perspective of clinical laboratories on the economic challenges facing molecular diagnostics.
9:15 am	**Real World Perspectives Roundtable: Patient and Provider Community** Facilitator: Clifford Goodman, PhD The facilitator will lead a discussion with interested panel members and summit attendees representing the perspective of patients and how economic issues are limiting access to advanced molecular diagnostics.
9:45 am	**Coffee Break** *Empire Foyer*
10:15 am	**Real World Perspectives Roundtable: Manufacturer Community** *Empire Room* Facilitator: Clifford Goodman, PhD The facilitator will lead a discussion with interested panel members and summit attendees representing the perspective of IVD test manufacturers on the economic challenges facing molecular diagnostics.
11:00 am	**Real World Perspectives Roundtable: Pharmaceutical Community** *Empire Room* Facilitator: Clifford Goodman, PhD The facilitator will lead a discussion with interested panel members and summit attendees representing the perspective of pharmaceutical partners on how the economic challenges facing molecular diagnostics are affecting the ability to bring the most advanced biomarker driven treatments to patients.

11:45 am — **Lunch**

Empire Foyer

12:30 pm — **Introduction to Afternoon Sessions**

Empire Room

Speakers: **Samuel Caughron**, MD and Clifford Goodman, PhD

12:45 pm — **Navigating the Future Economic Challenges of Precision Medicine**

Facilitator: Clifford Goodman, PhD

Attendees will be sorted into four different breakout roundtables to discuss selected topics related to the challenges in the structure and process that underpin molecular diagnostic testing. Questions and prompts will be provided for discussion initiations.

Discussion Topics

1. Ensuring the Perception of the Quality of Molecular Diagnostic Tests
2. Creating space for labs to give feedback to private payer policies
3. Education on molecular diagnostics to payers
4. Streamlining the coding system

This session provides a forum for ideas to be shared – with the goal of identifying 1 or 2 action items (per table) that the community can do to work towards addressing these issues. Each table will present their solutions for further discussion in the latter session.

1:30 pm	**Coffee Break** *Empire Foyer*
2:00 pm	**Facilitated Discussion: Identifying Solutions and Action Items** *Empire Room* Facilitator: Clifford Goodman, PhD The afternoon session will begin with attendees discussing different solutions and/or action items that were agreed upon during the breakout sessions. Attendees will then prioritize action items according to their potential impact and feasibility. The end goal: To determine the most attainable **action items** for implementation by stakeholders in their respective fields and move forward addressing the economic challenges facing precision medicine.
2:45 pm	**Facilitated Discussion: Looking into the Future** This discussion will focus on the future of the Molecular Diagnostics Industry. What will the field look like in the next decade? The discussion will focus on potential innovations, AI, and predicted problems. Facilitator: **Samuel Caughron**, MD
3:15 pm	**Closing Remarks and Next Steps** Speaker: **Samuel Caughron**, MD
3:30 pm	**Depart**

Biographies

Program Chair

Samuel K. Caughron, MD FCAP practices pathology in Kansas City where he is President & CEO, and Director of the Molecular Lab at MAWD Pathology, as well as Chair of Pathology for AdventHealth Kansas City. He received his medical degree and AP/CP pathology training at Creighton University and completed a fellowship in Molecular Genetic Pathology at Vanderbilt.

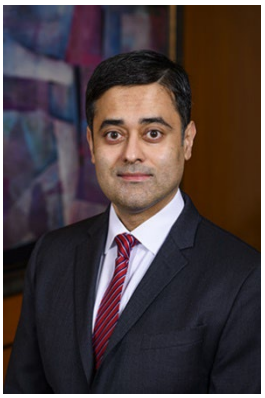
Dr. Caughron has served on numerous local, regional, and national professional boards, committees, and advisory panels for pathologists within multiple organizations including the American Medical Association (AMA), College of American Pathologists (CAP), the American Pathology Foundation (APF) and the Association for Molecular Pathology (AMP). He is nationally recognized for his expertise in molecular coding, coverage, and pricing, and has served as Chair of AMP's Economic Affairs Committee since 2015. In that role, Dr. Caughron leads the organization's strategy and efforts around recognition and reimbursement for molecular services. In 2019 he created and served as Chair for the inaugural AMP Economic Summit.

Program Facilitator

Clifford Goodman, PhD, has 35 years of experience in such areas as health technology assessment, evidence-based health care, clinical practice guidelines, health economics, and studies pertaining to health care innovation, regulation, and payment. He directs studies and projects for an international range of government agencies; pharmaceutical, biotechnology, and medical device companies; health care provider institutions; and professional, industry, and patient advocacy groups. His recent work has involved such areas as chronic disease, infectious disease, cancer, rare diseases, diagnostic testing, gene therapy, pharmacogenomics, personalized medicine, biosimilars, value frameworks, value-based contracting, social determinants of health, and applications of real-world data. Dr. Goodman is an internationally recognized health policy issues moderator and facilitator of expert panels, advisory boards, workshops, and focus groups.

Dr. Goodman served as chair of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC, 2009-12) for the Centers for Medicare and Medicaid Services (CMS). He served as president of the professional society, Health Technology Assessment international (HTAi, 2011-13), and is a Fellow of the American Institute for Medical and Biological Engineering. In 2022, he received the David Banta Distinguished Career Award in Health Technology Assessment from HTAi. He earned a PhD from The Wharton School of the University of Pennsylvania, a Master of Science from The Georgia Institute of Technology, and a Bachelor of Arts from Cornell University.
After 27 years, including as Senior Vice President, Dr. Goodman recently retired from The Lewin Group and is an independent consultant in health care technology and policy.

Planning Committee Members



Pranil Chandra, DOF, CAP, FASCP joined PathGroup in 2011 as Associate Medical Director of Molecular Pathology and now currently serves as Senior Vice President and Chief Genomics Officer at PathGroup. Dr. Chandra holds board certifications in anatomic and clinical pathology, hematopathology and molecular genetic pathology. He completed his AP/CP training and fellowships in hematopathology, oncologic pathology and molecular pathology at NYU Langone Medical Center and the University of Texas-MD Anderson Cancer Center, respectively. While at MD Anderson, he served as Chief Fellow and received numerous awards for his research in acute myeloid leukemia. He has presented numerous abstracts and platform presentations at various pathology meetings and has published peer-reviewed articles and book chapters. Dr. Chandra is a member of the American Society of Clinical Pathology, College of American Pathologists, and Association of Molecular Pathology where he also serves in a leadership capacity to the Economic Affairs Committee as Vice-Chair of Coverage. Dr. Chandra is a recognized medical consultant in molecular pathology and personalized medicine and is considered a national thought leader in Precision Medicine and Cancer Genomics.

Erin H. Graf, Ph.D., D(ABMM) is an Associate Professor and Co-Director of Microbiology at the Mayo Clinic Arizona. She was formerly the Director of the Infectious Disease Diagnostics Laboratory at the Children's Hospital of Philadelphia and an Assistant Professor of Clinical Pathology at the Perelman School of Medicine at the University of Pennsylvania. Dr. Graf completed her Ph.D. in Cell and Molecular Biology at The University of Pennsylvania studying HIV latency. She then went on to complete an ASM accredited postdoctoral training program in medical and public health microbiology at ARUP Laboratories and the University of Utah. Dr. Graf is board certified in medical microbiology. Her research interests include the applications of next generation sequencing and metagenomics for diagnostic and epidemiologic investigations, as well as emerging rapid diagnostic technologies paired with diagnostic stewardship

Jay Patel, MD, MBA is Professor of Pathology at the University of Utah School of Medicine and Vice President of Clinical Trials and PharmaDx at ARUP Laboratories. He is a member of the Association for Molecular Pathology where he serves as Co-Chair of the Economic Affairs Committee. Dr. Patel is certified by the American Board of Pathology in anatomic and clinical pathology, with subspecialty boards in hematology, and is a fellow of the College of American Pathologists. Dr. Patel's clinical interests include companion diagnostics development and commercialization as well as the application of molecular diagnostics in the diagnosis and management of patients with hematologic malignancies.

Keyur Pravinchandra Patel MD, PhD, is a professor of pathology and laboratory medicine at the University of Texas M.D. Anderson Cancer Center. Dr. Patel serves as the director of the molecular diagnostics laboratory and the director of molecular genetic pathology fellowship program. His clinical interest includes developing innovative molecular biomarker testing for solid tumors and hematologic malignancies. His professional interest includes developing sustainable clinical molecular testing platforms incorporating evidence-based framework, quality and patient safety, test utilization management, billing and reimbursement.

Dr. Patel is actively involved in several national and international efforts to standardize molecular testing and, to develop clinical practice guidelines. He contributes actively to efforts related to the economics aspect of molecular testing. He has contributed to more than 300 peer-reviewed publications and is passionate about training the next generation of molecular genetic pathology (MGP) experts.

Victoria M. Pratt, Ph.D., FACMG, is the Director of Scientific Affairs for Pharmacogenetics at Agena Bioscience. Dr. Pratt is the Past President of Association for Molecular Pathology. Dr. Pratt continues to serve on the Centers for Disease Control and Prevention (CDC) GeT-RM program for reference materials for Molecular Genetics, the National Academy of Medicine's Roundtable on Genomics and Precision Health, and the American Medical Association's (AMA) Molecular Pathology Current Procedural Terminology (CPT) Advisory committee.

Dr. Pratt graduated with a Ph.D. in Medical and Molecular Genetics from Indiana University School of Medicine. Her fellowship training was in Ph.D. Medical and Clinical Molecular Genetics at Henry Ford Hospital, Detroit MI.

Ester Stein, BS, MBA, is Director of Corporate Reimbursement and reports into Abbott's Government Affairs' office which is based in Washington DC. Ester is highly knowledgeable in diagnostic reimbursement strategies for traditional diagnostics, molecular and point of care. In her capacity, she has spearheaded efforts to ensure that there is appropriate coverage, coding and payment by public and private insurers for Abbott products in the United States. Ester has also been involved in healthcare economics in the area of infectious disease, oncology, specifically breast and bladder cancer. She is active with AdvaMed's Payment Work Group and served as Chair, she serves on the AMP Economic Affairs Committee and is a member of the AACC Coding and Reimbursement Committee. Ester earned her M.B.A. from Loyola University of Chicago.

Eric Vail, MD, is the Director of Molecular Pathology at Cedars-Sinai Medical Center as well as an assistant professor of Pathology and Laboratory Medicine and the Associate Director of the Molecular Genetic Pathology Fellowship. His clinical and research focus is on utilization of biomarker profiling in oncology. Dr. Vail has extensive experience in economic issues pertaining to laboratory medicine and serves as the vice chair of the AMP Economic Affairs Committee Coverage Subcommittee.

Heather E. Williams, PhD, MBA, MS, PgD, ErCLG, CG(ASCP)CMMBCM, is a Pathology & Laboratory Medicine Executive and Clinical Laboratory Geneticist. She serves as Vice President, Clinical Genomics Operations & Chief of Staff at Cache DNA, a biotechnology startup in the San Francisco Bay, California, US. Dr. Williams's completed an Executive MBA from Yale School of Management and holds European Board of Medical Genetics (EBMG) certification, and is a United Kingdom Health and Care Professions Council (HCPC) registered Clinical Scientist (Genomics).

Previously, she led Cancer Testing at Harbinger Oncology (Harbinger Health) and was a Principal Clinical Scientist/Deputy Head at King's College Hospital in London. She's a recognized authority on ISO15189 medical laboratory standards, health equity in genomic medicine, and standards for genomic data usage. Dr. Williams has authored significant publications, including Advocacy and Government Affairs issues and recommendations on the classification of pathogenicity of somatic variants in cancer.

Her commitment extends beyond the lab. An advocate for women in science and biotechnology, she's been acknowledged with accolades like the ASCP "40 Under Forty," Women Who Code's 2023 "Applaud Her Awards," and shortlisted for StartUp Magazine's "Inspirational Womxn of the Industry." Dr. Williams focuses on the collaborative open sharing and standardization for the classification of variants to determine clinical significance, addressing emerging issues in access to genomic testing, and supporting the recognition, certification, and global awareness of Laboratory Genomic Professionals.

About AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,900+ members include individuals from academic and community medical centers, government, and industry, including pathologists and PhD scientists, and medical technologists.

Through the efforts of its Board of Directors, Committees, Working Groups, and members, AMP serves as a primary resource for molecular pathology education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing.