Over-the-Counter Diagnostics: Advancing Home as a Health Care Hub

Hybrid Public Meeting

Rooftop Meeting Space | 1333 New Hampshire Ave NW | Washington, DC 20036

March 25, 2026 | 1–4:30pm ET

Speaker Biographies

Tanya Altmann, MD, FAAP
Calabasas Pediatrics

A UCLA-trained pediatrician and working mom, Dr. Altmann is a nationally recognized child health expert. She is the author of several best-selling parenting books including the *American Academy of Pediatrics*, *Baby and Toddler Basics*, *What to Feed Your Baby* and is Editor-in-Chief of the *American Academy of Pediatrics, Caring for Your Newborn and Young Child: Birth to Age 5 and Your Baby's First Year*. As a regular child health expert for numerous news programs and talk shows, Dr. Altmann communicates complicated medical issues into easily understood concepts, discusses breaking medical news stories, and controversial parenting issues. She started Calabasas Pediatric Wellness Center to provide personalized and integrative comprehensive pediatric healthcare. With over 25 years of experience caring for children, Dr. Altmann is sought after for her expertise in helping parents raise healthy, resilient kids with a desire to learn and succeed in school and life. From start-ups to Fortune 500 companies, Dr. Altmann consults on research and development, educational materials, marketing, and media strategies for a variety of child products and health companies. Her expertise lies in nutrition, safety, and overall wellness for children from birth through college.

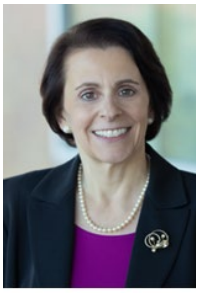
James C. Appleby, BSPharm, MPH, ScD (Hon)
Gerontological Society of America

James C. Appleby is the Chief Executive Officer of the Gerontological Society of America (GSA), the nation's largest interdisciplinary organization devoted to research, clinical practice, education, and policy in the aging field. The Society's 6,500 expert members advance innovation in aging and disseminate research insights for scientists, practitioners, policy makers and the public. GSA's Concentric Value of Vaccinations platform showcases the way one vaccination has a positive impact well beyond the individual to include family members, co-workers, communities, and society. GSA's National Center to Reframe Aging is the trusted source for proven communication strategies reshaping the conventional narrative around aging and advancing new approaches to end ageism. Prior to joining GSA, Mr. Appleby served as Chief Operating Officer at the American Pharmacists Association. He is a pharmacist, holds an MPH degree from Temple University, and has been awarded an Honorary ScD degree from the University of the Sciences in Philadelphia. He is a member of the National Alliance for Caregiving Board of Directors and serves as Co-Chair of the Mayor's Age-Friendly DC Task Force in Washington, DC.

Ramy Arnaout, MD, DPhil, FCAP, FASCP
Beth Israel Deaconess Medical Center

Ramy Arnaout, MD, DPhil, is Associate Director of Clinical Microbiology at Beth Israel Deaconess Medical Center (BIDMC), Director of the Arnaout Laboratory for Immunomics and Informatics, Associate Professor of Pathology at Harvard Medical School, and a faculty member of the Division of Clinical Informatics at BIDMC. He is past president of the American Society of Microbiology Northeast Branch and past Chairman of the FDA/CMS/CDC CLIA Committee. He received his SB from MIT, DPhil from Oxford University (Marshall Scholarship), and MD from Harvard Medical School (Soros Fellow). He completed a residency in pathology at Brigham and Women's Hospital and postdoctoral work at the Broad Institute. During the COVID-19 pandemic, he spearheaded de novo development and clinical validation of 3D-printed nasopharyngeal swabs, as well as worked on the limits of detection of OTC and other COVID-19 tests. His work has been published in Nature, Nature Biotechnology, Proceedings of the National Academy of Sciences, and elsewhere. He is a past Reagan-Udall Foundation for the FDA and FDA contract awardee. His current research focuses on generative data, machine learning in complex datasets, and appropriateness of laboratory testing. His work on research policy, genomics, clinical best practices, and medical utilization has been the subject of editorials and covered in the lay press.

Deborah M. Autor, Esq
Hims & Hers



Deborah M. Autor, Esq. has over 30 years of experience at the highest levels of government and FDA-regulated industry. Deb Autor currently serves as Chief Policy Officer of telehealth provider Hims & Hers, as well as a member of its Board of Directors. She is also a Board Director of Amneal Pharmaceuticals, Inc. (AMRX) and Chair of the Board of the FDA Alumni Association. Ms. Autor has also served as CEO of strategic regulatory consulting firms Healthcare Innovation Catalysts, Inc. and Autor Strategies, LLC; Global Head of Regulatory Excellence at AstraZeneca; and Head of Strategic Global Quality and Regulatory Policy and Head of Global Quality Mylan N.V. Before entering industry, Ms. Autor was a senior leader at the FDA, most recently as Deputy Commissioner for Global Regulatory Operations and Policy where she oversaw all FDA inspections, criminal investigations and international operations for human and veterinary drugs, biologics, medical devices, tobacco and food. Before that, Ms. Autor served as Director of the Office of Compliance of the Center for Drug Evaluation and Research, leading enforcement and policy making for compliance with drug-related requirements. Before joining the FDA, Ms. Autor was a Trial Attorney in the Office of Consumer Litigation of the U.S. Department of Justice, where she litigated civil and criminal cases on behalf of the FDA. Ms. Autor received a Juris Doctor, Magna Cum Laude, from Boston University School of Law and a Bachelor of Arts in Psychology from Columbia University, Barnard College.

Julie Barnes, JD
Maverick Health Policy

Julie Barnes is a strategic advisor to organizations that need guidance about federal health policies and how to develop relationships with policymakers and influential advocacy organizations. As a former Capitol Hill staffer, healthcare attorney, and policy program director, Ms. Barnes informs business strategy in several healthcare arenas, including artificial intelligence, interoperability, data privacy, public and private health insurance and new payment models, and price transparency.

Kathryn Capanna, MBA
U.S. Food and Drug Administration

Kathryn Capanna has over 20 years of experience in MedTech innovation and evaluation. At FDA, she leads Strategy Development for cross-cutting initiatives within the Center for Devices and Radiological Health (CDRH), Office of Strategic Partnerships and Technology Innovation. She also serves as Executive Sponsor for the Home as a Healthcare Hub Initiative. She is dedicated to building partnerships and programs to cultivate a more patient-centered MedTech ecosystem, along the continuum from innovation to evaluation to access and care delivery. Her current focus is on FDA's Home as a Healthcare Hub initiative and the TAP Pilot: FDA's Medical Device Accelerator. Together, these efforts aim to catalyze patient-centered medtech innovation, through clear regulatory pathways and by facilitating skillful integration of patient, clinician and payer insights into early medtech product development strategies. At FDA, Kathryn has led many cross-functional teams to design, build and operationalize a portfolio of strategic programs to advance innovation and protect patient safety. This includes significantly expanding CDRH's involvement in public-private consortia and other strategic partnerships tackling challenges facing the medtech ecosystem. This also includes related policy development, culture change and organizational capacity building efforts in clinical trials innovation, incorporating patient experience data and perspectives, improving representation in medical device clinical research and product development, and advancing use of real-world eEvidence. Ms. Capanna was also part of the management team responsible for driving FDA's emergency response to COVID-19, focused on continued availability of critical medical devices and supplies, by monitoring for shortages and coordinating regulatory and US government mitigations. Prior to FDA, she worked in MedTech industry and academic research environments. Ms. Capanna's education includes biomedical engineering at the University of Pittsburgh, public health through Johns Hopkins, and a healthcare MBA from George Washington University.

Marcia Howard, PhD, CAE
Consumer Healthcare Products Association

As CHPA Vice President of Regulatory Affairs & Quality, Marcia D. Howard, PhD, CAE, provides support to the Regulatory & Scientific Affairs Committee (RSAC), is the staff liaison for the OTC Medical Device (OTC Device) Committee, and works to further policy objectives with the U.S. Food and Drug Administration (FDA) for drugs and medical devices. Dr. Howard assumed the role of scientific liaison for the CHPA Pediatric Cough Cold Task Group in 2009 and continues to lead this key initiative. She also assists with over-the-counter medicine issues and plays a critical role in coordinating the association's annual Regulatory, Scientific & Quality Conference (RSQ). Dr. Howard coordinates many of CHPA's internal and external meetings with members, regulators, and other stakeholders. Dr. Howard joined CHPA in 2004 from the Department of Physiological Sciences at the Oklahoma State University College of Veterinary Medicine. Prior to Oklahoma State, she worked at the School of Pharmacy at the University of Louisiana at Monroe; State Farm Insurance Company; and the Frederick Cancer Research Facility at Program Resources, Incorporated. Dr. Howard has degrees in biochemistry and pharmaceutical sciences. She is a member of the Drug Information Association (DIA), Regulatory Affairs Professional Society (RAPS), Society of Toxicology (SOT), and the American Society of Association Executives (ASAE). In 2016, she was named as an ASAE Diversity Executive Leadership Program (DELP) scholar (class of 2016-2018) and received her designation as a certified association executive (CAE) in January 2018. Dr. Howard currently serves on the ASAE CAE Professional Conduct Committee (2019-2020). She is also a member of the Southern Regional Educational Board (SREB) Chapter of the Institute for Teaching and Mentoring, and serves on the American Foundation for Pharmaceutical Education (AFPE) Planning and Education Committee.

Courtney H. Lias, PhD
U.S. Food and Drug Administration

Dr. Lias studied at the Johns Hopkins University School of Medicine where she received her PhD in Biochemistry, Cellular, and Molecular Biology. Currently, Dr. Lias is the Director of FDA's Office of In Vitro Diagnostic Devices. During her FDA career of over two decades, she has led efforts to promote development of new therapeutic and diagnostic devices, including devices for diabetes, genetic testing, infectious disease, and drug dosing and monitoring. In 2017, Dr. Lias received the Samuel J. Heyman Service to America Medal in Management Excellence. This honor was awarded for work promoting the efficient development and approval of the first automated insulin dosing system.

Michael Mina, MD, PhD
HTR Advisors

Michael Mina, MD, PhD, is a physician-scientist and expert in infectious disease epidemiology and immunology, vaccines, diagnostics, and public health innovation. He serves as a lecturer at MIT and leads initiatives focused on advancing next-generation public health tools and diagnostic systems. Dr. Mina's work centers on the development and deployment of rapid, accessible diagnostics and technologies that enable earlier detection of disease and more resilient health systems. He advises governments and corporations on the convergence of accessible tools for public health and previously led the US Government's nationwide Home Test-to-Treat Program to make diagnostics and treatment more accessible. He currently leads HTR Advisors, a leading consultancy focused on Technology, Health and Regulation, and serves as the Chief Medical and Strategy Officer of Truvian, creator of TruVerus, the first FDA-cleared multi-modal point of care instrument to run hematology, chemistry, and immnoassays in a single benchtop platform from small blood volumes. He is also the Chief Medical Officer of Invivyd, the leading manufacturer of monoclonal antibody therapeutics for infectious diseases. He previously served as an Assistant Professor of Epidemiology and Immunology and Infectious Diseases at the Harvard T.H. Chan School of Public Health and of Pathology at Harvard Medical School where he was also an associated medical director of the Brigham and Women's Hospital core molecular virology clinical lab and helped lead the Broad Institute of MIT and Harvard's infectious disease clinical lab. His research has spanned virology, immunology, and diagnostic technologies, including pioneering work on rapid antigen testing during the COVID-19 pandemic and broader efforts to expand decentralized and consumer-accessible testing. He has been recognized for his pioneering work in public health and technology, including being named by the Economist Magazine as a "Global Progress Maker" for pioneering work in clean water technologies, with an NIH Directors's Early Independence Award for his work on understanding the immune system across populations; was invited to receive an honororary doctorate from Colby College; and received the Medical Merit Award from the Kingdom of Bahrain for his work on how to use rapid diagnostics to comabt the COVID-19 pandemic.

Anita Nosratieh, PhD
Abbott

Anita Nosratieh, PhD, is a regulatory and technology leader with expertise spanning biomedical engineering, government, industry, and health policy. She currently serves as Director of Global New Product Introduction and U.S. Regulatory Affairs at Abbott Rapid Diagnostics, where she provides strategic oversight for regulatory pathways supporting new product development and commercialization. In this role, she partners closely with R&D, quality, clinical, manufacturing, and commercial teams to align global regulatory requirements, enabling timely access to compliant, high quality, rapid diagnostics worldwide. Prior to joining Abbott, Dr. Nosratieh served as Vice President of Technology and Regulatory Affairs at AdvaMed, the leading U.S. medical technology trade association. There, she led technical, regulatory, and scientific policy initiatives across areas including cybersecurity, premarket approvals, combination products, robotic assisted surgical devices, radiation therapy

devices, and key activities focused on international regulatory harmonization. Dr. Nosratieh began her career at the U.S. Food and Drug Administration, Center for Devices and Radiological Health, where she served as a lead reviewer of breast cancer screening and diagnostic devices. She earned her PhD in Biomedical Engineering from the University of California, Davis, and holds a BS in Electrical Engineering from California State University, Fullerton.

Patty Post, BA
Checkable

Patty Post is the Founder and CEO of Checkable Medical, a diagnostics company advancing the shift toward consumer-driven healthcare. She is leading the development of what is expected to become the first over-the-counter at-home rapid strep test in the United States, currently under FDA de novo review. Ms. Post founded Checkable to address what she describes as the "first mile problem in healthcare"— helping patients determine when medical care is necessary by enabling reliable testing from home. Her work sits at the intersection of diagnostics, regulatory innovation, and consumer health access. She actively engages with healthcare leaders, regulators, and policymakers on the future of over-the-counter diagnostics, telehealth integration, and expanding access to care through at-home testing.

Elizabeth Richardson, MSc
Canal Row Advisors

Elizabeth Richardson, MSc, is a VP at Canal Row Advisors. Prior to joining the firm, she was a Senior Manager of Public Policy at Amazon, leading health policy for the company's devices business. She has also previously held positions at the Pew Charitable Trusts, the Duke-Margolis Institute for Health Policy, the Brookings Institution, and the Urban Institute, where she principally focused on strengthening and improving medical product regulation to support innovation and safeguard patients and consumers.

Sam Surette, BS
Apple

Sam Surette leads the New Product Introduction (NPI) Regulatory Affairs team at Apple, responsible for Apple's health and wellness products. Prior to joining Apple, Sam led regulatory and quality at Caption Health (acquired by GE HealthCare), and served as a reviewer at FDA in the Division of Cardiovascular Devices (OHT2).

Stacey Swartz, PharmD
Neighborhood Pharmacy of Del Ray

Stacey Swartz, PharmD, is co-owner and Pharmacist in Charge at Neighborhood Pharmacy, a independent community pharmacy in Alexandria, VA which was founded in 2009. A graduate of Duquesne University, Dr. Swartz started her career with the National Community Pharmacist Association (NCPA) where she served as Senior Director, Pharmacy Affairs before leaving to open her own independent pharmacy. She has served on both the Virginia Board of Health and Del Ray Business Association boards. She currently a member of NCPA's Long Term Care Committee and previously served on their Technology and Federal Government Affairs committees. The Neighborhood Pharmacy of Del Ray has both retail and long-term care practices serving the greater Alexandria community and residents in group homes, city programs and private health at home patients.

Michael Umbleby, RPh
Walgreens

Mike Umbleby is Vice President, Pharmacy Administration and Services at Walgreens, specifically focusing on pharmacy services, including immunizations and adherence programs at Walgreens. Mike began his career at Walgreens in 1996 where he held various roles including pharmacy management and clinical oversight across several stores and regions. In 2008, Mr. Umbleby moved to Walgreens corporate headquarters and has held multiple leadership positions where he was responsible for launching enterprise-wide change initiatives across the organization, overseeing pharmacy innovation projects, leading sales operations and client services for sales and account management teams, and responsible for Walgreens clinical services and product innovation to support payer, bioPharma and plan sponsor partners. He also led the clinical model integration and joint products and services with value-based care provider VillageMD. Mike most notably led Walgreens pandemic response efforts around COVID-19 testing. Mike received his Bachelor of Science in Pharmacy from the University of Pittsburgh.

Paul Wardle, MA, MMath
Klick USA Inc.

Paul Wardle is SVP, Innovation Consulting, at Klick USA Inc., with more than 30 years of healthcare product experience. His work focuses on advancing consumer-centric solutions that improve the availability, access, and adoption of healthcare products through innovative regulatory and consumer engagement strategies. Mr. Wardle has led and supported numerous prescription-to-nonprescription initiatives across a broad range of therapeutic areas, both in the US and globally. He currently leads a Health Equity & Access practice, which supports initiatives designed to address patient and consumer barriers to care and expand medication and device access. This includes programs across telehealth-enabled models, the ACNU NDA pathway, Rx-to-OTC switches, and other nonprescription access strategies. Mr. Wardle has published articles and presented on multiple occasions on the consumer interest, regulatory, public health, and business implications of transforming

medication access. Mr. Wardle has master's degrees in mathematics and theoretical physics from the University of Cambridge. He also serves as an adjunct instructor at New York University, teaching graduate level courses in statistics, measurement, and analysis.

John Whyte, MD, MPH
American Medical Association

John Whyte, MD, MPH, serves as the CEO and Executive Vice President of the American Medical Association (AMA), the nation's largest physician organization. Prior to the AMA, Dr. Whyte served as the Chief Medical Officer at WebMD, leading initiatives that expanded strategic partnerships, created new business opportunities, and positioned WebMD at the forefront of digital health innovation. He was a pivotal force in evolving WebMD's digital platforms from content delivery engines to powerful tools connecting consumers directly to care, establishing critical new revenue models. He is a recognized leader in healthcare delivery and regulation and is consistently named as one of the Top 20 Health Influencers. Before joining WebMD, Dr. Whyte served as Director of Professional Affairs and Stakeholder Engagement at the U.S. Food and Drug Administration's Center for Drug Evaluation and Research. There, he spearheaded groundbreaking initiatives to modernize clinical trial design, expand diversity in research, and advance the regulatory use of real-world evidence – efforts that continue to impact patient-centered drug development today. Earlier, as Chief Medical Expert and Vice President of Health and Medical Education at Discovery Channel, Dr. Whyte launched educational programming that captured both medical and mainstream audiences, successfully aligning mission-driven health education with corporate funding strategies and building new multimedia brand identities. At the Centers for Medicare & Medicaid Services (CMS), Dr. Whyte played a pivotal role in formalizing Medicare's national coverage decision process, directly shaping payment policies and advancing innovative models to improve healthcare outcomes. His experience at CMS demonstrates a deep understanding of health policy, reimbursement strategies, and the critical intersection of clinical innovation and payment models. A board-certified internist, Dr. Whyte completed his MD at Hahnemann University School of Medicine, his residency at Duke University Medical Center, and earned his MPH in Health Policy and Management at Harvard University. He previously served as a health services research fellow at Stanford University. An accomplished author, Dr. Whyte has written extensively for both professional and consumer audiences, including five best-selling books.

Moderator

Susan C. Winckler, RPh, Esq
The Reagan-Udall Foundation for the FDA

Susan Winckler is CEO of the Reagan-Udall Foundation for the Food and Drug Administration. Prior to accepting the Foundation post, Ms. Winckler served as President of Leavitt Partners Solutions. As President and Chief Risk Management Officer for the Leavitt Partners family of businesses, Ms. Winckler advised corporate executives on policy and business matters. As CEO of the Food & Drug Law Institute, she provided attorneys, regulators, and other stakeholders with a neutral forum to address domestic and global issues. As Chief of Staff for the

FDA (2007-2009), Ms. Winckler managed the Commissioner's Office, served both Republican and Democratic commissioners as their senior-most staff adviser, analyzed complex policy challenges, and represented FDA with myriad government entities and external stakeholders. Her earlier career service included more than a decade at the American Pharmacists Association. Ms. Winckler earned a bachelor's degree from the University of Iowa College of Pharmacy and her law degree magna cum laude from Georgetown University Law Center. She is an APhA Fellow and an elected member (2015-2020, 2020-2025) and Chair (2018- mid-2025) of the United States Pharmacopeial Convention (USP) Board of Trustees. In 2023, she received the Distinguished Alumni Award of the Food and Drug Administration Alumni Association and, separately, was awarded the Osterhaus Medal for Lifetime Achievement by the Univ. of Iowa College of Pharmacy.