SPEAKER BIOGRAPHIES

ANNE C. BEAL, MD, MPH
Global Head of Patient Solutions
Sanofi

Dr. Beal joined Sanofi as the Chief Patient Officer in 2014. In that role, she supports a culture of patient-centeredness that ensures patients, their needs and priorities, come first in all the work of Sanofi.

Prior to that, she was the Deputy Executive Director and Chief Engagement Officer for The Patient-Centered Outcomes Research Institute. As The Patient-Centered Outcomes Research Institute's first Chief Officer for Engagement, Dr. Beal was charged with ensuring that the voices of patients and other stakeholders are reflected in their research portfolio. Earlier in her career, Dr. Beal was president of the Aetna Foundation, the independent charitable and philanthropic arm of Aetna Inc., overseeing programs focused on addressing the rising rates obesity in the U.S.; promoting racial and ethnic equity in health and health care; and advancing integrated health care and care coordination.

Dr. Beal's career in philanthropy started at the Commonwealth Fund as Assistant Vice President for the Program on Health Care Disparities and oversaw programs on eliminating health disparities. Dr. Beal is a board-certified pediatrician and began her career working on mobile medical units delivering healthcare services to children living in homeless shelters throughout New York City. She was also a health services researcher at Harvard Medical School within the Center for Child and Adolescent Health Policy at Massachusetts General Hospital. In addition, she was Associate Director of the Multicultural Affairs Office of Massachusetts General Hospital, an attending pediatrician within the division of General Pediatrics, and held faculty positions both within Harvard Medical School and the Harvard School of Public Health.

COURTNEY E. BAIRD, MS
Research Data Analyst
Weill Cornell Medicine

Courtney Baird, M.S., is a Research Data Analyst in the Healthcare Policy & Research Department, Division of Comparative Effectiveness and Outcomes Research, at Weill Cornell Medicine. She carries out statistical analyses using large administrative databases to conduct comparative effectiveness and outcomes research on surgical medical devices and procedures. She holds a Master of Science in Health Policy & Economics from Weill Cornell Graduate School of Medical Sciences and a Bachelor of Arts in International Economics from The Johns Hopkins University.

She also serves as the Program Manager for the Medical Device Epidemiology Network's (MDEpiNet) Coordinating, Science and Infrastructure Center at Weill Cornell. MDEpiNet recently launched a CRN Community of Practice made up of CRNs in 12+ clinical areas with the primary objective to assist CRN development as a robust source of evidence for device evaluation and to

serve as a foundational component of NEST. Ms. Baird has been working to increase MDEpiNet's engagement with patients by recruiting patient partners to join the CRN leadership teams. The CRN patient partners bring the knowledge, experience and perspective of the patient community to CRN projects, advise CRN working groups on the needs and interests of the patient community and help develop real-world data infrastructure that collects and communicates clinical evidence and outcomes that are of interest to patients.

DANICA MARINAC-DABIC, MD, PhD, FISPE, MMSc
Director, Division of Epidemiology, Office of Surveillance and Biometrics
Center for Devices and Radiological Health,
Food and Drug Administration

Danica Marinac-Dabic has over twenty years of experience in obstetrics, gynecology, perinatal epidemiology, and regulatory science and surveillance settings. A physician and an epidemiologist by training Dr. Marinac-Dabic heads scientific oversight of device post market studies mandated by Food and Drug Administration. Dr. Marinac-Dabic also oversees the Center for Devices and Radiological Health's Epidemiologic Regulatory Science Program charged with advancing the methodologies and infrastructure for evidence development and appraisal with application to medical device regulatory science.

In 2010, under Dr. Marinac-Dabic' s leadership, the Food and Drug Administration launched the Medical Device Epidemiology Network Initiative to develop national/international infrastructure and innovative methodological approaches for conducting robust studies and surveillance to improve medical device safety and effectiveness understanding throughout the device life cycle through Public Private Partnership with academia and other stakeholders. In this context Dr. Marinac-Dabic leads the Food and Drug Administration's International Consortium of Orthopedic Registries Initiative (launched in 2011), focusing on development and utilization of distributed model of over 30 national and international orthopedic registries capturing information on over 5.5 million orthopedic procedures worldwide.

Under her leadership, the Food and Drug Administration launched its International Consortium of Cardiac Registries in 2013 and in 2014 International Consortium of Vascular Registries Initiatives designed to expand collaborative work between international cardiovascular registries and integrate it into medical device regulatory science, active surveillance and comparative effectiveness and safety research. Dr. Marinac-Dabic serves as a Fellow of the International Society of Pharmaco-epidemiology and Therapeutic Risk Management, Food and Drug Administration Principal and the member of the Executive Committee of the Medical Device Epidemiology Network Public Private Partnership, member of the Steering Committee of the STS/ACC Transcathether Valve Therapies Registry, National Breast Implants Registry and Oxford-based IDEAL Collaborative, EXCITE International Collaborative.

Dr. Marinac-Dabic leads the Registry Working Group at the International Medical Device Regulators Forum to develop essential for international convergence of registry-generated data for regulatory decision making. She authored several book chapters, several dozens of manuscripts and invited presentations on various topics in the fields of medical device epidemiology and surveillance, registry development and utilization for medical device research, innovative methods for evidence synthesis and comparative effectiveness and safety research. Prior to coming to the Food and Drug Administration, Dr. Marinac-Dabic garnered experience in obstetrics, gynecology, and epidemiology in the academic and hospital settings as well as teaching experience in academic environment.

C. DANIEL MULLINS, PhD

Professor and Chair, Pharmaceutical Health Services Research Department
Director, PATIENTS Program
University of Maryland School of Pharmacy

Dr. Mullins' research and teaching focus on pharmacoeconomics, comparative effectiveness research, patient-centered outcomes research, and health disparities research. He has received funding as a Principal Investigator from the Agency for Healthcare Research and Quality, National Institute on Aging, the National Heart, Lung, and Blood Institute, the Patient-Centered Outcomes Research Institute, various pharmaceutical manufacturers including Bayer, Pfizer and Sanofi-Aventis, patent advocacy organizations, and the insurance industry. For more information on Dr. Mullins' research projects, please see the Research Projects section.

In addition to his faculty appointment, Dr. Mullins also serves as the Associate Director of the Center on Drugs and Public Policy at the School of Pharmacy, as well as the Co-Editor-in-Chief for Value in Health.

Outside the university, Dr. Mullins actively conducts training programs, which include continuing education lectures and similar activities for the Food and Drug Administration, professional organizations, and training in developing countries.

Dr. Mullins received his Bachelor's in Economics from M.I.T. and his PhD in Economics from Duke University.

FADIA T. SHAYA, PhD, MPH

Professor and Vice-Chair,
Pharmaceutical Health Services Research Department
Associate Director, Center on Drugs and Public Policy
Institute for Clinical and Translational Research
Bioinformatics University of Maryland School of Pharmacy

Fadia T. Shaya PhD, MPH, is a tenured Professor of Pharmacoeconomics and Pharmacoepidemiology in the Department of Pharmaceutical Health Services Research at the University of Maryland School of Pharmacy, and a member of the Maryland-Food and Drug Administration Center for Excellence in Regulatory Sciences, the Executive Director of the Behavioral Health Research and Policy Program, and Director in the Center on Drugs and Public Policy. Dr. Shaya is the Informatics core co-lead in the Institute for Clinical and Translational Research.

Dr. Shaya's research supports stakeholder engagement, including patients and providers, in drugs and medical devices value assessment. Her work spans all stages of drug development, from pre-clinical trials to post-marketing surveillance. She has experience developing comparative effectiveness research, clinical, economic, policy, decision analytic and budget impact models. She has reviewed over 500 papers, federal grant proposals and published over 230 articles.

She regularly presents at national and international scientific and policy meetings, with over 200 presentations and posters to date. Dr. Shaya obtained her doctorate from the Johns Hopkins Bloomberg School of Public Health, her doctoral health economics degree from the Sorbonne University Paris-IX Dauphine in France and her Master of Public Health and Bachelor of Science in Pharmaceutical Sciences from the American University of Beirut.

FRANCIS B. PALUMBO, PhD, JD

Professor, Pharmaceutical Health Services Research Department
Executive Director, Center on Drugs and Public Policy,
University of Maryland School of Pharmacy

Dr. Palumbo is a member of the Maryland and District of Columbia Bars and a licensed pharmacist. He has practiced both pharmacy and law. As an adjunct professor at the University Of Maryland School Of Law, he teaches the course in food and drug law. In addition, he served as chair of the editorial advisory board of the *Food and Drug Law Journal*.

Dr. Palumbo has been the principal investigator on major federal research grants and he served as a member of a NIH study section for more than four years. In addition to law, he maintains a strong interest in public policy, pharmacoeconomics, pharmacoepidemiology, and health services research. He has many journal articles and presentations to his credit, covering a wide range of topics including law and public policy, and he co-authored a book on containing costs in third party drug programs. He has also been very active in several national professional organizations, including the American Pharmacists Association, where he served as President of the Academy of Pharmaceutical Research and Science, and the American Society for Pharmacy Law, where he is a past president.

He received his Bachelor of Science in pharmacy from the Medical University of South Carolina, masters and doctorate in health care administration from the University of Mississippi, and Juris Doctorate from the University Of Baltimore School Of Law. He served in the US Army from 1969-1971.

JEFFREY E. SHUREN, MD, JD

Director, Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)

Jeffrey Shuren, MD, JD is the Director of the Center for Devices and Radiological Health (CDRH) at the Food and Drug Administration. He previously served as Acting Center Director. Dr. Shuren has held various policy and planning positions within Food and Drug Administration from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner.

Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, Dr. Shuren joined the Food and Drug Administration as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. From 1998 to 2003, he served as a Staff Volunteer in the National Institutes of Health's National Institute of Neurological Disorders and Stroke Cognitive Neuroscience Section supervising and designing clinical studies on human reasoning. Dr. Shuren returned to the Food and Drug Administration as the Assistant Commissioner for Policy in 2003 and assumed his current position in September 2009.

JOEY MATTINGLY, PharmD, MBA

Assistant Professor and Director of Operations for the PATIENTS Program

University of Maryland School of Pharmacy

After graduating from pharmacy school, Dr. Mattingly managed four different Kroger Pharmacy locations between 2010 and 2012 before being promoted to serve as District 6 Pharmacy Coordinator in Carbondale, Illinois, overseeing operations for 12 pharmacies. In 2013, Dr. Mattingly left The Kroger Company to lead Indianapolis operations as general manager for a start-up long-term care company called AlixaRx, providing pharmacy services and remote automated dispensing systems to 23 skilled nursing facilities across Indiana, Kentucky, and Ohio.

He currently serves as an assistant professor in the Department of Pharmacy Practice and Science at the University of Maryland School of Pharmacy, where he teaches business strategy to students in the professional program and is a strategic consultant for the University of Maryland Medical Center Department of Pharmacy. In 2016, Dr. Mattingly was selected as the graduating class Teacher of the Year.

In addition to his work as a faculty member, he serves as the Director of Operations for the PATIENTS Program and is a PhD candidate in Pharmaceutical Health Services Research with a special focus in pharmacoeconomics and patient engagement. His research focuses on a mixed-method approach to incorporate the patient voice in economic evaluations and other value assessment frameworks.

KATHLEEN M. HEWITT, DNP, RN, CPHQ

Associate Vice President

National Cardiovascular Data Registry (NCDR)

American College of Cardiology (ACC)

Kathleen M. Hewitt is responsible for the management and operation of a broad range of data registries measuring and improving quality patient care throughout the nation. Under Dr. Hewitt's leadership the National Cardiovascular Data Registry has grown into an unprecedented quality measurement program that over 2,500 hospitals and healthcare systems view as their gold standard benchmark and measurement tool.

Dr. Hewitt's twenty-year healthcare career reflects her dedication and passion for improving cardiovascular care. Her special interest in healthcare informatics combined with her "hands-on" experience in providing cardiovascular related care brought her to the National Cardiovascular Data Registry. Prior to coming to the American College of Cardiology, Dr. Hewitt held several positions focusing on quality patient care and performance improvement at INOVA Fairfax Hospital, an 833-bed tertiary care hospital in Northern Virginia. As a Case Manager, Cardiac Surgery; Assistant Patient Care Director, PCCU/CCU; Assistant Director, EP Lab; and Invasive Cardiovascular Clinical Practice Specialist, Dr. Hewitt gained a critical awareness of the value of accurate, complete, and timely information when evaluating the quality of patient care.

Dr. Hewitt obtained her Bachelor of Science in Nursing and Master of Science in Nursing from George Mason University in 1988 and 1997, respectively. In 2001, she received her Certified Professional for Healthcare Quality.

KATHRYN M. O'CALLAGHAN
Assistant Director for Strategic Programs
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)

Katie is dedicated to building productive partnerships and promoting use of actionable information to reduce health disparities and to drive more patient-centric medical product innovation, evaluation, access, and care. Katie oversees a broad and diverse program portfolio at CDRH, with teams supporting a number of strategic partnership and regulatory science programs. Her focus is on an organization-wide change effort aimed at promoting a culture of meaningful patient engagement between patients and CDRH's employees and increasing use of patient input as evidence in regulatory decisions and actions. Execution impacts more than 1700 employees and dozens of programs and processes across eight organizational departments and strengthens CDRH's ability to meet its mission to protect and promote public health.

Katie is a biomedical engineer by training and worked in academic research and MedTech industry prior to her 12+ years at FDA. She can be contacted at kathryn.ocallaghan@fda.hhs.gov.

LISA MILLER NOEL, BSN, MPH, PhD
Senior Fellow in the Office of Center Director
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA).

As Patient Engagement Lead, Dr. Noel is implementing a strategic framework to support a culture of meaningful patient engagement between patients and Center staff . Over a 40-year career, she has a diverse and unique background that includes critical care nursing, public health, clinical trial research, and teaching. Dr. Noel served as co-director of the American Andes Biomedical Expedition that conducted several international medical research expeditions studying the impact of prophylaxis medication on Acute Mountain Sickness. Based on a CDC grant, Dr. Noel established the statewide, population-based birth defects surveillance program for the Massachusetts Department of Public Health, that included 56 birthing hospitals. She published the first comprehensive, state-wide report on birth defects for the state of Massachusetts and collaborated with several other states on the National Birth Defects Prevention Study. She has served as faculty at the George Washington University School of Public Health. Dr. Noel received her PhD from the Johns Hopkins School of Public Health and Hygiene (now, Bloomberg School of Public Health, receiving the Ruth B. Freeman award for her dissertation, "The Widening Gap in Death Rates among Social Classes in the United States, 1967, 1986."

NATALIE D. EDDINGTON, PhD, FAAPS, FCP
Dean, University of Maryland School of Pharmacy
Professor of Pharmaceutical Sciences
Executive Director, University Regional Partnerships

Dr. Eddington earned a bachelor's in pharmacy from Howard University and a doctorate in pharmaceutical sciences from University of Maryland School of Pharmacy. After completion of her doctorate, Dr. Eddington was appointed as the clinical director of new drug development at Pfizer

Inc. After three years at Pfizer, Dr. Eddington began her academic career at University of Maryland School of Pharmacy as an assistant professor, where she also served as chair of the Department of Pharmaceutical Sciences and director of the Pharmacokinetics-Biopharmaceutics Laboratory.

Dr. Eddington is a nationally-known expert in drug delivery and pharmacokinetics. Her research focuses on various medications used in the treatment of cancer, epilepsy, arthritis, drugs of abuse and on understanding the role of biopharmaceutics and pharmacokinetics in elucidating the underlying mechanisms important in optimizing drug therapy. Her research has been supported by the National Institutes of Health (NIDA, NIBIB, NIMH, NCI), the U.S. Food and Drug Administration, the Department of Defense, and the pharmaceutical industry. Dr. Eddington is the author of more than 125 publications and has given more than 150 presentations and 100 invited lectures on topics related to pharmacokinetics, pharmacodynamics, transporter processes, and academic pharmacy.

Dr. Eddington's research served as the basis for numerous regulatory guidance's implemented by the Food and Drug Administration. Specifically, the School of Pharmacy's research in support of the Scale Up and Post Approval Changes guidance's has directly saved the pharmaceutical industry more than $1.5 billion and has saved the Food and Drug Administration timeless hours of review through reductions in regulatory burden. This research was supported by an $11 million grant from the Food and Drug Administration.

Under Dr. Eddington's leadership, the School of Pharmacy has established a number of centers and programs, including the Center for Innovative Pharmacy Solutions; the Patients, Pharmacists, Partnerships Program; the Patient-centered Involvement in Evaluating the effectiveness of Treatment (PATIENTS) Program; the Bio- and Nano-technology Center, the Center for Translational Medicine, the Mass Spectrometry Center, and the Food and Drug Administration-supported Maryland Center of Excellence in Regulatory Science and Innovation, which is a collaborative agreement with the Food and Drug Administration to promote innovation in support of the development and evaluation of safe and effective products. Dr. Eddington has designed numerous international regulatory courses for clinicians and scientists from South Korea, Argentina, Brazil, the United States, and Japan on the United States' drug development process and the Food and Drug Administration regulatory infrastructure surrounding medication and device development. Most recently, under Dr. Eddington's leadership, the School has launched a transformational pharmapreneurism initiative, which seeks to position the School's world class faculty, its wonderful students, and exceptional staff to achieve their career aspirations and address our nation's health care, research, policy, and societal needs.

Dr. Eddington has served as co-chair of the University of Maryland, Baltimore's Middle States Accreditation Committee and as chair of the National Institute of Pharmaceutical Technology and Education, a non-profit, sixteen-member university consortium conducting research and education on the science of pharmaceutical technology manufacturing and regulatory sciences.

Dr. Eddington has been very active within the American Association of Colleges of Pharmacy, serving as chair of its Council of Deans Diversity Task Force, as the Administrative Board representative, and as dean facilitator and mentor in its Academic Leadership Fellows program. She is past chair of American Association of Colleges of Pharmacy's Council of Deans and is completing her service as chair of the association's Research and Graduate Affairs Committee. She has also served on the American Society of Health-System Pharmacists' Council on Workforce and Education, and as chair of the American Association of Pharmaceutical Scientists' Program Coordinating Committee and its Annual Meeting Programming Committee.

Dr. Eddington is a fellow of American Association of Pharmaceutical Scientists and of the American College of Clinical Pharmacology.

PHILIP P. GOODNEY, MD, MS

Surgeon and Health Services Researcher

Vascular Quality Initiative/Society for Vascular Surgery Patient Safety Organization

Dr. Goodney maintains an active clinical practice in vascular surgery, at both Dartmouth Hitchcock and the VA Medical Center in White River Junction, and he enjoys performing a wide spectrum of open and endovascular procedures for patients with vascular disease.

With funding from NIH, AHRQ, VA, FDA, PCORI, and others, Dr. Goodney has enjoyed studying ways to help patients obtain the best results when they face surgical treatments using observational approaches and clinical trials. Within the Vascular Quality Initiative, with Drs. Art Sedrakyan and Jack Cronenwett, he leads efforts funded by FDA to develop the Vascular Implant Surveillance and Interventional Outcomes Network (VISION), a claims/registry-based surveillance distributed research network for vascular care.

RACHEL R. RATH, MPH

Deputy Director

NEST Coordinating Center

Medical Device Innovation Consortium

Rachel R. Rath joined the Medical Device Innovation Consortium from the Patient-Centered Outcomes Research Institute (PCORI). Since joining the Patient-Centered Outcomes Research Institute in 2014, she helped build and manage the development of the PCORnet, the National Patient-Centered Clinical Research Network, a transformational effort to engage patients and leverage electronic health data to improve the speed and efficiency of clinical research in the United States.

Most recently she focused her on governance, sustainability, and communications efforts to advance the mission of PCORnet. The Patient-Centered Outcomes Research Institute's investment in PCORnet has exceeded $400 million from a combination of infrastructure and research investments. In March 2017, the PCORnet partners successfully launched an independent non-profit entity to advance the long-term sustainability of PCORnet. Prior to joining the Patient-Centered Outcomes Research Institute, she worked with disease-specific organizations including the National Multiple Sclerosis Society and the COPD Foundation and served as an Applied Behavioral Analysis Therapist for children with Autism Spectrum Disorders.

Rachel received her MPH in global health policy from The George Washington University and is currently pursuing an MBA from Georgetown University.

STEPHEN N. DAVIS, MBBS, FRCP, FACE, MACP
Theodore E. Woodard Professor of Medicine
Professor of Physiology
Chairman, Department of Medicine
University of Maryland School of Medicine
Vice President of Clinical Translational Science
University of Maryland, Baltimore
Physician-in-Chief
University of Maryland Medical Center

An internationally recognized endocrinologist and research scientist, Dr. Davis's major research interests include studying neural control of metabolism, exercise physiology and metabolic regulation of in-vivo vascular biology in obese, diabetic and healthy individuals. His studies have demonstrated novel treatment strategies to restore the deficient autonomic nervous system responses during hypoglycemia and exercise.

Dr. Davis has substantial expertise and experience in the design, conduct, and interpretation of in-vivo human clinical physiology studies using glucose clamp and isotope dilution methodologies. He has published more than 220 original articles, reviews and textbook chapters in premier scientific journals, and has been recognized with many distinguished awards, including the prestigious Novartis Award for Diabetes Research.

TERRIE COWLEY
President and Co-Founder
The TMJ Association, Ltd.

Terrie Cowley's enduring work and dedication has been instrumental in increasing awareness of the needs of TMJ patients among key groups, including the public, patients, healthcare providers, policy-makers, Congress, NIH, FDA and media.

Ms. Cowley co-chairs the TMJ Patient RoundTable, the first patient-led project conducted under the auspices of the Medical Device Epidemiology Network, a public-private partnership developed to bring real world data-patient experiences together with a broad array of experts to conduct studies aimed at improving treatment outcomes for TMJ patients.