SPEAKER BIOGRAPHIES

Keynote

Robert M. Califf, MD
Commissioner of Food and Drugs
Food and Drug Administration

Robert M. Califf, M.D., is Commissioner of Food and Drugs. President Joe Biden nominated Dr. Califf to head the U.S. Food and Drug Administration and Dr. Califf was sworn in on February 17, 2022. Previously, Dr. Califf served as Commissioner of Food and Drugs from February 2016 to January 2017. As the top official of the FDA, Dr. Califf is committed to strengthening programs and policies that enable the agency to carry out its mission to protect and promote the public health. Dr. Califf served as the FDA's Deputy Commissioner for Medical Products and Tobacco from February 2015 until his first appointment as Commissioner in February 2016.

Prior to rejoining the FDA, Dr. Califf was head of medical strategy and Senior Advisor at Alphabet Inc., contributing to strategy and policy for its health subsidiaries Verily Life Sciences and Google Health. He joined Alphabet in 2019, after serving as a professor of medicine and vice chancellor for clinical and translational research at Duke University. He also served as director of the Duke Translational Medicine Institute and founding director of the Duke Clinical Research Institute. A nationally and internationally recognized expert in cardiovascular medicine, health outcomes research, health care quality, and clinical research, Dr. Califf has led many landmark clinical trials and is one of the most frequently cited authors in biomedical science, with more than 1,300 publications in the peer-reviewed literature.

Dr. Califf became a Member of the National Academy of Medicine (formerly known as the Institute of Medicine (IOM)) in 2016, one of the highest honors in the fields of health and medicine. Dr. Califf has served on numerous IOM committees, and he has served as a member of the FDA Cardiorenal Advisory Panel and the FDA Science Board's Subcommittee on Science and Technology. Dr. Califf has also served on the Board of Scientific Counselors for the National Library of Medicine, as well as on advisory committees for the National Cancer Institute, the National Heart, Lung, and Blood Institute, the National Institute of Environmental Health Sciences and the Council of the National Institute on Aging.

While at Duke, Dr. Califf led major initiatives aimed at improving methods and infrastructure for clinical research, including the Clinical Trials Transformation Initiative (CTTI), a public-private partnership co-founded by the FDA and Duke. He also served as the principal investigator for Duke's Clinical and Translational Science Award and the NIH Health Care Systems Research Collaboratory Coordinating Center.

Dr. Califf is a graduate of Duke University School of Medicine. He completed a residency in internal medicine at the University of California, San Francisco and a fellowship in cardiology at Duke.

Source: https://www.fda.gov/about-fda/fda-organization/robert-califf

Plenary

Patrizia Cavazzoni, MD
Director
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Patrizia Cavazzoni, MD, is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. The Center's mission is to ensure that safe, effective, and high-quality drugs are available to the public. To achieve this, CDER regulates the medical products under its jurisdiction throughout their lifecycle, oversees the development of new and generic drugs, evaluates applications to determine whether drugs should be approved, monitors the safety of drugs after they are marketed, conducts research to advance regulatory science and takes enforcement actions to protect the public from harmful products. Dr. Cavazzoni joined the FDA in January 2018 as CDER's Deputy Director for Operations where she has led several key initiatives on behalf of the organization. She also served as Acting Principal Deputy Commissioner of Food and Drugs from January 2019 to February 2019.

Dr. Cavazzoni received her medical degree at McGill University and completed a residency in psychiatry and a fellowship in mood disorders at the University of Ottawa. During her training, she was an investigator in clinical trials of novel antipsychotic and antidepressant medications and became a research collaborator within the International Group for The Study of Lithium Treated Patients. She subsequently received a full-time appointment to the Faculty of Medicine at the University of Ottawa and joined the Mood Disorders Program at the Royal Ottawa Hospital, where she treated patients suffering from severe mood disorders, taught students and conducted research on genetic predictors of bipolar disorder as part of a multidisciplinary international collaborative effort, authoring numerous peer-reviewed scientific publications.

After her tenure in academic medicine, Dr. Cavazzoni worked in the pharmaceutical industry for several years and held senior executive positions in clinical development, regulatory affairs, and safety risk management in large companies across multiple therapeutic areas, until she joined the FDA.

Dr. Cavazzoni obtained certification by the American Board of Neurology and Psychiatry in 1997 and 2008 and is a fellow of the Canadian Royal College of Physician and Surgeons. She is a fellow of the Canadian College of Neuropsychopharmacology and a recipient of the American College of Psychiatrists' Laughlin Fellowship.

Peter Marks, MD, PhD
Director
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Peter Marks, MD, PhD is the director of the Center for Biologics Evaluation and Research (CBER) at the Food and Drug Administration. The center is responsible for assuring the safety and effectiveness of biological products, including vaccines, allergenic products, blood and blood products, and cellular, tissue, and gene therapies.

Dr. Marks and center staff are committed to facilitating the development of biological products and providing oversight throughout the product life cycle. Examples of these activities include:

- reviewing and providing advice during product development
- evaluating applications and making approval decisions based on safety and effectiveness data
- monitoring the safety of biological products
- conducting research that supports product development and characterization

"The center regulates and does research on complex biologic products that touch people's lives on a daily basis," says Dr. Marks. "Many of the products that we regulate are vital for promoting and protecting the public health, including

vaccines, blood products, and tissues for transplantation. I'm very proud to lead a team of highly committed individuals whose efforts help to ensure the timely development of safe and effective products to meet important medical needs."

Dr. Peter Marks received his graduate degree in cell and molecular biology and his medical degree at New York University. Following this, he completed an Internal Medicine residency and Hematology/Medical Oncology fellowship at Brigham and Women's Hospital in Boston, where he subsequently joined the attending staff as a clinician-scientist and eventually served as Clinical Director of Hematology.

He then moved on to work for several years in the pharmaceutical industry on the clinical development of hematology and oncology products prior to returning to academic medicine at Yale University where he led the Adult Leukemia Service and served as Chief Clinical Officer of Smilow Cancer Hospital. He joined the FDA in 2012 as Deputy Center Director for CBER and became Center Director in 2016. Dr. Marks is board certified in internal medicine, hematology, and medical oncology, and is a Fellow of the American College of Physicians.

Jeffrey E. Shuren, MD, JD
Director
Center for Devices and Radiological Health (CDRH)
Food and Drug Administration (FDA)

Jeffrey E. Shuren, MD, JD became the director of the Center for Devices and Radiological Health at the Food and Drug Administration (FDA) in January 2010. He previously served as Acting Center Director, beginning in September 2009. The center is responsible for assuring the safety, effectiveness, and quality of medical devices; assuring the safety of radiation-emitting products (such as cell phones and microwave ovens); and fostering device innovation.

"Our center experts and programs help get safe and effective technology to patients and health care professionals on a daily basis," says Dr. Shuren. "Rapid technological advances enable us to approve such innovations as a diagnostic test for the H1N1 influenza virus, an expandable prosthetic rib for children with abnormal growth conditions, and a test that can help detect ovarian cancer."

Dr. Shuren received his B.S. and M.D. degrees from Northwestern University under its Honors Program in Medical Education. He completed his medical internship at Beth Israel Hospital in Boston, his neurology residency at Tufts New England Medical Center, and a fellowship in behavioral neurology and neuropsychology at the University of Florida. He received his J.D. from the University of Michigan.

Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including acting deputy commissioner for policy, planning, and budget; associate commissioner for policy and planning; special counsel to the principal deputy commissioner; assistant commissioner for policy; and medical officer in the Office of Policy.

Dr. Shuren has served in a leadership role at FDA or on behalf of the agency on numerous initiatives, including:

- reauthorization of the Medical Device User Fee Act, which dramatically shortens review times for device applications
- creation of the Sentinel Initiative, which works toward a national electronic system for monitoring medical product safety
- development of FDA's Pandemic Influenza Preparedness Strategic Plan
- development of FDA's Counterfeit Drug Task Force Report
- development of the Interagency Food Safety Working Report to the President
- implementation of FDA provisions of the Medicare Prescription Drug Improvement and Modernization Act
- development and implementation of the Interagency Import Safety Working Group's Report to the President: Action Plan for Import Safety

From 1999 to 2000, Dr. Shuren served as a detailee on Senator Edward Kennedy's staff on the Senate Health, Education, Labor, and Pensions Committee. From 1998 to 2003, he also was a staff volunteer in the National Institutes of Health's Cognitive Neuroscience Section where he supervised and designed clinical studies on human reasoning.

As director of the Division of Items and Devices, Coverage and Analysis Group at the Centers for Medicare and Medicaid Services, Dr. Shuren oversaw the development of Medicare national coverage determinations for drugs, biologics, and non-implantable devices.

Douglas C. Throckmorton, MD
Deputy Director for Regulatory Programs
Center for Drug Evaluation and Research (CDER)

As Deputy Director for Regulatory Programs, Dr. Throckmorton shares the responsibility for overseeing the regulation of research, development, manufacture and marketing of prescription, over-the-counter, and generic drugs in the United States. He is committed to ensuring that the benefits of approved drugs outweigh their known risks.

Dr. Throckmorton received his medical degree from the University of Nebraska Medical School and completed his residency and fellowship at Case Western Reserve University and Yale University, respectively. Prior to coming to the FDA in 1997, he conducted basic science research and practiced medicine at the Medical College of Georgia, Augusta, Georgia and Augusta Veterans Administration Hospital. He is a board-certified physician**.**

Center Drug Evaluation and Research (CDER) Speakers

Patricia Bright, PhD
Acting Sentinel Program Lead
Sentinel Core Team
Office of Surveillance and Epidemiology (OSE)

Patricia Bright, PhD, MSPH is an epidemiologist in FDA's Center for Drug Evaluation and Research with the Office of Surveillance and Epidemiology. Dr. Bright received her PhD and master's degree in Epidemiology from the University of North Carolina, Chapel Hill. In addition to her prior work as an Epidemiology Reviewer for FDA, Dr. Bright's experience includes coordinating Clinical Trials for Johns Hopkins Medicine. Dr. Bright is currently the Acting Lead for CDER's Sentinel Core Team.

The Sentinel System is an active surveillance system that uses pre-existing electronic healthcare data from multiple sources to assess the use, safety, and effectiveness of regulated medical products. The electronic healthcare data used by the FDA's Sentinel system is maintained by a distributed network of Data Partners. These data are all structured into a common data model to allow for simultaneous querying at multiple sites. Queries are performed using pre-defined, reusable querying tools that allow FDA investigators flexibility to adapt the tool using their parameters of choice. All data and tools undergo extensive quality assurance processes so that they are fit for use.

Kevin Bugin, PhD, MS, RAC
Deputy Director of Operations
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Dr. Kevin Bugin is the acting Deputy Director of Operations in the Office of New Drugs (OND) in FDA's Center for Drug Evaluation and Research (CDER). Prior to his current role, from May 2020 through May 2021, Dr. Bugin served as the Chief of Staff for the Therapeutics Response Efforts as part of the US Government's HHS and DOD operation formerly known as Operation Warp Speed. Dr. Bugin is adjunct faculty at the George Washington University in the Clinical Leadership Program, focusing on areas of clinical research and medicines development. Dr. Bugin joined the FDA in 2008 in the Office of Business Process Support, then joined the Division of Gastroenterology and Inborn Errors Products within OND as a Regulatory Health Project Manager in 2010, and as the Chief of Project Management from 2015 to 2017. From 2017 until 2020, he served as the Director of Special Programs and the lead of CDER's New Drugs Regulatory Program Modernization. Prior to joining the FDA, Dr. Bugin held roles in multiple areas and phases of drug development, including discovery (molecular biology) at the Virginia Bioinformatics Institute, translational research and technology transfer at the National Institute of Health's Office of Technology Transfer, safety and pharmacovigilance with NIH's National Cancer Institute's Cancer Therapy Evaluation Program, and regulatory affairs and quality assurance at Amarex Clinical Research. Kevin received a BS in Biology and Chemistry from Virginia Tech in 2005, a MS in Biotechnology from American University in 2006, and a PhD in translational health science from George Washington University in 2020, with a focus on the Science of Team Science in drug development and regulatory science teams. He is certified in US regulatory affairs (RAC) and participates in numerous policy and regulatory science program working groups across the FDA.

Eric Brodsky, MD
Associate Director
Labeling Policy Team
Office of New Drug Policy (ONDP)
Office of New Drugs (OND) | CDER

As the Associate Director of the Labeling Policy Team, Dr. Brodsky oversees the Office of New Drugs' implementation of Prescribing Information regulations, guidances, and policies to help promote consistency in labeling practices across

CDER; provides labeling review training; develops labeling resources for CDER staff and industry; provides oversight of labeling quality; and assists review teams in review and development of Prescribing Information. Prior to joining the FDA, Dr. Brodsky practiced as an internist with a focus in primary care and hospital medicine in the Washington D.C. area. He received his medical degree from Tufts University School of Medicine, completed an internal medicine residency program at the University of Massachusetts Medical Center, and is board certified in Internal Medicine.

Heather Crandall
Cloud Collaboration Capability Team
DDMSS | OBI | OSP | CDER

Heather Crandall has been with the FDA since 2012, working in CDER's Office of Business Informatics. She currently focuses on standards and processes around electronic submissions.

Suranjan De, MS, MBA
Deputy Director
Regulatory Science Staff (RSS)
Office of Surveillance & Epidemiology (OSE)
CDER

Suranjan De has over seventeen years of demonstrated achievements, across Food and Drug Administration (FDA), National Institute of Health (NIH) & Pharma, impacting superior program performance through alignment of policies and regulation and innovative healthcare informatics solutions with strategic business objectives. His experience includes providing strategic direction to the life sciences industry for the use of innovative tools and products. He has also served as a SME/liaison between the IT management and the business owner in integrating methods and process with technology. Suranjan received a Masters in Computer Science from the Institute for Technology and Management, India and a Masters in Business Administration from Johns Hopkins University.

Currently, Mr. De is the Deputy Director at FDA's CDER, Office of Surveillance and Epidemiology, in the Regulatory Science Staff. He provides expert advice and technical direction on regulatory science for developing new tools, standards, and approaches to assess the safety, efficacy, quality, and performance of all FDA-regulated products. This includes interpretation of regulations, guidance documents and/or other policies relevant to activities in the Office of Surveillance and Epidemiology (OSE) in order to implement best practices and provide the right tools and technology. His current work includes, but is not limited to compounding reporting guidance, data management of FDA Adverse Events Reporting System (FAERS) and automating triaging of voluntary reporting and Safety Reporting Portal for mandatory post-marketing electronic submissions.

Jamie Gamerman, JD
Regulatory Counsel
Office of Medical Policy (OMP)
Office of Medical Policy Initiatives (OMPI)
CDER | FDA

Jamie Gamerman is a Regulatory Counsel in the Office of Medical Policy (OMP) in FDA's Center for Drug Evaluation and Research (CDER), where she leads multi-disciplinary workgroups across multiple FDA Centers to draft guidance documents and regulations. Jamie has worked at the FDA since 2014. Jamie received her J.D. from the University of Maryland School of Law and her bachelor's degree from the University of Maryland.

Rhonda M. Hearns-Stewart, MD
Associate Director for Implementation
Integrated Assessment of Marketing
Applications
OND Special Programs
OND | CDER

Dr. Rhonda Hearns-Stewart is the Associate Director of Implementation for the New Integrated Assessment of Marketing Applications. She is also on the staff at Walter Reed National Military Medical Center where she sees patients once a week. In 2013, Dr. Hearns joined the FDA as a Medical Officer in the Office of New Drugs (OND) within the Center for Drug Evaluation and Research (CDER). As a senior clinical reviewer in the Division of Bone, Reproductive, and Urologic Products (DBRUP), Dr. Hearns was responsible for reviewing the majority of ART and infertility products. In 2017, she joined the Drug Trials Snapshot Team in the Division of Professional Affairs and Stakeholder Engagement (PASE) within CDER's Office of the Center Director. Drug Trials Snapshots is part of an overall FDA effort to provide consumers with demographic data from clinical trials that supported the FDA approval of new drugs.

Dr. Hearns-Stewart is a graduate of Georgetown University School of Medicine. She is board-certified in obstetrics/gynecology and reproductive endocrinology and infertility (REI), and is a Fellow of the American College of Obstetrics and Gynecology (ACOG). Following residency training at Rutgers-New Jersey Medical School, she completed an REI Fellowship at the Combined National Institute of Child Health and Human Development (NICHD) Federal Fellowship in REI. After completion of fellowship training, Dr. Hearns remained on the clinical and research staff at the National Institutes of Health (NIH) and joined the staff of the Uniformed Services University of the Health Sciences (USUHS) as an associate professor. She left NIH to accept a position as Director of Reproductive Endocrinology and Benign Gynecology at Franklin Square Hospital Center. After leaving Franklin Square Hospital Center, Dr. Hearns practiced at two Assisted Reproductive Technology (ART) centers, Genetics and IVF Institute and the Reproductive Science Center.

Connie Jung, RPh, PhD
Captain, United States Public Health Service
Senior Advisor for Policy
Office of Drug Security, Integrity, and Response (ODSIR)
Office of Compliance (OC) | CDER

Dr. Jung is currently Senior Advisor for Policy in the Office of Drug Security, Integrity, and Response (ODSIR) in FDA's Center for Drug Evaluation and Research, Office of Compliance. Her work focuses on development of policy and regulatory strategies to improve the security and integrity of the U.S. drug supply to protect patients from counterfeit or stolen product. She received her B.S. in Pharmacy from The Ohio State University and her Ph. D. in Pharmaceutical Sciences from the University of Cincinnati. Dr. Jung joined the FDA in 1999 as a toxicology researcher in the Center for Food Safety and Applied Nutrition, and later served as a Regulatory Reviewer of bioequivalence studies in the Office of Generic Drug before working on supply chain issues.

Renu Lal, PharmD
Lieutenant Commander, USPHS
DDI | OCOMM | CDER

LCDR Renu Lal currently serves as Team Leader and Deputy Director of SBIA. In addition to growing and expanding the services SBIA provides to the regulated pharmaceutical industry, she leads a team of five drug information officers, responding to drug related inquiries from the public regarding a wide range of topics, and managing outreach and educational programs.

Renu is an officer of the United States Public Health Service and has been with CDER's Division of Drug Information since 2002, and SBIA since 2010. She and has also worked in retail and hospital pharmacy, and in the pharmaceutical industry. Renu received her Doctor of Pharmacy from the Medical University of South Carolina, and her Bachelor's degree in Pharmacy from the University of Connecticut.

Kerry Jo Lee, MD
Associate Director for Rare Diseases
Rare Diseases Team

Division of Rare Diseases and Medical Genetics (DRDMG)
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine (ORDPURM)
OND | CDER

Kerry Jo Lee, MD, is currently the acting Associate Director for Rare Diseases in the Division of Rare Diseases and Medical Genetics, Office of New Drugs (OND), Center for Drug Evaluation and Research (CDER). Dr. Lee joined the FDA as a medical officer in 2014 with the former the Division of Gastroenterology and Inborn Errors Products, OND, CDER, where she led and contributed to external efforts and publications to advance drug development in pediatric gastrointestinal disease in the areas of inflammatory bowel disease and biologic therapy, pediatric trial design, and the expedition of pediatric drug development. Dr. Lee then moved to a position as a clinical advisor for the Office of New Drug Policy, CDER, where she served as a lead in the areas of benefit-risk assessment, modernization efforts (including the Integrated Assessment), and real-world data/evidence programming.

Dr. Lee is a graduate of Princeton University and the New York University School of Medicine with an honors degree conferred in microbiology. She completed her residency in pediatrics at the Children's Hospital of Los Angeles followed by a post-doctoral clinical fellowship in Pediatric Gastroenterology, Hepatology, and Nutrition at Columbia University College of Physicians and Surgeons in New York. She completed published research involving the microbiome and viral pathogens from her time at the Center for Infection and Immunity of Columbia University Medical Center. Dr. Lee also maintains a steadfast interest in international policy and bioethics and worked for several years at the National Bioethics Advisory Commission on reports advising the executive branch on ethical and policy issues in both international and domestic clinical trials as well as interning at the World Health Organization.

Tamy Kim, PharmD
Director for Regulatory Affairs and Policy
Oncology Center of Excellence (OCE) and
Supervisory Associate Director for Regulatory Affairs Office of Oncologic Diseases (OOD)
OND | CDER

Tamy Kim is the Associate Director for Regulatory Affairs (ADRA) in the Office of Oncology and Hematology Products (OHOP) and Acting ADRA in the Oncology Center of Excellence (OCE) at the FDA. In OHOP, her responsibilities include developing policies related to review processes, including for breakthrough therapies, expedited reviews and safety. In the OCE, Dr. Kim is responsible for developing policies and procedures affecting the review of products under the OCE across CDER, CBER and CDRH.

Claudia Manzo, PharmD
Director
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)

Claudia Manzo, PharmD is currently Director of Office of Medication Error Prevention and Risk Management (OMEPRM) Office of Surveillance and Epidemiology (OSE).

J. Lowell Marshall, PMP, FAC-COR III
Office of Information Management Technology (OIMT)
Office of Digital Transformation (ODT)
Office of the Commissioner (OC)

J. Lowell Marshall serves as FDA ESG Information Technology Program Manager since July 2020. Previously, he was FDA IT Program\Project Manager, overseeing various Infrastructure and software development projects from June, 2005 – July, 2020. He holds a Bachelor of Science degree from Frostburg University, 1982.

Edward D. Millikan, PharmD, RPh
Senior Clinical Informatics Pharmacist
Division of Mitigation Assessment and Medication Error Surveillance (DMAMES)
Office of Medication Error Prevention and Risk Management (OMEPRM)
Office of Surveillance and Epidemiology (OSE)
CDER

Ed Millikan, Pharm.D., is the Senior Informatics Pharmacist in the Division of Mitigation Assessment and Medication Error Surveillance in the Office of Surveillance and Epidemiology (OSE), within FDA's Center for Drug Evaluation and Research. With over 20 years of experience as an Informatics Pharmacist, his background includes: REMS, drug information database development, healthcare terminologies (e.g., NLM RxNorm, SNOMED CT) and data standards (e.g., NCPDP SCRIPT, HL7® FHIR®), interoperability, and coding.

Before joining FDA in 2020, Dr. Millikan served as the Director of Product Development and Maintenance within American Society of Health-System Pharmacists (ASHP) Publishing. He and his team handled the development and support of online drug information databases. Since 2005, Dr. Millikan was involved with incorporating FDA Structured Product Labeling (SPL) in drug information database development. In 2010, he developed a software system to extract National Drug Codes (NDCs) linked with SPL Medication Guide content to supply a weekly updated module to large database vendors.

Dr. Millikan has worked with the National Council for Prescription Drug Program's (NCPDP) since 2010 and received a Most Valuable Participant (MVP) Award in 2012 for his work in developing and presenting to FDA, the first draft prototype for use of structured and codified REMS content using SPL to assist in automation and processing medications with REMS requirements.

Dr. Millikan graduated magna cum laude from the Campbell University School of Pharmacy and completed a residency in Drug Information and Pharmaceutical Informatics at the University of California, San Francisco and First Databank.

George Neyarapally, PharmD, JD, MPH, RPh
Regulatory Science Research Policy Lead
Regulatory Science & Applied Research Team
OSE | CDER

George Neyarapally works as a subject matter expert at the FDA in the Office of Surveillance and Epidemiology (OSE), Center for Drug Evaluation and Research (CDER) on regulatory science and policy initiatives and research. George also previously worked at MITRE/the Health Federally Funded Research and Development Center for the U.S. Department of Health and Human Services (HHS), as a Medicaid Pharmacy Director, in HHS at the Agency for Healthcare Research and Quality and the Assistant Secretary for Preparedness and Response (Fellow), as a Congressional Health Fellow in the U.S. Senate, and as a drug information and safety pharmacist.

George received his B.S. in Finance from the University of Connecticut, Pharm.D. from the University of North Carolina, M.P.H. from the Johns Hopkins Bloomberg School of Public Health, and J.D. from the University of Maryland.

Keith Olin, PharmD
Captain, United States Public Health Service
Director of Process and Knowledge Management
Office of Therapeutic Biologics and Biosimilars (OTBB)
OND | CDER

CDR Olin graduated from Duquesne University, Mylan School of Pharmacy with a B.S. in Pharmacy in 1997 and obtained a Doctor of Pharmacy Degree from Shenandoah University in 2007. He has worked at the Food and Drug Administration

(FDA) for over eighteen years and currently serves as the Director for Process and Knowledge Management for the Office of Therapeutic Biologics and Biosimilars in the Office of New Drugs. During his time at the FDA, he has worked as a project manager in the Division of Non-Prescription Drug Products, Office of Compliance, and in the Office of Pharmaceutical Quality.

Amy Ramanadham, PharmD., MS
Lieutenant Commander, USPHS
Acting Associate Director for Drug Safety Operations
Office of the Center Director (OCD) | CDER

LCDR Amy Ramanadham, Pharm.D., M.S., serves as CDER's Acting Associate Director for Drug Safety Operations. She is responsible for the management of significant and timely drug safety issues, as well as the creation and oversight of CDER processes for management of complex safety issues.

Jonathon Resnick
Project Management Officer
Cloud Collaboration Capability Team
Division of Data Management Services & Solutions
Office of Business Informatics (OBI)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Jonathan Resnick is a member of CDER's Division of Data Management Services and Solutions. His focus is on electronic submissions and has been with FDA since 2011. Prior to joining FDA, Jonathan spent 18 years working in IT project management supporting federal and private sector clients.

Sandra Retzky, DO, JD, MPH
Director, Office of Clinical Policy and Programs (OCPP)
Office of Orphan Product Development (OOPD)
Office of the Commissioner (OC) | FDA

Sandra Retzky is the Director, Office of Orphan Products Development (OOPD) within the Office of Clinical Policy and Programs, Office of the Commissioner. Sandy joined the FDA in 2016 and worked in CTP as a Medical Reviewer on applications for marketing authority of tobacco products, followed by time in CBER as a Medical Reviewer where she managed many gene and cell therapy files to treat rare diseases.

Sandy initially trained as a pharmacist, receiving her degree from the University of Illinois College of Pharmacy. Sandy graduated from Midwestern University, an osteopathic medical school in Chicago, and obtained board certification in Obstetrics and Gynecology, as well as fellowship training in Urogynecology, and licensure to practice medicine in Delaware.

After practicing medicine for many years, Sandy returned to academia, receiving an MBA degree from the Wharton School at the University of Pennsylvania. She worked in the pharmaceutical and biotech industries where she evaluated the commercial and clinical potential of externally sourced new medicines and negotiated licensing rights to these assets.

Sandy obtained a Master of Public Health degree from Johns Hopkins Bloomberg School of Public Health, where she retains a faculty position. Sandy also holds a J.D. degree from the Delaware Law School at Widener University,

In the legal and medical fields, Sandy has authored or co-authored twelve peer reviewed journal articles, two invited book chapters, and one commissioned publication on urinary incontinence for what is commonly known by medical students and physicians as *The Netter Series*.

Jeannie Roule
Chief, Project Management Staff

Urology, Obstetrics, and Gynecology
Division of Regulatory Operations for Rare Diseases,
Pediatrics, Urologic and Reproductive (DRORDPURM)
Office of Regulatory Operations (ORO)
OND | CDER

Jeannie Roule joined the Center for Drug Evaluation and Research as a Regulatory Project Manager in 2008 in the Division of Bone, Reproductive, and Urologic, Products. In 2020, she became a Chief, Project Management Staff in the Office of Regulatory Operations, Urologic, Obstetric, and Gynecologic.

As CPMS, Jeannie co-leads the regulatory health project management staff aligned with the Division of Urologic, Obstetric, and Gynecologic during the review process of drug applications for products such as testosterone, female and male sexual dysfunction, peyronies, uterine acting agents, contraception, preterm birth, overactive bladder, among others.

She has expert knowledge of FDA regulations, legislation, and administrative processes involved in the drug approval process including the regulatory cycle and the review and evaluation processes necessary for product approval/tentative approval/disapproval. In addition, Jeannie assists with communicating with industry and other OND review divisions on regulatory issues to resolve issues related to applications, and the explanation of regulatory requirements to ensure compliance with all legal, regulatory and policy requirements.

She is also experienced with working with multidisciplinary teams at all levels from both public and private organizations, including the Office of the Commissioner, other FDA Centers, other agencies, and the scientific/medical community and industry, which requires tact and technical expertise in coordinating and communicating Center and Agency policies and regulations.

Prior to joining the FDA, Jeannie gained more than 25 years of experience from her employment at the University of Pittsburgh Medical Center histocompatibility laboratory and Walter Reed National Military Medical Center. She monitored and performed immunological procedures necessary to determine the compatibility of patients and donors for heart, liver, kidney, pancreas, and lung transplants.

Mary Ann Slack
Director
Office of Strategic Programs (OSP) | CDER

Mary Ann Slack serves as Director of CDER's Office of Strategic Programs (OSP). OSP plays a lead role in many of the center's strategic initiatives and modernization efforts, including development of benefit-risk and other decision support tools, data standardization, lean process management, program analysis, informatics, capacity planning, and major user fee negotiations. OSP leads implementation of CDER's business informatics governance function in support of business modernization objectives.

Seyoum Senay, MS
Supervisory Operations Research Analyst
Office of Business Informatics (OBI)
Center for Drug Evaluation and Research (CDER)
Food and Drug Administration (FDA)

Mr. Senay is leading the FDA CDER mission-critical Informatics initiatives in support of human drug regulatory review process with a customer focus through analysis and pragmatic solutions that work to advance CDER's public health mission. He represents CDER in the FDA cloud strategy working group for decision making, collaboration, coordination, and execution of programs. Mr. Senay earned a reputation among many clients for ensuring customer satisfaction and delivering desired outcomes. Currently, Mr. Senay is leading innovative cloud transformation effort to enable

collaboration and improve operational efficiency. This capability continues to reduce regulatory overhead for sponsors, research institute, academia, and small businesses.
In addition, Mr. Senay successfully completed the U.S Excellence in Government Leadership Fellow (EIG) program to solve national problems by driving innovation, inspiring employees, and delivering results. Mr. Senay holds a master's degree in Information Systems from The Johns Hopkins University and a Certified Program Manager by Federal Acquisition Institute.

Norman Schmuff
Associate Director
Office of Pharmaceutical Manufacturing
Assessment (OPMA)
Office of Pharmaceutical Quality (OPQ) | CDER

Norman R. Schmuff has a Ph.D. in organic chemistry from University of Wisconsin, Madison (Barry Trost Group). After working in the chemical information and intellectual property areas for Telesystems-Questel, and American Cyanamid, he joined the FDA as a chemistry reviewer in 1990. Subsequently, he has served as Team Leader, Branch Chief, and Associate Director. Currently he is a member of the management team in the CDER's Office of Pharmaceutical Manufacturing Assessment.

He had participated in the following ICH groups:
- M4 (CTD-Q) Expert Working Group (Common Technical Document-Quality)
- M4 (CTD-Q) Rapporteur, Implementation Working Group
- M2 Expert Working Group (Electronic Standards for Transmission of Regulatory Information)
- Q4B Expert Working Group (Regulatory Acceptance of Pharmacopoeial Interchangeability)

He currently participates in many of FDA's standards activities, including the FDA's Data Standards Advisory Board, CDER Product Data Control Board, FDA IDMP group, and the PQ/CMC and KASA projects.

Julienne Vaillancourt, RPh, MPH
Captain, United States Public Health Service
Policy Advisor and Rare Disease Liaison
Office of the Director
Center for Biologics Evaluation and Research (CBER)

CAPT Julienne Vaillancourt is a pharmacist in US Public Health Service Commissioned Corps. She joined FDA in 1995, serving in CBER's Office of Vaccines Research and Review, first as a Regulatory Project Manager (RPM) and then in 2010 as an RPM Team Leader. She left FDA for two years (1999-2001) to serve as an Emergency Health Consultant at the US Agency for International Development and returned to the CBER's Office of Vaccines Research and Review afterward. Since mid-2015, CAPT Vaillancourt has served as a policy advisor in CBER's Office of the Director and as the Center's Rare Disease Liaison. She facilitates collaboration across CBER and with partners across the Agency and with external stakeholders on rare disease related issues and contributes to relevant policy development.

Center for Devices and Radiological Health (CDRH) Speakers

CAPT Terri L. Cornelison, MD, PhD, FACOG
Director, Health of Women Program
Chief Medical Officer, Health of Women
Office of Strategic Partnerships and Technology Innovation (OST)
Center for Devices and Radiological Health (CDRH)

Dr. Terri Cornelison is the first Director of the Health of Women Program, and Chief Medical Officer for the Health of Women, Office of Strategic Partnerships and Technology Innovation, Center for Devices and Radiologic Health (CDRH), U.S. Food and Drug Administration (FDA), double-boarded in gynecologic oncology and obstetrics and gynecology, and a Fellow of The American Congress of Obstetricians and Gynecologists. She is a forward-thinking leader who builds programs, cultivating and accelerating ground-breaking solutions to meet the critical health dilemmas facing the nation's population – solutions that are person-centered, data-driven, and co-created with the cross-sector partnerships requisite to actualize vision. As the Director of the Health of Women Program, Dr. Cornelison has built an innovative program with an overarching mission to improve the health of all women. Key focus is to improve availability, analysis, and communication of sex- and gender-specific information for the safe and effective use of medical devices to improve the performance of medical devices in women and in men; develop research priorities for the device health of women ecosystem; and lead and coordinate development and implementation of major health science and medical programs and initiatives across CDRH. Dr. Cornelison has an extensive broad-based background in molecular and cellular oncology, laboratory and regulatory science, clinical care, academia, public health, program building, administration, policy development, and executive leadership.

Dr. Cornelison's entire professional career has been deeply rooted in the spaces where innovation, science and medicine converge. Before joining the FDA, Dr. Cornelison was the first Associate Director for Clinical Research, Office of Research on Women's Health (ORWH), Office of the Director, National Institutes of Health, where she was responsible for the clinical oversight of a complex biomedical national research program involving basic and pre-clinical studies, clinical trials, and epidemiologic studies. She led and mentored the inaugural ORWH Medical Officer team to strengthen and enhance research related to diseases, disorders, and conditions that affect women. From 2015 to 2016, in addition to duties of Associate Director for Clinical Research, she assumed the scientific and administrative duties of both Deputy Director and Associate Director for Special Projects and Centers providing senior administrative leadership in planning, implementing, coordinating, and evaluating programs, initiatives, and policies in women's health across ORWH. Prior to this, Dr. Cornelison was the Acting Chief and Program Director of the Breast and Gynecologic Cancer Research Group of the Division of Cancer Prevention, National Cancer Institute, and was an integral part of the Division of Cancer Prevention's effort to bring clinicians into the realm of cancer prevention research.

Dr. Cornelison received her Bachelor of Arts from Bryn Mawr College, Bryn Mawr, Pennsylvania in 1981, her medical degree from Yale University, New Haven, Connecticut in 1985 and her Ph.D. from George Washington University, Washington D.C. in 2000. She completed her internship and residency in obstetrics and gynecology at the Beth Israel Hospital, Boston, Massachusetts, and her clinical fellowship in gynecologic oncology at Roswell Park Cancer Institute, Buffalo, New York. Dr. Cornelison has completed research fellowships at the National Cancer Institute and at the Uniformed Services University of the Health Sciences. She has held academic appointments at Harvard University School, State University of New York, and currently holds an appointment as Associate Professor at the Johns Hopkins University and School of Medicine, where she has her clinical and academic practice. Dr. Cornelison is an officer in the United States Public Health Service where she holds the rank of Captain.

Lili Duan, PhD
Policy Analyst/Chemist
Division of Regulatory Programs 4 (DRP4)
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Dr. Lili Duan is a member of the Tools and Templates Team in CDRH's Office of Regulatory Programs (ORP) in the Office of Production Evaluation and Quality (OPEQ). She is currently involved in the development and implementation of medical device related templates for both internal reviewers and external applicants. She started her career at FDA as a Scientific Reviewer in 2012. Prior to joining FDA, Dr. Duan worked in medical device industry for more than a decade and was a Diplomat of American Board of Clinical Chemistry (DABCC). She received her B.S. in Chemistry from Peking University and Ph.D. in Chemistry from Michigan State University.

Brittani Franklin
Consumer Safety Officer
Office of Medical Devices Radiological Health Operations (OMDRHO) - Division II
Office of Regulatory Affairs (ORA)

Brittani Franklin joined FDA in 2014, working in the Chicago District Office as an Import Investigator. She inspected and reviewed the compliance of FDA regulated products that were being imported from around the globe through the international port of entry, Chicago International Mail Facility and through airport cargo. Later, she transitioned to solely conducting inspections related to medical devices and combination products. Due to her expertise in the field, she became a member of the dedicated foreign cadre conducting complex medical device investigations and inspections internationally, training new investigators, and sitting on panels to provide educational resources to industry to fulfill the Agency's mission. Brittani Franklin continues to be an advocate for the health of all Americans, but specifically minorities.

Melissa Hall, MS
510(k), 513(g), Device Determination Program Expert
Division of Regulatory Programs 1 (DRP1)
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Melissa Hall is currently a 510(k), 513(g), Device Determination Program Expert in the Office of Regulatory Programs (ORP), Office of Production Evaluation and Quality (OPEQ), in the Center for Devices and Radiological Health (CDRH). Her work focuses primarily on interpreting, updating, and developing policy related to both 510(k) and 513(g) submissions. Melissa began her career at the U.S. Food and Drug Administration (FDA) as a lead reviewer focused primarily on the review of spinal devices. She then served as the Assistant Director for the Spinal Devices Division within CDRH, providing leadership and serving as an expert in the guidance, regulation, and review of spinal devices. Prior to her current role, she worked as a consumer safety officer in the Division of Industry and Consumer Education (DICE) educating external stakeholders about the various regulatory resources and requirements established by FDA. Before joining the FDA, Ms. Hall worked at the U.S. Patent and Trademark Office, reviewing orthopedic devices patents. She received her Master of Science in Biomedical Engineering at the New Jersey Institution of Technology (NJIT), and a Bachelor of Science in Biological Sciences from the University of Maryland Baltimore County (UMBC).

Joseph Hillring, MS
Consumer Safety Officer
Postmarket and Consumer Branch
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH)

Joseph Hillring is a Consumer Safety Officer in the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), in Center for Devices and Radiological Health's (CDRH's) Office of Communication and Education (OCE). His work focuses on helping external stakeholders locate and understand various regulatory resources and requirements established by FDA, with a specialization in Quality System regulation (Title 21 Code of Federal Regulation Part 820). In 2016, Mr. Hillring began working in OCE as a Staff Fellow in DICE. Prior to his FDA career, Mr. Hillring

worked for several consulting firms working across the spectrum of medical devices including developing submissions and Quality Systems. Mr. Hillring received his Bachelor's Degree in Arts and Science, Majoring in Biology with a Minor in Public Health from the University of South Florida and a Master of Science Degree from Northeastern University Majoring in Regulatory Affairs for Drugs, Biologics, and Medical Devices.

Lowell Howard, PhD
Electrical Engineer, Electronic Products
Division of Health Technology 8B (DHT8B) - Imaging Devices and Electronic Products
Office of Health Technology 8: Office of Radiological Health (OHT8)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Dr. Lowell Howard is an Electrical Engineer specializing in radiation-emitting electronic products within Center for Devices and Radiological Health's (CDRH's) Office of Production Evaluation and Quality (OPEQ), Office of Health Technology 8, Division of Imaging Devices and Electronic Products (DHT8B). Dr. Howard is involved in efforts to improve public outreach and communication about FDA's electronic product regulations as well as drafting regulatory policies for new solid-state lighting and laser products. Prior to 2015, he worked as a researcher and metrologist at the National Institute of Standards and Technology, in addition to private-sector employment in the semiconductor manufacturing, and fiber-optic telecommunications equipment industries.

Elias Mallis
Director
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH)

Elias Mallis is the Director of the Division of Industry and Consumer Education (DICE) in the Office of Communication and Education (OCE), in the Center for Devices and Radiological Health (CDRH), a position he has held since 2011. Mr. Mallis leads a division whose mission is to educate industry and consumer stakeholders with understandable and accessible science-based regulatory information about medical devices and radiation-emitting electronic products. He's a member of the Regulatory Affairs Professionals Society (RAPS) education committee.

Mr. Mallis began his 28-year FDA career in 1994 and devoted the next 17 years in the Office of Device Evaluation (now known as the Office of Product Evaluation and Quality or OPEQ) where he conducted regulatory review and developed policy for a diverse range of medical device programs, such as 510(k)s, IDEs, PMAs and HDEs. As an Electrical Engineer in the Gastroenterology and Renal Devices Branch, he was responsible for lead, engineering, and software review of medical products in the fields of hemodialysis, extracorporeal therapeutics, gastric motility and incontinence, and endometrial ablation. He was Branch Chief of the Cardiac Electrophysiology and Monitoring Branch, responsible for cardiovascular disciplines such as cardiac ablation for treatment of atrial fibrillation, implantable heart failure diagnostics, and non-invasive cardiac monitors. Mr. Mallis served as a Policy Analyst in the ODE Immediate Office, contributing to 510(k) Program, Clinical Studies, Device Reclassifications and De Novo policy. Mr. Mallis received a Bachelor of Science Degree in Electrical Engineering at the University of Maryland at College Park.

Edward "Ed" Nyack, BS, MPP
Senior Program Analyst
Product Owner, FURLS/DRLM
Division of Regulatory Programs 2 (DRP2)
Office of Regulatory Programs (ORP)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Ed Nyack is a Senior Program Analyst in the Imports and Registration and Listing Team within Center for Devices and Radiological Health's (CDRH's) Office of Regulatory Programs (ORP) in the Office of Product Evaluation and Quality

(OPEQ). He is currently serving as the Product Owner for the FDA Unified Registration and Listing System (FURLS) Device Registration and Listing Module (DRLM). FURLS/DRLM is responsible for managing over 235,000 listings for nearly 30,000 foreign and domestic establishments. Additionally, Ed also creates reports in several Business Object platforms, and provides regulatory and policy guidance related to registration and listing. He earned his bachelor's degree in Government and Politics from University of Maryland, College Park and his Masters of Public Policy degree from George Mason University.

Berk Oktem, PhD, DABT
Chemist
Division of Biology, Chemistry, and Materials Science (DBCMS)
Office of Science and Engineering Laboratories (OSEL)
Center for Devices and Radiological Health (CDRH)

Dr. Berk Oktem is a Chemist at the Center for Devices and Radiological Health (CDRH), Office of Science and Engineering Laboratories, Division of Biology, Chemistry and Materials Science (DBCMS). He serves as a technical expert for pre-market reviews and conducts regulatory science research focused on extractables, leachables analysis, polymer degradation and proteomics. He received his Ph.D. in Analytical Chemistry from the University of Delaware and performed post-doctoral research at Johns Hopkins School of Medicine specializing in mass spectrometry-based analysis of microorganisms and biological macromolecules.

CDR Kimberly Piermatteo, MHA
Education Program Administrator
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH)

CDR Kimberly Piermatteo is a Commissioned Officer in the United States Public Health Service and currently serves in the Center for Devices and Radiological Health's Office of Communication and Education, Division of Industry and Consumer Education as the Education Program Administrator who is responsible for leading and directing the CDRH External Webinar Program. She has been with the FDA in various capacities since 2006 spanning premarket review and postmarket adverse event and compliance work. CDR Piermatteo received her Bachelor of Science degree in Engineering Science and Minors in Bioengineering and Mathematics from the Pennsylvania State University and her Master of Health Administration (MHA) from the University of Maryland.

Ouided Rouabhi, MS
Acting Assistant Director, Policy and Operations Team 1
Division of Clinical Evidence and Analysis 1 (DCEA1)
Office of Clinical Evidence and Analysis (OCEA)
Office of Product Evaluation and Quality (OPEQ)
Center for Devices and Radiological Health (CDRH)

Ouided Rouabhi currently serves as the Acting Assistant Director for the Policy and Operations Team 1 within the Division of Clinical Evidence and Analysis (DCEA1) in FDA's Center for Devices and Radiologic Health (CDRH), Office of Product Evaluation and Quality (OPEQ), Office of Clinical Evidence and Analysis (OCEA). Her current role includes providing regulatory guidance to internal and external stakeholders regarding the interpretation and application of policies and procedures related to the IDE, Breakthrough Devices, Safer Technologies, and Expanded Access Programs, among others. Prior to this role, Ouided served as a policy analyst within this team, and prior to that, as a premarket reviewer in the Office of Cardiovascular Devices where she reviewed cardiac electrophysiology devices. Ouided also previously served as a biomedical engineer and reviewer in FDA's Center for Tobacco Products, where she specialized in electronic cigarette research and policy. Ouided received her MS and BSE degrees in Biomedical Engineering from The University of Iowa.

Joseph Tartal
Deputy Director
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH)

Joseph Tartal is Deputy Director of the Division of Industry and Consumer Education (DICE), Office of Communication and Education (OCE), in FDA's Center for Devices and Radiological Health (CDRH). In this role, he directs the division's effort to educate the medical device industry to understand its regulatory requirements and responsibilities with medical devices. Mr. Tartal serve as FDA faculty for the Association for the Advancement of Medical Instrumentation (AAMI) and is a member of the Regulatory Affairs Professionals Society (RAPS) education committee. Prior to his 16-year FDA career, Mr. Tartal served as a Quality Assurance Manager for small medical device manufacturers, primarily responsible for implementing and maintaining compliant quality management systems. He has over 28 years of experience in the medical device industry, including premarket submissions. Mr. Tartal received a Bachelor Degree in Biology from Pennsylvania's Slippery Rock University.

Melissa Torres
Associate Director for International Affairs
Office of Center Director (OCD)
Center for Devices and Radiological Health (CDRH)

Melissa Torres is the Associate Director for International Affairs at the Center for Devices and Radiological Health (CDRH), where she is responsible for the oversight of CDRH's involvement in international programs such as the International Medical Device Regulators Forum and Medical Device Single Audit Program. She is also responsible for managing communications on technical and regulatory issues with foreign governments and international organizations and developing policy in response to emerging international issues. Before her current position, Ms. Torres worked in CDRH's Office of Device Evaluation (now known as the Office of Product Evaluation and Quality or OPEQ) as a Branch Chief and Deputy Director responsible for the premarket evaluation of cardiovascular devices and the Office of Compliance as a reviewer, branch chief, and policy analyst working on postmarket and good manufacturing practices (GMP) issues. Ms. Torres received a Bachelor of Engineering in Biomedical Engineering from Vanderbilt University and Master of Engineering and Science degrees in Biomedical Engineering and Engineering Management from the Catholic University of America. Ms. Torres is also an ASQ Certified Quality Auditor.

Tonya A. Wilbon
Branch Chief, Postmarket and Consumer Branch
Division of Industry and Consumer Education (DICE)
Office of Communication and Education (OCE)
Center for Devices and Radiological Health (CDRH)

Tonya A. Wilbon is the Branch Chief for the Postmarket and Consumer Branch, Division of Industry and Consumer Education (DICE), in CDRH's Office of Communication and Education. Tonya leads DICE's efforts to educate and inform the medical device and radiological health industry on its FDA regulatory requirements for marketing medical devices and radiation-emitting products. In addition, she leads the division's efforts to educate and inform consumers, health care professionals, and patients on issues with these medical devices and radiation-emitting products. Ms. Wilbon has been with FDA for over 22 years with more than 10 years of clinical laboratory experience. She initially began with the FDA as a Microbiology Scientific Reviewer for CDRH's Office of *In Vitro* Diagnostics and Radiological Health (OIR) and served as the Quality System Specialist within OIR.

Ms. Wilbon also currently serves as an FDA instructor for the Association for the Advancement of Medical Instrumentation (AAMI) new Quality System Regulation 21 CFR 820 and ANSI/AAMI/ISO 13485: Navigating Regulatory Requirements, Integrating Risk Management into the Product Life Cycle Course, and Design Control Requirements-Integrating the QSR and AAMI/ANSI/ISO 13485 Course. She assisted with updating the course ancillary document, The Quality System Compendium. She also serves on FDA's Content Advisory Group and serves as an instructor for the FDA

Basic Medical Device Course for FDA Investigators and Staff. Ms. Wilbon has previously served as a member of the Consensus Committee for Quality System and Laboratory Practices and the Subcommittee on Antimicrobial Susceptibility testing of Human Mycoplasmas for the Clinical and Laboratory Standards Institute (CLSI).

Ms. Wilbon received a Bachelor of Science Degree in Microbiology from Howard University and is a certified Microbiologist by the American Society of Clinical Pathology (ASCP).

Center for Devices and Radiological Health (CDRH) Speakers

Meghna Alimchandani, MD
Deputy Director
Division of Pharmacovigilance (DPV)
Office of Biostatistics and Pharmacovigilance (OBPV)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Meghna Alimchandani, M.D., serves as the Deputy Director of the Division of Pharmacovigilance (DPV), Office of Biostatistics and Pharmacovigilance (OBPV) at FDA's Center for Biologics Evaluation and Research (CBER), where her work focuses on pharmacovigilance planning, and passive and active postmarket safety surveillance for products regulated by the Center. She supervises DPV staff in pharmacovigilance plan reviews for Biologics License Application (BLAs), including original submissions and supplements. The pharmacovigilance review encompasses evaluation of safety-related postmarketing requirement/commitment (PMR/PMC) studies, Risk Evaluation and Mitigation Strategy (REMS), and spontaneous adverse event data.
She joined FDA in 2014 as a medical officer in DPV, OBPV and her past roles have included serving as the Branch Chief in DPV, and Associate Director in OBPV. She also gained experience in regulatory review of investigational biologics and clinical trial data while serving as a medical officer in the Office of Tissues and Advanced Therapies in CBER. Prior to FDA, Dr. Alimchandani received her medical degree from the Albert Einstein College of Medicine of Yeshiva University, Bronx, NY and completed her residency in Anatomic Pathology at the National Institutes of Health, Bethesda, MD.

Judith Arcidiacono, MS
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Judith Arcidiacono is regulatory expert on xenotransplantation products in the Office of Tissues and Advanced Therapies. She also serves as an International Regulatory Expert and Lead for the Standards Program for Regenerative Medicine Therapies. Prior to joining OTAT IOD in 2007, Judith worked as a research/reviewer staff scientist in the OTAT Division of Cell and Gene Therapy where she conducted research on human immune responses to porcine cells as a model to study xenograft rejection. In addition to research, Judith conducted regulatory reviews of INDs and IDEs for xenotransplantation products, and NK and T cell therapies. Judith holds a B.S. from West Virginia University and an M.S. from Clarion University of Pennsylvania.

Patricia Beaston, MD, PhD
Medical Officer
Division of Clinical Evaluation, Pharmacology, and Toxicology (DCEPT)
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Dr. Beaston has been a Medical Officer at the Food and Drug Administration for more than 20 years. She began in the Center for Drug Evaluation and Research evaluating endocrine drug products. She then moved to the Center for Devices and Radiological Health (CDRH) where she provided clinical consultation on endocrine related devices including diagnostic, software, drug delivery and combination products. She is now in Division of Clinical Evaluation and Pharmacology/Toxicology (DCEPT)/ Office of Tissues and Advanced Therapies (OTAT)/ Center for Biologics Evaluation and Research (CBER) where her review work includes regulatory applications for islet cell transplant, gene therapies for inborn errors of metabolism, and xenotransplantation. She is a member of the xenotransplant working group. Dr. Beaston earned a B.S. in Zoology from the University of Maryland, College Park, a Ph.D. in Anatomy and Neurobiology, and an M.D. from the Medical College of Pennsylvania, Philadelphia. She completed her residency in Internal Medicine

at the Medical College of Pennsylvania and was a Fellow in Diabetes, Endocrinology, and Metabolism at Penn State/Hershey where she did basic research in addition to her clinical responsibilities.

Wilson Bryan, MD
Director
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Wilson Bryan is a neurologist who graduated from the University of Chicago Pritzker School of Medicine. Dr. Bryan served on the neurology faculty of the University of Texas Southwestern Medical School for 13 years. He has been an investigator on clinical trials in cerebrovascular disease and neuromuscular disorders, particularly amyotrophic lateral sclerosis. Dr. Bryan joined the United States Food and Drug Administration (FDA) in 2000. Since 2016, he has served as Director of the Office of Tissues and Advanced Therapies (OTAT) in the Center for Biologics Evaluation and Research (CBER).

Eden Chane
Regulatory Project Manager
Division of Regulatory Project Management (DRPM)
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Eden Chane is Regulatory Project Manager in the Office of Tissues and Advanced Therapies in CBER. Eden joined the CBER/OTAT/DRPM in May 2020 as a Regulatory Project Manager. Prior to her joining CBER in 2020, Eden worked at Lupin Pharmaceutical in regulatory Affairs supporting the regulatory approval process of Abbreviated new Drug application (ANDA), Investigational New drug application (INDs) and New Drug applications (NDA) for brand and generic products. Prior to Lupin she also worked at Thermofisher scientific and AstraZeneca as a scientist supporting quality control testing for drug products. Eden received her bachelor's degree with cell and molecular Biology from Towson University and a Master's degree in Biotechnology with concertation in Drug design and discovery from Georgetown University.

Asha Das, MD
Medical Officer
Oncology Branch
Division of Clinical Evaluation, Pharmacology, and Toxicology (DCEPT)
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Asha Das, MD serves as a Medical Officer in FDA's Oncology Branch in the Center for Biologics Evaluation and Research. Dr. Das earned her bachelor's and medical degrees from Cornell University. Following internship and residency in internal medicine and neurology at New York-Presbyterian Hospital/Weill Cornell Medicine, she completed a fellowship in neuro-oncology at Massachusetts General Hospital. Certified in neurology by the American Board of Psychiatry and Neurology and in the sub-specialty of neuro-oncology by the United Council for Neurologic Subspecialties, Dr. Das has held academic appointments at the University of California, Los Angeles, University of California, San Francisco, and the National University of Singapore. Previously, she was Head of the Neuro-oncology Program at Cedars-Sinai Medical Center. Prior to joining the FDA, Dr. Das held positions of increasing responsibility and leadership at several pharmaceutical and biotechnology companies.

Alyssa Kitchel, PhD
Device Team Lead
Tissue Engineering Branch
Division of Cellular and Gene Therapies (DCGT)
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Alyssa Kitchel, Ph.D. serves as the Device Team Lead in the newly formed Tissue Engineering Branch (TEB) in the Division of Cell & Gene Therapies (DCGT) in CBER. She began her career at the FDA in 2015 as a lead reviewer in the Office of Device Evaluation in CDRH. In 2017, she joined OTAT as a Chemistry & Manufacturing Controls (CMC)/Product reviewer in the Cell Therapies Branch (CTB) in DCGT. Alyssa received her B.S. in Chemical Engineering from Tufts University and her Ph.D. in Biomedical Engineering from Georgia Tech and Emory University.

Larissa Lapteva, MD, MHS, MBA
Associate Director
Division of Clinical Evaluation, Pharmacology, and Toxicology (DCEPT)
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Larissa Lapteva, M.D., M.H.S., M.B.A. is the Associate Director in the Division of Clinical Evaluation, Pharmacology, and Toxicology, Office of Tissues and Advanced Therapies, Center for Biologics Evaluation and Research. Dr. Lapteva is a physician with long-standing experience in clinical research with novel drugs and biological products, including cell and gene therapies. Prior to her work at FDA, Dr. Lapteva served as a clinical investigator in studies conducted at the National Institute of Arthritis, Musculoskeletal and Skin Diseases (NIAMS), National Institutes of Health (NIH). Since joining FDA in 2006, Dr. Lapteva has held review and supervisory positions in the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research and provided scientific and regulatory advice for clinical development programs with investigational products across different therapeutic areas. Dr. Lapteva received her degrees of Master of Health Sciences from Duke University and Master of Business Administration from R.H. Smith School of Business.

Carrie Laurençot, PhD
Associate Director
Division of Cellular and Gene Therapies (DCGT)
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Carrie Laurençot, Ph.D. joined the Division of Cellular and Gene Therapies (DCGT), in the Office of Tissues and Advanced Therapies (OTAT) in the FDA's Center for Biologics Evaluation and Research (CBER) in 2019 and serves as the Associate Director for Regulatory Science and Review. In this role, she advises DCGT leadership on regulatory and scientific issues, provides input on development and evaluation of new policies, and on scientific and regulatory programs pertinent to the Agency. Carrie obtained a BA in Biology from Douglass College, Rutgers University, and a Ph.D. in Pharmacology from The George Washington University. She has over 25 years of experience in medical product development in the pharmaceutical industry and the U.S. federal government where she provided regulatory support and advice for numerous gene and cell therapy development projects, as well as projects for other biologics and drugs.

Crystal Melendez, MT, RN, BSN, DCPM
Regulatory Health Project Manager
Division of Regulatory Project Management (DRPM)

Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Crystal Melendez is a Regulatory Project Manager in the Division of Regulatory Management, in the Office of Tissues and Advanced Therapies, at the Center for Biologics Evaluation and Research at the FDA. Crystal received her Bachelor of Science degree in Medical & Research Technology at the University of Maryland, School of Medicine in 2008 and a Bachelor of Science degree in Nursing from Stevenson University in 2011. Prior to joining the FDA, Crystal worked at the National Institutes of Health (NIH) in the HLA (Immunogenetics) Laboratory for 9 years specializing in Bone Marrow, Cord Blood, and Stem Cell transplantation in the Transfusion Medicine Department. She also has previous experience in the Immunogenetics laboratory including solid organ transplantation at the University of Maryland Medical Center (UMMC) in Baltimore, MD. At UMMC, she also gained experience as a Novice Nurse on the Acute Medicine Unit.

Joyce O. Obidi, PhD
Office of Biostatistics and Pharmacovigilance (OBPV)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Dr. Obidi's research background is in translational oncology research. In 2012, Dr. Obidi graduated from Johns Hopkins University School of Medicine with a doctoral degree in Cellular and Molecular Medicine. After completing her dissertation, Dr. Obidi completed her post-doctoral research at MedImmune, the global biologics R&D arm of AstraZeneca. She worked on developing assays that could be used to optimize new therapeutic strategies and personalized medicine which could aid in the stratification of cancer patients. Currently, Dr. Obidi's efforts at FDA are directed toward building and utilizing a post-marketing surveillance system for monitoring the safety of biologics regulated by CBER. Dr. Obidi joined FDA in 2016 as a recipient of the FDA Commissioner's Fellowship. She focused on understanding how to harness electronic health records to complement FDA's post market surveillance activities. After her fellowship, she joined the Office of Biostatistics and Epidemiology (OBE) as a Health Scientist. As a member of the CBER Surveillance Team, she is working toward building the foundation of a national biologics surveillance system.

Manuel Osorio

Senior Scientist for Emerging Technologies and Medical Countermeasures
Office of Center Director
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Manuel Osorio is currently the lead for the Advanced Manufacturing Technologies portfolio in the Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration (FDA). Prior to this role, Dr. Osorio was a researcher/reviewer for 16 years in the Office of Vaccines Research and Review in CBER. He received a BS degree from UCLA in Biochemistry and PhD degree in cellular immunology from the University of California at Santa Cruz. He was a postdoctoral fellow at the National Institutes of Health for two years before joining the FDA.

Mikhail Ovanesov, PhD

Division of Plasma Protein Therapeutics (DPPT)
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Dr. Ovanesov is a Research Biologist and Principal Investigator in the Office of Tissues and Advanced Therapies at CBER, FDA. Dr. Ovanesov conducts regulatory submission reviews and pharmaceutical manufacturing sites inspections for a variety of biological products, including plasma derived and recombinant plasma protein therapeutics, frozen and dried

plasma and platelet products intended for transfusion, and gene therapies for hemophilia. Dr. Ovanesov's research laboratory investigates safety and efficacy of hemostasis products and participates in international collaborative studies on plasma protein standards. Dr. Ovanesov serves as FDA Liaison to standards development organizations, European Pharmacopeia and U.S. Pharmacopeia.

Anne Rowzee, PhD
Associate Director for Policy, Stakeholder Outreach and Engagement
Office of Tissues and Advanced Therapies (OTAT)
Center for Biologics Evaluation and Research (CBER)
Food and Drug Administration (FDA)

Anne M. Rowzee, Ph.D. joined the Center for Biologics Evaluation and Research, Office of Tissues and Advanced Therapies in October 2018 as an Associate Director for Policy. Dr. Rowzee supports OTAT's stakeholder engagement efforts and coordinates its proactive patient outreach program. As part of OTAT's patient-focused outreach, Dr. Rowzee has launched the regenerative medicine therapy outreach and education campaign, including the *#RegenMedEd* patient webinar series and annual patient workshops. Before moving to CBER, Anne was a Science Policy analyst in the Office of Therapeutic Biologics and Biosimilars in the Center for Drug Evaluation and Research where she provided scientific guidance to ensure consistency in agency recommendations across biosimilar development programs. Dr. Rowzee joined FDA in 2011, spearheading communications covering CDER regulatory and research programs for the Office of Communications. During her time in OCOMM, Dr. Rowzee wrote and directed manuscripts for high-visibility peer-reviewed journals and led the OCOMM Editorial Team.

Rosa Sherafat-Kazemzadeh, MD
Medical Officer
General Medicine Branch 2
Division of Clinical Evaluation, Pharmacology, and Toxicology (DCEPT)
Office of Tissues and Advanced Therapies (OTAT)
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