

New Drugs Regulatory Program Modernization:
**Implementation of the Integrated Assessment of Marketing
Applications and Integrated Review Documentation**
Virtual Public Workshop

Friday, October 30, 2020
9:00 AM – 3:00 PM EST

Public Meeting Webpage is accessible [here](#)

Federal Register Notice FDA–2020–N–1550 is accessible [here](#)

AGENDA

- 9:00 AM** **Introduction to the Integrated Assessment: Presentations from the Integrated Assessment Workstream**
- Welcome & Introduction to the Modernization
Peter Stein, MD, *FDA*
Rationale for Development & Core Design Features
Kerry Jo Lee, MD, *FDA*
Nancy Sager, *FDA*
Implementation
Rhonda Hearn-Stewart, MD, *FDA*
External Feedback: Synthesis & Emerging Themes
Yoni Tyberg, MS, PMP, *FDA*
- 10:15 AM** **BREAK**
- 10:30 AM** **External Stakeholder Perspectives: Panel – Impressions of the New Integrated Review Template**
- Moderators:
Sarah Connelly, MD, *FDA*
John Farley, MD, MPH, *FDA*
Panelists:
Naga P. Chalasani, MD, FAASLD, *American Association for the Study of Liver Diseases*
Gregory Curfman, MD, *Journal of the American Medical Association*
Jonathan Darrow, SJD, LL.M., JD, MBA, *Harvard Medical School*
Kristin Dolinski, *Pharmaceutical Research & Manufacturers of America*
Danielle Friend, PhD, *Biotechnology Innovation Organization*
Richard J. Kovacs, MD, MACC, *American College of Cardiology*
Eleanor Perfetto, PhD, MS, *National Health Council*
Joseph S. Ross, MD, MHS, *Yale-New Haven Hospital*
Richard White, *National Organization for Rare Disorders*

12:00 PM External Stakeholder Perspectives: Open Public Comments

Comment by Combination Products Coalition

Jason Lipman, *Sanofi*

Comment by Gilead Sciences

Emily Huddle, *Gilead Sciences*

Closeout

Rhonda Hearn-Stewart, MD, *FDA*

12:30 PM LUNCH

1:30 PM FDA Perspective: Integrated Assessment Panel – Working with the New Integrated Review Template

Moderator:

Yoni Tyberg, MS, PMP

Panelists:

Sarah Connelly, MD

John Farley, MD, MPH

Kerry Jo Lee, MD

Stephanie Leuenroth-Quinn, PhD

Jinzhong Liu, PhD

Jennifer Mercier

Florence Moore, MS, PhD

Kellie Schoolar Reynolds, PharmD

Lisa Skarupa, MSN

Kimberly Struble, PharmD

Aliza Thompson, MD, MS

Therri Usher, PhD

2:45 PM Wrap-Up and Next Steps

Kevin Bugin, MS, PhD, RAC, *FDA*

3:00 PM ADJOURN

FDA PRESENTER BIOGRAPHIES

Kevin Bugin, MS, PhDc, RAC, Presenter



Kevin Bugin, MS, PhDc, RAC, is the Director of Special Programs in the Office of New Drugs (OND) in FDA's Center for Drug Evaluation and Research (CDER) and serves as the program lead of CDER's New Drugs Regulatory Program Modernization (NDRP). He is also adjunct faculty at the George Washington University in the Clinical Leadership Program, instructing in areas of clinical research and medicines development. Kevin joined the FDA in 2008 in the Office of Business Process Support, in the electronic review and regulatory support division to facilitate a transition to modernized, electronic ways of working in CDER. In 2010, he joined the Division of Gastroenterology and Inborn Errors Products in OND as a Regulatory Health Project Manager and in 2015 as a Chief of Project Management. Prior to joining the FDA, Kevin's professional experience included 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 (NIH) 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 is currently detailed to the FDA's Office of the Commissioner in support of Dr. Janet Woodcock and the US government's Operation Warp Speed effort to accelerate the development of therapeutics for COVID-19.

Rhonda Hearn-Stewart, MD, Presenter



Rhonda Hearn-Stewart, MD, 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. Hearn 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. Hearn 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. Hearn 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. Hearn 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. Hearn practiced at two Assisted Reproductive Technology (ART) centers, Genetics and IVF Institute and the Reproductive Science Center.

Kerry Jo Lee, MD, Presenter



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.

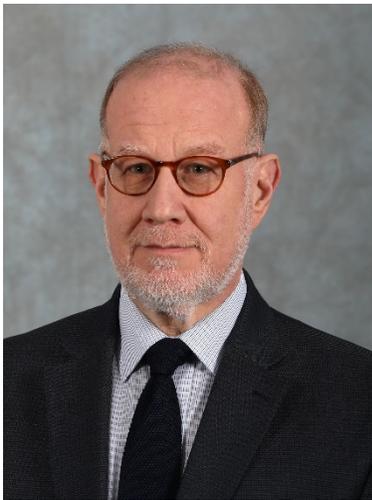
Nancy Sager, Presenter



Nancy Sager serves as Director, Division of Information Disclosure Policy (DIDP), Center for Drug Evaluation and Research (CDER), FDA. Her staff is responsible for reviewing and redacting a large variety of documents including internal memoranda, scientific reviews, and inspection documents to respond to Freedom of Information Act (FOIA) requests submitted by the public, third-party subpoenas and FOIA lawsuits, Congressional inquiries, and requests from federal, state, local, and foreign government officials. Prior to moving to DIDP, she held various positions in CDER including as a review chemist in the Office of Generic Drugs and as Special Assistant to the Director and Associate Director for Quality Implementation Chemistry in the Office of Pharmaceutical

Science.

Peter Stein, MD, Presenter



Peter Stein, MD, is the Director of CDER's Office of New Drugs (OND). OND is responsible for the regulatory oversight of investigational studies during drug development and decisions regarding marketing approval for new (innovator or non-generic) drugs, including decisions related to changes to already marketed products. OND provides guidance to regulated industry on a wide variety of clinical, scientific, and regulatory matters.

A nationally-recognized leader in pharmaceutical research and development, Dr. Stein joined CDER in 2016 as the OND Deputy Director. Before coming to FDA, he served as Vice President for late stage development, diabetes, and endocrinology at Merck Research Laboratories. He also served as Vice President, head of metabolism development at Janssen. He has more than 30 years of academic, clinical, and industry experience.

Dr. Stein holds a bachelor's degree in history from the University of Rochester in New York and a medical degree from University of Pennsylvania. He trained at Yale University and Yale-New Haven Hospital in internal medicine and in endocrinology and metabolism.

Yoni Tyberg, MS, PMP, Presenter



Yoni Tyberg, MS, PMP, is the acting Team Leader of Special Program Staff (SPS) at the Office of New Drugs within CDER. In this role, Mr. Tyberg assists the Director of SPS with overseeing the strategic planning, project development and execution of the New Drug Regulatory Program Modernization efforts across OND and CDER. He also serves as the evaluation lead for all project evaluation activities across the NDRP workstream. Before arriving to SPS, Mr. Tyberg served as a project management officer with CDER's Office of Program and Strategic Analysis (OPSA), Program Evaluation and Implementation staff, where he helped design and oversee the PDUFA VI IND communication program evaluation as well as manage other program evaluation activities across CDER. Prior to joining FDA, Mr. Tyberg served as Division

Chief of the Clinical Surveillance and Medical Intelligence Division within the Defense Health Agency, where he oversaw and managed the RAND program evaluation research portfolio and supervised a team of epidemiological and health informatics experts that provided needed health data and clinical information to military treatment facilities and other directorates within DoD. Mr. Tyberg has a Master's in Health Administration and Informatics as well as a Master's in Social Work.

EXTERNAL STAKEHOLDER PANEL BIOGRAPHIES

Sarah Connelly, MD, Co-Moderator

Sarah Connelly, MD, is currently an acting Clinical Team Leader in the Division of Antivirals in the Office of Infectious Diseases, CDER, FDA. The Division of Antivirals is responsible for the regulation and review of antiviral drug and biologic products. Dr. Connelly joined the FDA in 2007 and has provided expertise in all phases of antiviral clinical drug development including for HIV infection, hepatitis B and C, influenza, and other emerging viral infections. She received her undergraduate degree from Dartmouth College, medical degree from Georgetown University School of Medicine, and completed her Internal Medicine and Infectious Disease training at Duke University.

John Farley, MD, MPH, Co-Moderator



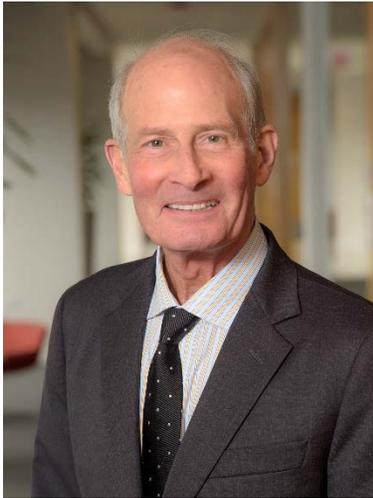
John Farley, MD, MPH, is presently Director of the Office of Infectious Diseases in the Office of New Drugs at CDER, FDA. His office is responsible for the review of new antiviral and antibacterial drugs. In addition to new drug review work, Dr. Farley's work at FDA has included implementation of the breakpoints provisions of the Cures Act, providing scientific leadership for establishment of the antimicrobial resistance focused regulatory science research program, and serving as a workstream lead for the Integrated Review as part of the Office of New Drugs Modernization. Prior to joining the FDA, Dr. Farley was on the faculty of the University of Maryland School of Medicine and directed the Pediatric AIDS Program, the Center for Clinical Trials, and the AIDS Care and Treatment in Nigeria (ACTION) Project. Dr. Farley trained at the George Washington University School of Medicine, the Children's National Medical Center, and the Johns Hopkins University Bloomberg School of Public Health.

Naga P. Chalasani, MD, FAASLD, Panelist



Naga Chalasani, MD, FAASLD, currently serves as David W. Crabb Professor of Medicine and Interim Chair of the Department of Medicine at Indiana University School of Medicine. He previously served as the Director of the Division of Gastroenterology and Hepatology at the same institution from 2007 to 2020. He completed his medical education in India and subsequently completed Internal Medicine Residency and Gastroenterology & Hepatology subspecialty training at Emory University in Atlanta. His research interests include CYP450 enzymes and liver disease and hepatic safety of xenobiotics. His research has been continuously funded by the National Institutes of Health since 1999. He is currently the PI for three U01 awards and an R01 award from the National Institutes of Health. He published over 300 original papers, 3 Practice Guidelines, 47 book chapters/review articles, 31 editorials/commentaries, 16 symposium proceedings, and more than 500 abstracts. He is the lead author for the AASLD Practice Guideline on the Diagnosis and Management of Nonalcoholic Fatty Liver Disease and is the lead author on the ACG Practice Guideline on the Diagnosis and Management of Drug Induced Liver Injury. He is an elected member of the American Society of Clinical Investigation (ASCI) and the American Association of Physicians (AAP).

Gregory Curfman, MD, Panelist



Gregory Curfman, MD, is a deputy editor of the Journal of the American Medical Association (JAMA), based in the journal's Chicago office. During his career as a medical journal editor, he previously served as executive editor of the New England Journal of Medicine and the health care policy and law editor of JAMA Internal Medicine. He attended Princeton University and Harvard Medical School, and trained as an internal medicine physician and cardiologist at Massachusetts General and Brigham & Women's Hospitals in Boston. He serves as a member of the Midwest Clinical Effectiveness Advisory Council of the Institute for Clinical and Economic Review (ICER) and is a member of the American Society of Law, Medicine, and Ethics. His scholarly interests in health law include the regulation of prescription drugs and medical devices. In his position at JAMA, Dr. Curfman is pleased to receive inquiries about articles that may have potential for publication in JAMA.

Jonathan Darrow, SJD, LL.M., JD, MBA, Panelist



Jonathan Darrow, SJD, LL.M., JD, MBA, is an Assistant Professor of Medicine at Harvard University and an Associate Professor of Law at Bentley University. He received his research doctorate (SJD) in pharmaceutical policy from Harvard University, where he completed an LL.M. program in intellectual property (waived). He has served as a senior law clerk at the U.S. Court of Appeals for the Federal Circuit, worked in private law practice at Cooley LLP and Wiley Rein LLP, taught on the faculties of four universities and for the World Intellectual Property Organization, authored several textbooks, supported the intellectual property divisions of WHO and WTO, lectured widely on issues of FDA regulation, and published numerous articles on issues such as expanded access, the breakthrough therapy designation, competition policy, pharmaceutical patenting, gene therapies, drug efficacy, biological products, therapeutic vaccines, and expedited development and approval programs.

Kristin Dolinski, Panelist



Kristin Dolinski is a Deputy Vice President of Science and Regulatory Advocacy at Pharmaceutical Research and Manufacturer's of America (PhRMA). In her role, she leads regulatory policy initiatives focused on the human drug review program, innovative tools and approaches, digital health, and informatics. Kristin works closely with biopharmaceutical companies and stakeholders, including regulators, on the advancement of advocacy strategies, policy positions, and plans.

Prior to joining PhRMA, Kristin worked at the Association of Schools and Programs of Public Health where she led the data analytics program and worked on public health preparedness and training initiatives.

Danielle Friend, PhD, Panelist



Danielle Friend, PhD, is a Senior Director of Science and Regulatory Affairs at the Biotechnology Innovation Organization (BIO). In this role, Dr. Friend develops and advocates for policies that support the development of innovative therapies. Her portfolio includes issues pertaining to rare diseases and orphan drugs, pediatric drug development, cell and gene therapies, digital health technology tools, and PDUFA and 21st Century Cures Act implementation, including patient-focused drug development and she leads BIO's work related to the opioid crisis. Prior to joining BIO, Dr. Friend was selected as a Science and Technology Policy Fellow with the American Association for the Advancement of Science (AAAS). During her fellowship Danielle developed policies related to genomic and scientific data sharing within the Office of the Director, in the Office of Science Policy at the National Institutes of Health (NIH). Danielle Friend

received her Ph.D. in neuroscience in 2013 from the University of Utah. After completing her graduate work, Danielle conducted postdoctoral research at the NIH. Dr. Friend has published papers in peer-reviewed science journals on drug addiction and toxicity and the relationship between obesity and reward circuitry in the brain.

Richard J. Kovacs, MD, MACC, Panelist



Richard Kovacs, MD, MACC, is the Q.E. and Sally Russell Professor of Cardiology at Indiana University (IU) School of Medicine and the cardiology service line leader of IU Health.

A graduate of the University of Chicago and the University of Cincinnati, School of Medicine, Kovacs completed an internship and residency at IU Medical Center. His fellowship training also was at IU, where he served as chief fellow and chief medical resident.

He joined the Indiana University School of Medicine in 1986 as assistant professor, subsequently serving as the medical director and CEO of Methodist Research Institute. He also served as senior clinical research physician at the Lilly Research Laboratories of Eli Lilly and Company. He returned to the full time IU School of Medicine faculty in 2003.

At the IU School of Medicine, Kovacs has served as the associate dean for Clinical Research and associate director of the Indiana Clinical and Translational Sciences Institute. He has also served as chair of Institutional Review Board for the Biomedical Sciences and the chair of the IRB Executive Committee.

Dr. Kovacs is a Past President of the American College of Cardiology. He also served as chair of the ACC Board of Governors and held leadership roles on the ACC's Science and Quality Committee and NCDR Management Board.

Kovacs's research interests include measuring and improving quality, drug safety and sports cardiology. He also oversees the cardiovascular evaluations of players at the Annual National Football League Scouting Combine.

Eleanor M. Perfetto, PhD, MS, Panelist



Eleanor M. Perfetto, PhD, MS, was named Senior Vice President of Strategic Initiatives for the National Health Council (NHC) in July of 2015 and was promoted to Executive Vice President in January 2019. She also holds a part-time faculty appointment at the University of Maryland, Baltimore School of Pharmacy where she is Professor of Pharmaceutical Health Service Research. Her research and policy work primarily focus on patient engagement in comparative effectiveness and patient centered-outcomes research, medical product development; patient-reported outcome selection and development; and health care quality. Dr. Perfetto holds BS and MS degrees in pharmacy from the University of Rhode Island, and a PhD from the

University of North Carolina School of Public Health with concentrations in health policy and epidemiology.

Joseph S. Ross, MD, MHS, Panelist



Joseph S. Ross, MD, MHS, is a Professor of Medicine (General Medicine) and of Public Health (Health Policy and Management) at the Yale School of Medicine, a member of the Center for Outcomes Research and Evaluation at Yale-New Haven Health System, and Co-Director of the National Clinician Scholars Program at Yale. With expertise in health services and outcomes research and the translation of clinical research into practice, his research examines the use and delivery of higher quality care and issues related to pharmaceutical and medical device regulation, evidence development, postmarket surveillance, and clinical adoption. Dr. Ross co-directs the Yale-Mayo Clinic Center for Excellence in Regulatory Science and Innovation (CERSI), the Yale Open Data Access (YODA) Project, and the

Collaboration for Research Integrity and Transparency (CRIT) at Yale Law School. He has published more than 400 articles in peer-reviewed biomedical journals and is currently the U.S. Outreach and Research Editor at BMJ.

Richard White, Panelist



Richard White joined the National Organization for Rare Disorders (NORD) as a Policy Analyst in mid-2020 and handles a portfolio that includes FDA, NIH, and CDC issues - specifically, issues relating to drug development and review as well as regulatory and scientific innovation. He also advocates for NORD's policies on Capitol Hill and across various stakeholders. Prior to joining NORD, Richard spent time at the Biotechnology Innovation Organization working on rare and orphan disease initiatives as well as regulatory processes in the drug development and approval life-cycle. Previously, Richard has held positions on Capitol Hill, patient advocacy groups, and a non-profit hospital. Richard is a graduate of Loyola University Maryland and resides in Washington, DC.

FDA STAKEHOLDER PANEL BIOGRAPHIES

Yoni Tyberg, MS, PMP, Moderator

See above.

Sarah Connelly, MD, Panelist

See above.

John Farley, MD, MPH, Panelist

See above.

Kerry Jo Lee, MD, Panelist

See above.

Stephanie Leuenroth-Quinn, PhD, Panelist



Stephanie Leuenroth-Quinn, PhD, is a Pharmacology/Toxicology Associate Director within the Office of New Drugs Immediate Office (OND IO) at the FDA. Her responsibilities in this role focus on issues surrounding the scientific review process, electronic data standards, and knowledge management efforts. She joined OND in the Division of Metabolism and Endocrinology Products (DMEP) in 2009 as a primary Pharmacology/Toxicology reviewer and advanced to a senior pharmacologist before joining the IO.

Dr. Leuenroth-Quinn continues to participate in several CDER modernization efforts including the design and implementation of the Integrated Review Template and associated processes. She is an active member of several subcommittee and working groups including those related to immunotoxicology, biologics,

IND and NDA/BLA review, and the Standard for Exchange of Nonclinical Data (SEND).

Dr. Leuenroth-Quinn's scientific background is one which has been focused on human health and disease research with direct experience in the development of small molecule therapeutics. She received her B.S. in Biotechnology from Rochester Institute of Technology and a Ph.D. in Pathobiology from Brown University. She completed her post-doctoral training at Yale University in the field of Chemical Biology and continued her work there as an Associate Research Scientist to gain further experience in nonclinical drug development.

Jinzhong Liu, PhD, Panelist



Jinzhong (Jin) Liu, PhD, leads the Office of New Drugs (OND) Clinical Data Scientist (CDS) team. Jin joined the FDA in 2014 to work on safety analyses of kinase inhibitors. After becoming a clinical pharmacology reviewer in the CDER/OTS/Office of Clinical Pharmacology (OCP), Jin reviewed numerous INDs, NDAs, and BLAs for the treatment of solid tumors and malignant hematology. After joining CDER/OND/Office of Oncologic Diseases (OOD) as a clinical analyst, Jin supported safety analyses for numerous INDs, NDAs, and BLAs. In August 2018, Jin was reassigned to OND Immediate Office to work under Dr. Peter Stein's direction to form the CDS team. Jin obtained his PhD in clinical pharmacology from Indiana University School of Medicine.

Jennifer Mercier, Panelist



Jennifer Mercier is the Director for the newly formed Office of Regulatory Operations in the Office of New Drugs. After graduating from Towson State University with a BS in Interdisciplinary Science in 1996, Jen joined FDA's Division of Reproductive and Urologic Drugs, now the Division of Urology, Obstetrics and Gynecology, as a Secretary. Jen quickly gravitated to the drug review process and started working as a Regulatory Project Manager for the Division. In 2002, Jen moved to the Office of Executive Programs in CDER supporting the Divisions within the former Office of Drug Evaluation II. Jen returned to her roots in 2003, becoming a CPMS within her original Division, and has been a Chief there ever since.

As a result of the CPMS work she routinely performed outside of her Division, Jen was asked to join the workstream tasked with developing the structure of the newly proposed Office of Regulatory Operations. With her extensive regulatory knowledge and management expertise, she helped the committee develop a structure that would build the Regulatory Project Managers into leaders and regulatory experts of their interdisciplinary review teams to effectively and efficiently complete their interdisciplinary reviews. The workstream also planned for the RPMs, CPMSs, and the newly formed role of Division of Project Management Staff (DPMSs) to obtain focused training and support and to utilize their expertise to further our mission. Following Jen's extensive work developing the Office of Regulatory Operations, she was named the Office Transition Lead in 2018. She continues as Office Transition Lead and CPMS, while also maintaining a portfolio of products as a Regulatory Project Manager.

Florence Moore, MS, PhD, Panelist



Florence Moore, MS, PhD, is a Science Policy Analyst with the Special Programs Staff in Office of New Drugs (OND) and serves as the Program Manager for Integrated Assessment of Marketing Applications. She joined the FDA in 2004 as a Consumer Safety Officer in CBER and has served as a Regulatory Health Project Manager (RPM), RPM Team Lead, RPM, Branch Chief in CDER, OND and Center for Tobacco (CTP), Office of Science, respectively. As a Health Science Administrator, she served as a Lead for Orphan Drugs Exclusivity reviews in Office of Orphan Products, in the Office of the Commissioner. Prior to joining the FDA, she worked in various positions in the biotechnology industries. She received a BS in Medical Research and Technology from the University of Maryland at Baltimore, MS in Biotechnology from John's Hopkins University and her PhD in Industrial and Organizational (I/O) Psychology at the Grand Canyon University.

Kellie Schoolar Reynolds, PharmD, Panelist



Kellie Schoolar Reynolds, PharmD, is Director of the Division of Infectious Disease Pharmacology in the Office of Clinical Pharmacology, CDER, FDA. She received her B.S. in Biochemistry from Virginia Tech, Pharm.D. from Virginia Commonwealth University, and completed a fellowship in Clinical Pharmacokinetics and Drug Development at University of North Carolina. Her work involves application of clinical pharmacology to development of antiviral and anti-infective drugs and drugs developed under the animal rule. Her interests include dose selection for sub-populations, drug interactions, risk/benefit assessment, and communication. Her work at FDA began in 1994 during a pivotal phase of HIV drug development, allowing her to experience the essential contribution of clinical pharmacology to development of drugs for a life threatening disease.

Dr. Reynolds is currently a member of the following groups in CDER: Drug Interaction Working Group, Drug Interaction Labeling Working Group, Renal Impairment Working Group, and OCP IND Review MAPP Working Group. She is the FDA topic lead for the International Council for Harmonization (ICH) Drug Interaction Working Group.

Over the past two years, Dr. Reynolds participated in a number of activities related to CDER modernization efforts. She helped draft the framework for the new Integrated Review for assessing NDAs and BLAs and the associated new review process. She currently supports the roll-out of the Integrated Assessment process.

Dr. Reynolds is a past president of the American Society for Clinical Pharmacology and Therapeutics and was an associate editor for Clinical Pharmacology and Therapeutics.

Lisa Skarupa, MSN, Panelist

Lisa Skarupa, MSN, is currently a Senior Regulatory Health Project Manager in the Division of Regulatory Operations-Specialty Medicine, in the Office of Regulatory Operations, CDER, FDA. She joined the FDA in 2007 as a Regulatory Project Manager and has gained her regulatory project management experience from various OND divisions. Her professional interest is on promoting scientific and regulatory education which led to her participating in committees for CDER and inter-agency workshops. Those workshops that she assisted in planning or coordinated included “Advances in Targeted Delivery of Biologics and Small Molecule Drugs” in CDER; a collaborative workshop for DMIP-NIAID-BARDA on “Regulatory Considerations for Drug Development for Lung Radiation Injury”; and two collaborative DIRM-NRC workshops - “Medical Radiation Safety” and “Enhancing Development of Emerging Technologies: Radiopharmaceuticals and Radiological Devices”. Lisa has supported efforts to facilitate the operation of New Drugs Regulatory Program Modernization, including the implementation of a resource page focused on educating OND Staff. Her current responsibilities include assisting the Integrated Assessment of Marketing Application initiative on educational projects as an ambassador for project management. Lisa obtained her Masters in Nursing from Johns Hopkins University School of Nursing.

Kimberly Struble, PharmD, Panelist

Kimberly Struble, PharmD, is currently a Senior Clinical Analyst Team Leader in the Division of Antivirals in the Office of Infectious Diseases, CDER, FDA. She received her B.S. in Pharmacy from the University of Connecticut and a Pharm.D. from the University of Arkansas for Medical Sciences. She provides expertise in all phases of antiviral clinical drug development and leads a team responsible for the development of new products for the treatment and prevention of HIV infection, hepatitis B and C, influenza, various herpes infections, and other emerging viral infections such as Ebola and COVID-19. She started at FDA in 1993 and worked as a project manager and clinical reviewer until 2002 then went to Tibotec-Virco as the Director of US Regulatory Affairs. She returned to FDA in 2003 as a clinical reviewer then became a team leader in 2006. She is a member of the Department of Health and Human Services HIV Treatment Guidelines Panel and she serves on various HIV-related committees including the Long-Acting/Extended Release Antiretroviral Drugs (LEAP). She is also the FDA representative to CDC for occupational and nonoccupational post-exposure prophylaxis public health service working group. She has over 30 publications and 50 presentations relating to HIV and HCV drug development and FDA regulations.

Aliza Thompson, MD, MS, Panelist



Aliza Thompson, MD, MS, is Deputy Director of the Division of Cardiology and Nephrology, Center for Drug Evaluation and Research at the U.S. Food and Drug Administration (FDA). The Division of Cardiology and Nephrology regulates and reviews Investigational New Drug applications and marketing applications for drug and biologic products for the treatment of cardiovascular and kidney diseases. Dr. Thompson joined the FDA in 2007. Prior to her current position, Dr. Thompson served as a clinical team leader for products being developed to treat kidney diseases. She received her medical degree from Johns Hopkins Medical School and completed her Internal Medicine and Nephrology training at Columbia University/New York-Presbyterian Hospital. She holds a Master of Science in Biostatistics/Patient Oriented Research

Track from Columbia University Mailman School of Public Health.

Therri Usher, PhD, Panelist



Therri Usher, PhD, is a Mathematical Statistician in the Center for Drug Evaluation and Research at the Food and Drug Administration. Dr. Usher provides statistical support to the regulation of drugs to treat inborn errors of metabolism (rare diseases) and, previously, for antiviral drugs. She has also provided statistical support for patient-focused drug development in the area of antimicrobial and antiviral products. Dr. Usher received her BS in Mathematical Sciences at the University of Texas at Dallas and her PhD in Biostatistics from Johns Hopkins University, where she conducted research on how health disparities impact the aging process.