NATIONAL ACADEMIES Sciences Engineering Medicine

Developing a Framework to Address Legal, Ethical, Regulatory, and Policy Issues for Research Specific to Pregnant and Lactating Persons

Day One

Real World Data and Real World Evidence: Challenges and Opportunities Panel Discussion

Kristin Veley, Pharm.D, M.P.H.
Executive Director, Partner, Evidera | Pharmaceutical Product Development

Dr. Kristin Veley serves as the scientific lead for REMS programs, pregnancy registries, and other related studies at Evidera. She earned her PharmD from the University at Buffalo, Buffalo, New York, and her MPH, with a focus in epidemiology and biostatistics and a certificate in maternal and child health, from Johns Hopkins University, Baltimore, Maryland. At Evidera – Evidence, Value, & Access by PPD, Kristin's focus is the design and analysis of REMS surveys and pregnancy registries. Prior to this, she was employed as a pharmacoepidemiologist at a specialty CRO in Baltimore, Maryland, where she analyzed and synthesized epidemiologic data and was involved in the design of patient registries for rare diseases. Kristin is a licensed pharmacist in the state of New York and practiced in the retail setting for six years prior to her employment in the pharmaceutical industry. During the course of her education, she also worked as a research assistant at Johns Hopkins University, participated in international field work in Bangladesh, and trained as a pharmacist in a variety of care settings. Kristin's experience extends across a broad range of therapeutic areas including infectious, chronic, and rare diseases. Her combined education in pharmacy and public health offer a unique perspective to pharmacoepidemiological research.

Tina Chambers, Ph.D., M.P.H.
Professor of Pediatrics, University of California San Diego

Dr. Chambers is a professor of pediatrics at University of California, San Diego and Vice Chair of Clinical Research for the Department of Pediatrics at UCSD and Rady Children's Hospital. She is a perinatal epidemiologist, whose research is focused on environmental exposures and pregnancy and child health outcomes, including birth defects. She co-directs the Center for Better Beginnings in the Department of Pediatrics at UCSD and is the Program Director of MotherToBabyCalifornia - a service providing evidence-based information on exposures during pregnancy and lactation to the public and health care providers. She is the founder and Program Director of Mommy's Milk, a nationwide human milk biorepository for research. Furthermore, she is the director of the UCSD ACTRI Center for Life Course and Vulnerable Populations Research, which brings together a unique multidisciplinary group of researchers to address study questions across the lifespan and special populations. Dr. Chambers leads a number of national and international complex longitudinal cohort studies and clinical trials of prenatal exposures and child health and development. Her research over the last 20 years has focused on environmental causes of birth defects, other adverse pregnancy outcomes and childhood disabilities, with a focus on pre- and postnatal exposure to recreational substances and medications. Her research has been instrumental in identifying previously unrecognized human teratogens, as well as ruling out substantial risk for other prenatal exposures.

Tamara Johnson, M.D., M.S.
Lead Medical Officer, Division of Pediatric and Maternal Health, FDA

Dr. Tamara Johnson is a Lead Medical Officer of the Maternal Health Team within the Division of Pediatrics and Maternal Health (DPMH), Office of New Drugs (OND), Center for Drug Evaluation and Research, US Food & Drug Administration. Dr. Johnson has been with the FDA for over 15 years. Initially, as a Medical Officer in the OND Division of Gastroenterology and Inborn Errors Products, she has lead the DPMH Maternal Health Team for 8 years. The Maternal Health Team is responsible for evaluating the safe use of drug and biologics products in pregnant and lactating women, and is involved in review of prescription drug labeling (including implementation of the Pregnancy and Lactation Labeling Rule (PLLR)), clinical lactation studies, and post-approval pregnancy safety studies. Dr. Johnson earned her Doctorate in Medicine from the Rutgers Robert Wood Johnson Medical School in New Jersey. She completed internship at the Georgetown/Providence Hospital Family Medicine program and completed residency training in General Preventive Medicine/Public Health at the University of Maryland Baltimore.

Jonathan Watanabe, Ph.D., Pharm.D., M.S.
Associate Dean of Pharmacy Assessment and Quality, University of California Irvine

Dr. Jonathan Watanabe is a board-certified geriatrics pharmacist, health economist, and outcomes researcher. He serves as a Member of the National Academies of Sciences, Engineering, and Medicine (NASEM) Forum on Drug, Discovery, Development, and Translation. He is an appointed member of the Board of Directors of the California Geriatrics Society of the American Geriatrics Society. Professor Watanabe has been involved in methods development for pragmatic clinical trials through the FDA-sponsored Real-World Evidence Series and served on the steering committee for the Drug Research Development in Older Adults Workshop. Professor Watanabe applies real-world data to develop policy solutions to improve patient care, bolster population-health, enhance access and equity for marginalized populations and reduce medical costs. He was a contributor to the NASEM report Making Medicines Affordable: a National Imperative and served on the committee for the Medications in Single-Dose Vials: Implications of Discarded Drugs Report. He has provided briefings to the Centers for Medicare and Medicaid Services, United States Senate Finance, Appropriations, House Ways and Means, Senate HELP, and House Energy and Commerce Committee and Briefings to United States House of Representatives Appropriations Committee Staff on the implications of discarded medications and steps to take to reduce wasted medications. He received his BS from the University of Washington, his PharmD from the University of Southern California, and his MS and PhD from the University of Washington Comparative Health Outcomes, Policy, and Economics (CHOICE) Institute.

Discussion about Liability for Pregnant and Lactating Persons Exclusion

Chris Seeger, J.D.
Partner, Seeger Weiss

Mr. Chris Seeger is a founding partner of Seeger Weiss and is widely recognized as a highly innovative and accomplished plaintiff attorney. Chiefly known for multidistrict mass torts and class actions involving drug injury, toxic injury and personal injury, Chris's versatile practice also includes product liability, property damage, antitrust, third-party payer litigation, as well as consumer, insurance, and securities fraud. Chris has led some of the most complex, groundbreaking, and high-profile litigations in the U.S., at both the state and federal level, including *In re National Football League Players' Concussion Injury Litigation*, *In re Volkswagen "Clean Diesel" Marketing, Sales Practices and Products Liability Litigation*, and *In re Syngenta AG MIR 162*

Corn Litigation. Often selected by the courts to serve as Lead Counsel, Co-Lead Counsel, Liaison Counsel, or member of the Plaintiffs' Executive and/or Steering Committee in dozens of proceedings, Chris received the most multidistrict litigation (MDL) appointments of any lawyer between 2016 and 2019 according to a 2020 ALM study. More recently, he has served on the Plaintiffs' Executive Committee in *In re: National Prescription Opiate Litigation*, and co-lead counsel in *In re 3M Combat Arms Earplug Products Liability Litigation*, *In re Proton-Pump Inhibitor Products Liability Litigation*, *In re Philips Recalled CPAP, Bi-Level Pap, and Mechanical Ventilator Products Litigation*, and *In re: Social Media Adolescent Addiction/Personal Injury Products Liability Litigation*. His unique experience makes him a knowledgeable and capable litigator and highly regarded among his colleagues.

Alan C. Milstein, J.D., M.A.
Shareholder & Chairman, Sherman, Silverstein, Kohl, Rose & Podolsky P.A.

Mr. Alan Milstein is a shareholder of the Sherman, Silverstein, Kohl, Rose, and Podolsky Firm and Chairman of the Firm's Litigation Department. He is nationally recognized as a preeminent litigator, expert, lecturer, and author. Mr. Milstein is particularly prominent in the following domains: insurance law and fire loss litigation, products liability, bioethics, and clinical trials litigation. In these specific areas, Mr. Milstein is more than prominent—he is acknowledged as a pioneer in establishing the rights of research subjects. His cases and arguments have been mentioned in numerous books and articles concerning current topics in healthcare. He was appointed an adjunct professor at the Temple University School of Law teaching Bioethics and his expertise on bioethics issues has made him a sought-after television guest. He has appeared on Dateline, Sixty Minutes, 48 Hours, Hannity and Colmes, The Today Show, Sunday Morning, CBS News, NBC News, CNN, BBC's Science and Nature, ZDF German Public Television, and NHK Japanese Public Television.

Presentation on Food and Drug Administration Commissioned Paper

Julie Tibbets, J.D.
Partner, Goodwin Procter LLP

Ms. Julie Tibbets chairs Goodwin's Life Sciences Regulatory & Compliance practice at the firm. In addition, she co-chairs Goodwin's firmwide Attorney Review Committee. Julie focuses her practice on FDA-regulated product development, crisis resolution, product marketing and corporate communications as well as the intersection of each of those with corporate strategy and securities disclosure obligations. Her product areas of focus include biologics, drugs, medical devices, in vitro diagnostics, as well as digital therapeutics, tools and apps. Julie advises clients on product development strategy, interactions with the FDA, clinical trial conduct and documentation, adverse event reporting, commercial strategy, product labeling and advertising, and FDA inspections. She also leads the regulatory due diligence reviews of FDA-regulated M&A or investment targets, potential collaborators and licensees, and guides the regulatory disclosures of FDA-regulated entities in their initial public offerings and follow-on offerings. Julie also works closely with the Food & Healthy Living practice team at Goodwin on the intersection of food, supplement, and cosmetic regulation with FDA's drug and device authorities.

Sarah Wicks, J.D., M.P.H.
Associate, Goodwin Procter LLP

Ms. Sarah Wicks is an associate in Goodwin's Technology and Life Sciences groups and a member of the firm's Life Sciences Regulatory & Compliance practice. She counsels pharmaceutical, biologic and medical device companies on FDA regulatory compliance issues, including those relating to human subject protections and the conduct of clinical trials, drug and device development, interactions with the FDA, advertising, promotion and labeling, internal corporate investigations and responding to FDA inspection observations and enforcement actions. Sarah also advises FDA-regulated entities in corporate transactions, offerings and licensing matters.

Day Two

Product Liability Discussion

Kirke Weaver, J.D.
General Counsel, Organon

Mr. Kirke Weaver is the General Counsel and Corporate Secretary for Organon, serving as the senior legal adviser and responsible for the company's worldwide legal affairs, compliance and global environmental, health and safety functions. He is focused on ensuring Organon maintains the highest ethical standards, which will help drive Organon's achievement of its vision as a leading women's healthcare company. Prior to his appointment as General Counsel and Corporate Secretary, Kirke served as Senior Vice President, Commercial, Regulatory, Securities, Employment and Deputy Corporate Secretary at Organon. He was critical to launching Organon as a standalone company in June 2021, acting as a senior member of the legal leadership team.