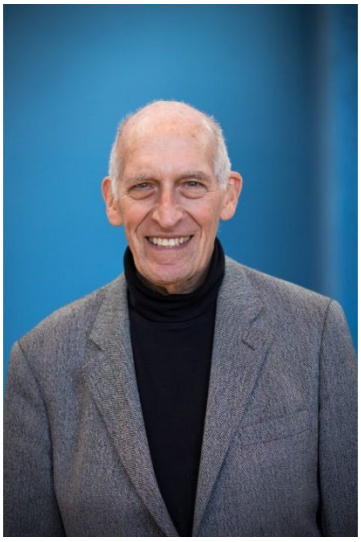
Menopause Workshop: Potential Impact on Clinical Pharmacology and Opportunities for Future Research

October 11, 2023

Hosted by the FDA Office of Women's Health (OWH), in collaboration with the Center for Drug Evaluation and Research (CDER) Office of Clinical Pharmacology (OCP)

Workshop agenda and information

WORKSHOP SPEAKERS AND MODERATORS



LESLIE Z. BENET, PhD
Professor and former Chair
Department of Bioengineering and Therapeutic Sciences
Schools of Pharmacy and Medicine
University of California San Francisco

Speaker, Session II: Menopause and PK/PD

Dr. Benet's >620 publications are in PKPD and drug delivery. He is among the most highly cited pharmacologists with >33,000 citations (Clarivate Analytics) and >51,000 (Google Scholar). He was Founder/President of the American Association of Pharmaceutical Scientists (1986) and elected to the National Academy of Medicine (1987). He chaired the FDA's CBER Peer Review Committee and Expert Panel on Individual Bioequivalence, serving on the initial FDA Science Board and Generic Drugs Advisory Committee.

SUSAN BERSOFF-MATCHA, MD
Deputy Director
Office of Women's Health
U.S. Food and Drug Administration

Workshop Chairperson

Susan Bersoff-Matcha, MD is the Deputy Director in the Office of Women's Health at FDA where she oversees the Office's scientific programs. Since coming to FDA in 2016, Dr. Matcha has worked in the Office of Medical Policy, and Office of Surveillance and Epidemiology. She has a longstanding interest on women's health and has published several peer-reviewed articles on this topic.

Dr. Matcha attended Georgetown University School of Medicine, completed her internship and residency training at Emory University, and subspecialty fellowship training at Washington University School of Medicine, Division of Infectious Diseases in St. Louis, Missouri. Dr. Matcha is board certified in both Internal Medicine and Infectious Diseases.

CHRISTINA CHANG, MD, MPH
Director, Division of Urology, Obstetrics and Gynecology (DUOG)
Office of Rare Diseases, Pediatrics, Urology, and Reproductive Medicine (ORPURM)
Office of New Drugs (OND)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration

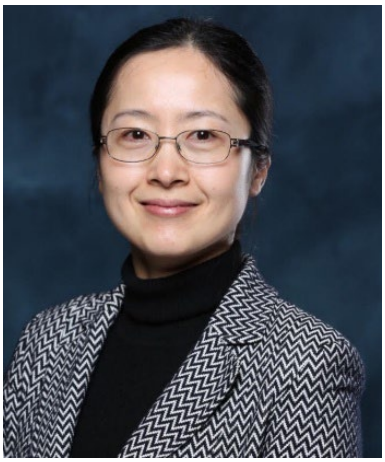
Moderator, Session I: Overview of Biological Changes of Menopause

Dr. Christina Chang is the Director of the Division of Urology, Obstetrics and Gynecology in the Center for Drug Evaluation and Research. A board-certified obstetrician/gynecologist, Dr. Chang obtained her bachelor's degree in Biochemistry from University of California at Berkeley and her medical degree from University of Chicago Pritzker School of Medicine. She also received her Master of Public Health from the Johns Hopkins University School of Hygiene and Public Health.

AUDREY GASSMAN, MD
Deputy Director
Division of Urology, Obstetrics, and Gynecology (DUOG)
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration

Speaker, Session II: Menopause and PK/PD

Dr. Audrey Gassman is the Deputy Director of the Division of Urology, Obstetrics and Gynecology (DUOG). Throughout her FDA tenure, she worked on numerous drug development programs and led several guidances through development. Dr. Gassman is board-certified in Obstetrics/Gynecology and Reproductive Endocrinology. After receiving her medical degree, she completed an Obstetrics/Gynecology residency and Reproductive Endocrinology fellowship. She practiced and taught for 7 years before joining the FDA.



YANHUI LU, PhD
Clinical Pharmacology Team Leader
Division of Cardiometabolic and Endocrine Pharmacology
Office of Clinical Pharmacology
Office of Translational Sciences
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

Speaker, Session II: Menopause and PK/PD

Dr. Yanhui Lu is the Clinical Pharmacology Team Leader supporting review of Urology, Obstetrics, and Gynecology drug products at the FDA. Dr. Lu received her Ph.D. in Pharmacology and Molecular Sciences from The Johns Hopkins University School of Medicine. She started her career as a Senior Scientist in Quantitative Pharmacology and Pharmacometrics at Merck & Co., Inc. and joined the FDA in 2016 as a Clinical Pharmacology reviewer supporting review of Dermatology and Dental products.

RAJ MADABUSHI, PhD
Associate Director, Guidance and Scientific Policy
Immediate Office, Office of Clinical Pharmacology
Center for Drug Evaluation and Research
Office of Clinical Pharmacology |Office of Translational Sciences
U.S. Food and Drug Administration

Moderator, Session II: Menopause and PK/PD

Rajanikanth (Raj) Madabushi has over 15 years of regulatory experience as a Pharmacometrics Reviewer and Clinical Pharmacology Team Lead in the Office of Clinical Pharmacology, OTS/CDER/FDA. He currently serves as the Associate Director, Guidance and Scientific Policy in the Immediate Office of Clinical Pharmacology. Dr. Madabushi is the CDER Point-of-Contact for the MIDD Paired Meeting Program. Dr. Madabushi is also involved in global harmonization activities as the Rapporteur for ICH M12 Expert Working Group – Drug Interaction Studies.

VIRGINIA M. MILLER, MBA, PhD
Professor Emerita, Surgery and Physiology
Mayo Clinic, Rochester, MN

Speaker, Session II: Menopause and PK/PD

Virginia M. Miller, MBA, PhD is Professor Emerita of Surgery and Physiology at Mayo Clinic, Rochester, MN. Her research focused on how sex steroids, and conditions unique to women, e.g., pregnancy and menopause, affect cardiovascular health and cognition. She was the Principal Investigator of the Mayo Clinic Specialized Center of Research on Sex Differences, directed their Women's Health Research Center, served on review and editorial panels and in leadership positions for professional societies.

GLORIA RICHARD-DAVIS, MD, MBA, NCMP, FACOG
Reproductive Endocrinology Obstetrician/Gynecologist
Executive Director, Division for Diversity, Equity & Inclusion
Department of Obstetrics and Gynecology
University of Arkansas for Medical Sciences (UAMS)

Speaker, Session I: Overview of Biological Changes of Menopause

Speaker information coming soon.

NANETTE SANTORO, MD
Professor and E. Stewart Taylor Chair
Department of Obstetrics and Gynecology
University of Colorado School of Medicine

Speaker, Session I: Overview of Biological Changes of Menopause

Dr. Nanette Santoro is the E Stewart Taylor Chair of OB-GYN at the University of Colorado School of Medicine. Her current research involves treatment of menopausal symptoms in women, understanding the mechanisms by which obesity causes relative infertility in women, clinical trials in reproductive medicine, and research training of Ob-Gyns and Reproductive Endocrinologists. She has been continuously funded by the NIH since 1989 and in 2018 was elected to the National Academy of Medicine.

CYNTHIA A. STUENKEL, MD
Clinical Professor of Medicine,
Endocrinology and Metabolism
UC San Diego School of Medicine

Speaker, Session I: Overview of Biological Changes of Menopause

Cynthia A. Stuenkel, MD, established one of the first menopause programs in the US in 1988. She is a Founding Member and Past President of the North American Menopause Society, chaired the Endocrine Society's 2015 Clinical Practice Menopause Guidelines and coauthored their 2023 Scientific Statement on Hormones and Aging. She has presented to the National Academies of Medicine, menopause leaders at home and abroad, and on World Menopause Day, 2023, will address Cardiovascular Disease in Women.

KAVEETA P. VASISHT, MD, PharmD
Associate Commissioner for Women's Health
Director, FDA Office of Women's Health
U.S. Food and Drug Administration

Welcome and Closing Remarks

Dr. Kaveeta Vasisht is the Associate Commissioner for Women's Health at the US Food and Drug Administration (FDA). She also directs the FDA Office of Women's Health (OWH), which serves to protect and advance the health of women through policy development, scientific programs, research, education, collaboration, and outreach. OWH leads efforts to advance regulatory science through understanding sex differences, promoting the inclusion of women and diversity in clinical trials, establishing women's health research priorities at FDA, and developing educational resources. In addition, OWH works to bridge important knowledge gaps on conditions that uniquely or disproportionately impact women, including pregnancy and lactation.

Prior to her current role, she served as the Deputy Director in FDA's Center for Drug Evaluation and Research (CDER) Office of Medical Policy, Division of Clinical Trial Quality. She has extensive expertise in leading regulatory policy development. She also served as the medical expert on multidisciplinary teams in the review and evaluation of scientific data to make regulatory decisions on the safety and effectiveness of therapeutics during her tenure in CDER's Office of New Drugs.

Dr. Vasisht is board-certified in both internal medicine and adult endocrinology. She completed her internal medicine residency and endocrinology fellowship at the University of Chicago Hospitals, where she also served on faculty. She received her medical degree from UMDNJ Robert Wood Johnson Medical School and also holds a Doctor of Pharmacy degree from Rutgers College of Pharmacy where she graduated with high honors from the Honors Research Program. Dr. Vasisht has received numerous recognitions for her contributions and is the recipient of the 2023 Health Public Service Visionary Award from the Society for Women's Health Research (SWHR).

JANET WOODCOCK, MD
Principal Deputy Commissioner
U.S. Food and Drug Administration

Keynote Address
Dr. Janet Woodcock is the FDA's Principal Deputy Commissioner. In this role she works closely with the Commissioner of Food and Drugs to develop and implement key public health initiatives and helps oversee the agency's day-to-day functions.

She served as the Acting Commissioner of Food and Drugs from Jan. 20, 2021, until Feb. 17, 2022.

Dr. Woodcock began her FDA career in 1986 at the Center for Biologics Evaluation and Research (CBER). At CBER, she served as Director of the Division of Biological Investigational New Drugs and as Acting Deputy Director. She later became Director of CBER's Office of Therapeutics Research and Review, which oversaw the approval of the first biotechnology-based treatments for multiple sclerosis and cystic fibrosis during her tenure.

In 1994, Dr. Woodcock was named Director of the FDA's Center for Drug Evaluation and Research (CDER), leading the Center's work that is the world's gold standard for drug approval and safety. There she conceived and implemented many of the FDA's drug initiatives, including introducing the concept of risk management as a new approach to drug safety; modernizing drug manufacturing and regulation through the Pharmaceutical Quality for the 21st Century Initiative; advancing medical discoveries from the laboratory to consumers more efficiently under the Critical Path Initiative; launching the Safety First and Safe Use initiatives designed to improve drug safety management within and outside the FDA, respectively; developing the Sentinel Network for drug safety and spearheading CDER efforts on patient-focused drug development.

In 2004, Dr. Woodcock became the FDA's Deputy Commissioner and Chief Medical Officer. Later she took on other executive leadership positions in the Commissioner's Office, including Deputy Commissioner for Operations and Chief Operating Officer.

In 2007, Dr. Woodcock returned as Director of CDER until she was asked to be the therapeutics lead for “Operation Warp Speed” in early 2020. This entailed supporting the development, evaluation, and availability of treatments such as monoclonal antibodies and antiviral drugs for patients with COVID-19.
Dr. Woodcock holds a Bachelor of Science in chemistry from Bucknell University (Lewisburg, PA), and a Doctor of Medicine from the Feinberg School of Medicine at Northwestern University Medical School (Chicago). She also completed further training and a fellowship in rheumatology, as well as held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She is board certified in internal medicine.

Dr. Woodcock has been bestowed numerous honors over her distinguished public health career, most notably: the Nathan Davis award from the American Medical Association in 1999; the Roger W. Jones Award for executive leadership from American University in 2000; the VIDA award from the Society for Hispanic Health and the first Leadership Award in Personalized Medicine from the Coalition for Personalized Medicine in 2005; the Garry Neil prize for Innovation in Drug Development in 2009; a Lifetime Achievement Award in 2015 from the Institute for Safe Medication Practices; the Florence Kelley Consumer Leadership Award in 2017 from the National Consumers League; and the 2019 Biotechnology Heritage Award from the Biotechnology Innovation Organization and Science History Institute.

Office of Women’s Health

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