U.S. FOOD & DRUG ADMINISTRATION

Public Workshop

FDA Office of Women's Health (OWH) and
Center for Drug Evaluation and Research (CDER) Present

Testosterone Use in Menopausal Women

September 17, 2026 | 9 AM - 4:30 PM ET

Agenda

9:00 – 9:05 AM **Welcome**

Lakshmi Kannan, PhD — Senior Advisor, Office of Women's Health, Office of the Commissioner, FDA

9:05 – 9:15 AM **Opening Remarks**

Kaveeta Vasisht, MD, PharmD — Associate Commissioner for Women's Health and Director, Office of Women's Health, FDA

Christina Chang, MD, MPH — Division Director, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA

9:15 – 9:30 AM **Keynote Address**

Admiral Brian Christine, MD — Assistant Secretary for Health, HHS; Head of the United States Public Health Service Commissioned Corps

Dorothy Fink, MD — Deputy Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health

Session I: Role Of Testosterone In Female Biology

9:30 – 9:50 AM **Physiological Roles of Testosterone Throughout a Woman's Life – What We Know and What We Don't**

Margaret E. Wierman, MD — Professor of Medicine, Integrative Physiology and OBGYN, University of Colorado School of Medicine

9:50 – 10:10 AM **Measuring and Assessing Testosterone Levels in Women: Navigating Challenges**

James A. Simon, MD, CCD, MSCP, IF, FACOG — Clinical Professor, Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology, The George Washington University School of Medicine; Medical Director, IntimMedicine Specialists, Washington DC

Session II: Clinical Guidelines, Practice, and Perspectives For Testosterone Use In Menopausal Women

10:10 – 10:30 AM **Clinical Guidelines for Testosterone Therapy in Menopausal Women**

Rajita Patil, MD, MSCP, FACOG — Associate Clinical Professor, Department of Obstetrics and Gynecology; Director of the UCLA Comprehensive Menopause Program; Complex Family Planning Subspecialist

10:30 – 10:50 AM **Benefit-Risk and Dosing Considerations**

Pelin Batur, MD, FACP, MSCP — Center Director of Women's Comprehensive Health and Research Center, Cleveland Clinic; Professor of Obstetrics and Gynecology & Reproductive Biology, Cleveland Clinic Lerner College of Medicine, Case Western Reserve University

10:50 – 11:10 AM **Clinician Perspective**

Rachel Rubin, MD — Urologist and Sexual Medicine Specialist, Assistant Clinical Professor, Department of Urology, Georgetown University School of Medicine

11:10 – 11:30 AM **Patient Perspective**

Ms. Susan Amanda Swain Lake, Menopause Hormone Therapy Patient

11:30 – 12:30 PM **Panel I: Discussion Based On Sessions I & II / Q&A**

Moderator: Christine Pham Nguyen, MD — Deputy Director Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, Office of New Drugs, CDER, FDA

12:30 – 1:30 PM **Lunch Break**

Session III: Regulatory Considerations and Charting A Path Forward

1:30 – 1:50 PM **General Considerations for Drug Approval**

Marcea B. Whitaker, MD — Senior Medical Officer, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA

1:50 – 2:10 PM **Efficacy Considerations for the Use of Testosterone in Menopausal Women**

Anandi D. Kotak, MD, MS, MPH, FACOG — Lead Physician, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA

2:10 – 2:30 PM **Clinical Outcome Assessments: Measuring What Matters**

Selena R. Daniels, PharmD, PhD — Deputy Director, Division of Clinical Outcome Assessment, CDER, FDA

2:30 – 2:50 PM **Safety Considerations for the Use of Testosterone in Menopausal Women**

Linda S. Jaffe, MD — Senior Physician, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA; Part-time Assistant Professor of Medicine, Harvard Medical School, Boston, MA

2:50 – 3:10 PM **Break**

3:10 – 3:30 PM **Role of Testosterone Concentration in Development of Testosterone Products for Female Indications**

Doanh Tran, PhD — Deputy Director, Division of Cardiometabolic and Endocrine Pharmacology, Office of Clinical Pharmacology, Office of Translational Science, CDER, FDA

3:30 – 4:20 PM **Panel II: Discussion Based On Session III / Q&A**

Moderator: Christina Chang, MD, MPH — Division Director, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA

4:20 – 4:30 PM **Closing Remarks**

FDA OWH

Workshop Speakers And Moderators

Pelin Batur MD, FACP, MSCP

Center Director of Women's Comprehensive Health and Research Center, Cleveland Clinic; Professor of Obstetrics and Gynecology & Reproductive Biology, Cleveland Clinic Lerner College of Medicine, Case Western Reserve University

Speaker, Session II: Benefit-Risk and Dosing Considerations/ Panelist, Panel I Discussion

Pelin Batur MD, FACP, MSCP has been at the Cleveland Clinic since 1998; she works in the Department of Subspecialty Care for Women's Health, within Ob/Gyn. Dr. Batur did both her internal medicine residency and women's health fellowship at the Cleveland Clinic. She is a Professor of Ob/Gyn & Reproductive Biology at Cleveland Clinic Lerner College of Medicine of Case Western Reserve University. Her practice is a referral resource for women with complex hormonal needs. Her areas of expertise include menopause, medically complex contraception (including menstrual migraine and menstrually associated neurologic conditions), osteoporosis, and sexual health.

She has been integral to the creation of several programs within the Ob/Gyn Institute, including the Sexual Health Program, Complex Contraception Clinic, and currently is the Center Director for the Women's Comprehensive Health and Research Center. She also serves as the hormone liaison for multidisciplinary programs in partnership with the Cancer Institute, including the Hereditary Breast and Ovarian Cancer as well the Young Onset Colorectal Cancer Programs.

She has held several educational leadership roles throughout her career, and is actively involved in the education of medical trainees, staff physicians, and nurses. She has authored over 100 articles, book chapters, and abstracts on a variety of women's health topics, and lectures internationally to general medicine, endocrinology and gynecology specialists. She works closely with multiple national medical organizations to advance women's healthcare. After 15 years of balancing a primary care and consultative women's health practice, she has transitioned to a purely women's health practice in efforts to be more accessible to those in need of specialized women's health services.

Christina Chang, MD, MPH

Division Director, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA

Opening Remarks and Moderator, Panel II: Discussion based on Sessions III / Q&A

Dr. Christina Chang is the Director of the Division of Urology, Obstetrics and Gynecology (DUOG) in the Office of New Drugs in the Center for Drug Evaluation and Research at U.S. FDA. DUOG oversees a diverse group of drugs and therapeutic biologics for the management of benign urologic, obstetric, and gynecologic conditions. She has led the facilitation and assessment of many development programs in these areas, including products to manage endometriosis-associated pain and heavy menstrual bleeding due to uterine fibroids, products to treat pre-malignant dysplasia of the cervix, and products to prevent preterm birth. Dr. Chang has co-authored several publications on regulatory science and complex FDA decisions. She started her FDA career in 2007 as a clinical reviewer in the Division of Nonprescription Clinical Evaluation and took on the role of clinical team leader in DUOG in 2013.

Dr. Chang is a board-certified obstetrician/gynecologist. She 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 with Honors from the Johns Hopkins University School of Hygiene and Public Health. She completed her obstetrics and gynecology residency at Washington Hospital Center in Washington D.C. Prior to joining the FDA, she provided full-scope obstetric and gynecologic care to adolescent and adult females in Fairfield County in Connecticut and founded her own practice.

Admiral Brian Christine, MD

Assistant Secretary for Health, HHS; Head of the United States Public Health Service Commissioned Corps

Keynote Speaker

Admiral Brian Christine serves as the 18th Assistant Secretary for Health at the U.S. Department of Health and Human Services (HHS). In this role, he provides leadership on the nation's public health priorities, including chronic disease prevention and efforts to strengthen the nation's overall health. ADM Christine also leads the U.S. Public Health Service Commissioned Corps, one of the nation's eight uniformed services, composed of more than 5,000 public health professionals dedicated to protecting, promoting, and advancing the health and safety of the nation.

Admiral Brian Christine, MD (continued)

President Donald Trump nominated ADM Christine for this position, and he was subsequently confirmed by the U.S. Senate.

As Assistant Secretary for Health, ADM Christine is focused on restoring trust in public health, radical transparency, and tackling the epidemic. His leadership emphasizes putting patients first, strengthening the integrity of public health institutions, and ensuring that every American has the opportunity to live a healthier, more fulfilling life. ADM Christine earned his Doctor of Medicine degree from Emory University and completed his residency in Urology at the University of Alabama at Birmingham. An internationally recognized leader in Men's Health, he established a practice regarded as a global Center of Excellence, treating patients from across the United States and abroad.

ADM Christine has published peer-reviewed research, lectured extensively, and trained surgeons around the world. He is a member of several leading professional organizations, including the American Urologic Association, the Sexual Medicine Society of North America, the International Society for Sexual Medicine, and the International Continence Society. As a "Mainstreet Physician" treating the men, the women, and children of our republic, ADM Christine has demonstrated a deep commitment to service, innovation, and improving the health and well-being of all Americans.

Selena R. Daniels, PharmD, PhD

Deputy Director, Division of Clinical Outcome Assessment, CDER, FDA

Speaker, Session III: Efficacy for Testosterone Clinical Trials in Women/ Panelist, Panel II Discussion

Dr. Selena Daniels serves as the Deputy Division Director in the Division of Clinical Outcome Assessment at the FDA. She provides direction, oversight, and leadership to a team of expert analysts who provide consultation and advice on clinical outcome assessment (COA) endpoint development and validation, including considerations for clinical trial design, conduct, analysis, interpretation, and reporting for regulatory determinations of medical product benefit.

Prior to joining the FDA in 2015, Dr. Daniels worked in the Health Economic and Outcomes Research (HEOR) group at Allergan, Inc (now Abbvie), where she developed and executed HEOR strategies, as well as developed and implemented innovative COA strategies and endpoints for clinical trials. Dr. Daniels received her Doctor of Philosophy degree in Education at Nova Southeastern University and Doctor of Pharmacy degree at Loma Linda University.

Dorothy Fink, MD

Deputy Director, Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health

Keynote Speaker

Dorothy Fink, M.D., became the Deputy Director of the Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Institutes of Health, on August 9, 2026. Previously, Dr. Fink served as Principal Deputy Assistant Secretary for Health in the Office of the Assistant Secretary for Health (OASH) at the U.S. Department of Health and Human Services (HHS). In these roles, she has led initiatives focused on improving health outcomes, including efforts related to maternal and infant health, reproductive health, and menopause. She has also served as the Acting Secretary of the Department of Health and Human Services and as the Acting Assistant Secretary for Health.

Dr. Fink is board certified in endocrinology, internal medicine, and pediatrics and is a nationally certified menopause practitioner. She has published peer-reviewed research on maternal and infant health, diabetes, osteoporosis, and other conditions affecting women across the lifespan.

Dr. Fink earned her medical degree from Georgetown University School of Medicine. She completed a combined internal medicine and pediatrics residency training at the University of Pittsburgh Medical Center and a postdoctoral fellowship in endocrinology and metabolism at Columbia University College of Physicians and Surgeons. Dr. Fink directed the Diabetes Pillar for the medical student curriculum at New York University School of Medicine and coordinated teaching for medical students throughout their medical training with a focus on nutrition and preventing and reversing diabetes. She also focused on optimizing peak bone mass in adolescents and diabetes care prior to surgical intervention at the Hospital for Special Surgery and New York Presbyterian/Weill Cornell Medical Center.

Linda S. Jaffe, MD

Senior Physician, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA; Part-time Assistant Professor of Medicine, Harvard Medical School, Boston, MA

Speaker, Session III: Safety of Testosterone in Women/ Panelist, Panel II Discussion

Dr. Linda Jaffe is a Senior Physician in FDA's Division of Urology, Obstetrics and Gynecology. She trained at Harvard Medical School and Brigham and Women's Hospital in Boston, with a career emphasizing women's health and endocrinology.

Linda S. Jaffe, MD (continued)

At FDA since 2017, she focuses on regulation of gynecological products, regulatory science, and medical education. Dr. Jaffe also has an academic appointment as a part-time Assistant Professor of Medicine at Harvard Medical School.

Lakshmi Kannan, PhD

Senior Advisor, Office of Women's Health, Office of the Commissioner, FDA

Workshop Chairperson

Lakshmi Kannan, Ph.D., serves as Senior Advisor to the Associate Commissioner and Director of the Office of Women's Health (OWH) at the FDA, where she provides scientific and strategic advice on regulatory and women's health matters, identifies emerging scientific issues affecting women's health, and advances cross-Center and interagency efforts to address them. She has over a decade of experience advancing public health priorities at the FDA. Dr. Kannan joined the FDA in 2015 as a Commissioner's Fellow, where she led development of scientific and consensus-driven endpoints for Traumatic Brain Injury (TBI), contributing to the qualification of FDA's first medical device development tool used as a biomarker in TBI diagnosis.

She subsequently served as a Regulatory Biologist and Senior Science Health Advisor in the Office of Strategic Partnerships and Technology Innovation in the Center for Devices and Radiological Health, where she directed strategic planning initiatives, led national cross-functional teams during public health emergencies, directed COVID-19 response teams, and coordinated national medical device shortage mitigation efforts.

Dr. Kannan holds a Ph.D. in Cell and Molecular Biology from the University of Arkansas, Fayetteville, where her research focused on identifying and characterizing immunoregulatory pathways for antimicrobial peptides in immune cells. She subsequently completed postdoctoral training and served as Instructor in Medicine at Harvard Medical School, where her research focused on complement-mediated signaling mechanisms, vascular injury, and tissue damage in models of trauma and ischemia. She is also a graduate of the National Preparedness Leadership Initiative executive education program at Harvard University.

Anandi D. Kotak, MD, MS, MPH, FACOG

Lead Physician, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA

Speaker, Session III: Efficacy for Testosterone Clinical Trials in Women/ Panelist, Panel II Discussion

Anandi D. Kotak, MD, MS, MPH, FACOG, is a Lead Physician in the Division of Urology, Obstetrics, & Gynecology in the Office of New Drugs in CDER. She is a board-certified obstetrician/gynecologist. She leads scientific review, guidance development, and interdisciplinary collaborations for products to treat obstetrical and benign gynecological conditions, including female sexual dysfunction, endometriosis, and cervical dysplasia.

Ms. Susan Amanda Swain Lake

Menopause Hormone Therapy Patient

Speaker, Session II: Patient Perspective/ Panelist, Panel I Discussion

Ms. Susan Lake is a married, 61-year-old HRT patient of Dr Rachel Rubin since early 2021. She started using testosterone as a part of her HRT after menopause derailed her life in numerous ways. Finding someone to help her with all the symptoms she had was very difficult and took years. She believes that the education of doctors and the availability of testosterone for women, both menopausal and post-menopausal, needs to change. She expresses that finding out that your body is completely void of any sex hormones is a shocking and sad thing to hear. She is here today to help by sharing her journey to acquire testosterone for women. She does not want any woman to suffer the loss of her libido, to suffer through brain fog and joint pain, to have her relationships/marriage to suffer or crumble, or for any woman to leave the work force. This is not a want; this is a need. She explains that women want to live their lives to the fullest and function at their best again.

Christine Pham Nguyen, MD

Deputy Director
Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine, Office of New Drugs, CDER, FDA

Moderator, Panel I: Discussion based on Sessions I & II / Q&A

Christine P. Nguyen, M.D., FACOG is a board-certified obstetrician-gynecologist and serves as the Deputy Director of the Office of Rare Diseases, Pediatrics, Urologic and Reproductive Medicine in the U.S. Food and Drug Administration's Center for Drug Evaluation and Research (CDER). In her role, she oversees divisions regulating therapies for obstetric, gynecologic, and urologic conditions, genetic metabolic rare diseases, and policies and programs involving rare diseases, pediatric and maternal health.

Dr. Nguyen's FDA career spans over two decades of advancing women's health through regulatory science and policy. She has led key regulatory actions in the areas of women's and men's reproductive health, with a special interest in obstetrics. She has co-authored publications in the New England Journal of Medicine, American Journal of Obstetrics and Gynecology, and other peer-reviewed journals on drugs in pregnancy, hormonal therapies, and reproductive safety.

Prior to FDA, Dr. Nguyen practiced clinical obstetrics and gynecology at Anne Arundel Medical Center and served as a Clinical Instructor at Johns Hopkins Hospital, where she also completed her residency in obstetrics and gynecology. She earned her M.D. with Thesis from the University of California, San Francisco, School of Medicine.

Rajita Patil, MD, MSCP, FACOG

Associate Clinical Professor, Department of Obstetrics and Gynecology; Director of the UCLA Comprehensive Menopause Program; Complex Family Planning Subspecialist

Speaker, Session II: Clinical Guidelines for Testosterone Therapy in Menopausal Women/ Panelist, Panel I Discussion

Dr. Rajita Patil, a board certified OB/GYN, Associate Clinical Professor, and Complex Family Planning subspecialist, is the founder and Director of UCLA's Comprehensive Menopause Program. She leads clinical, educational, and systems level innovation to advance scalable, evidence-based, whole-person menopause care.

Rachel Rubin, MD

Urologist and Sexual Medicine Specialist, Assistant Clinical Professor, Department of Urology, Georgetown University School of Medicine

Speaker, Session II: Clinician Perspective/ Panelist, Panel I Discussion

Dr. Rachel Rubin is a board-certified urologist, fellowship-trained sexual medicine specialist, researcher, educator and nationally recognized advocate for women's sexual and hormone health. She is a practicing clinician in Washington, D.C., providing care focused on menopause, hormone therapy, sexual dysfunction and genitourinary syndrome of menopause (GSM).

Dr. Rubin is an Assistant Clinical Professor of Urology at Georgetown University and former Education Chair of the International Society for the Study of Women's Sexual Health (ISSWSH). She co-directs Harvard Medical School's Testosterone Therapy, HRT, and Sexual Health course and teaches clinicians nationally and internationally about menopause, sexual medicine and hormone therapy.

A major focus of Dr. Rubin's work is advancing the science, education and regulatory pathways surrounding testosterone therapy. She advocates for greater research, clinician education and an FDA-approved testosterone therapy specifically studied and indicated for women. Her advocacy highlights the evidence supporting appropriate testosterone use and the gaps that remain without an FDA-approved product.

Dr. Rubin served on the multidisciplinary AUA/SUFU/AUGS panel that developed the first clinical guideline on Genitourinary Syndrome of Menopause. She also participated as an invited expert in the FDA's 2025 Expert Panel on Menopause and Hormone Replacement Therapy, advocating for evidence-based hormone care and modernization of hormone labeling.

She founded the Sexual Medicine Research Team (SMRT), a collaborative community advancing sexual medicine through research, education and mentorship. Her research and publications span sexual medicine, menopause, GSM and hormone therapy. Across her clinical care, research, teaching and advocacy, Dr. Rubin works to ensure women's sexual and hormonal health receives the scientific rigor, therapeutic innovation and regulatory attention it deserves.

James A. Simon, MD, CCD, MSCP, IF, FACOG

Clinical Professor, Department of Obstetrics and Gynecology, Division of Reproductive Endocrinology, The George Washington University School of Medicine; Medical Director, IntimMedicine Specialists, Washington DC

Speaker, Session I: Measuring and Assessing Testosterone Levels in Women: Navigating Challenges/ Panelist, Panel I Discussion

Dr. James A. Simon is a board-certified obstetrician/gynecologist, and reproductive endocrinologist. He is Clinical Professor of Obstetrics and Gynecology and Reproductive Endocrinology and Infertility at The George Washington University School of Medicine in Washington, DC. Dr. Simon also holds specialty certifications as an AASECT-Certified Sexuality Counsellor, an ISCD-Certified Clinical Bone Densitometrist, and a Menopause Society-Certified Menopause Practitioner. He has an active private practice, IntimMedicine Specialists®, in Washington, DC focused on complicated gynecology, sexual medicine for both men and women, and menopause.

Dr. Simon has received numerous awards including: The Menopause Society's Leon Speroff Outstanding Educator Award recognizing excellence in menopause-related education of clinicians or the general public, The International Society for the Study of Women's Sexual Health (ISSWSH) Distinguished Service Award in recognition of individuals who have demonstrated dedication and commitment to the field of women's sexual medicine/sexual health, and the Androgen Society's Lifetime Achievement Award for progressive contributions to androgen science and men's health. Dr. Simon has been selected to "Top Washington Physicians," "America's Top Obstetricians and Gynecologists," and "The Best Doctors in America."

He is the only physician to serve as President of both The Menopause Society and the International Society for the Study of Women's Sexual Health (ISSWSH). Nicknamed "The Menopause Whisperer," by Washingtonian Magazine, Dr. Simon is an established researcher and author--completing more than 450 research trials, and more than 850 published articles, abstracts, and chapters, including more than 40 on testosterone in women's health including the paperback book: Restore Yourself: A Woman's Guide to Reviving Her Sexual Desire and Passion for Life. Dr. Simon loves riding the best rollercoasters in the world, collecting fountain pens and wristwatches, and freshwater fishing. He is a five-time Master Angler of Manitoba, Canada.

Doanh Tran, PhD

Deputy Director, Division of Cardiometabolic and Endocrine Pharmacology, Office of Clinical Pharmacology, Office of Translational Science CDER, FDA

Speaker, Session 3: Exposure-Response Relationships/ Panelist, Panel II Discussion

Dr. Tran is a clinical pharmacologist at the US Food and Drug Administration. He serves as Deputy Director, Division of Cardiometabolic and Endocrine Pharmacology. He has more than 20 years of experience in clinical pharmacology, including review of testosterone products.

Kaveeta Vasisht, MD, PharmD

Senior Advisor, Office of Women's Health, Office of the Commissioner, FDA

Opening Remarks

Dr. Kaveeta Vasisht is the Associate Commissioner for Women's Health and Director of the Office of Women's Health (OWH) at the US FDA. OWH advances the health of women through research, policy, scientific programming, education and external engagement.

Dr. Vasisht leads efforts promoting participation of women in clinical trials and the study of sex differences in the clinical evaluation of medical products to facilitate regulatory decision making. In addition, her work in international harmonization has advanced global guideline development focused on good clinical practice and the appropriate inclusion of pregnant and breastfeeding women in clinical trials. Under her leadership, OWH has also strengthened FDA's commitment to regulatory science through research and cross-cutting scientific initiatives.

Prior to joining OWH, she served as a Division Deputy Director in the Center for Drug Evaluation and Research (CDER), Office of Medical Policy where she focused on clinical trial quality and modernization. Dr. Vasisht began her FDA career in CDER's Office of New Drugs providing medical expertise in the evaluation of safety, efficacy, and risk-benefit assessments across drug development in the Division of Metabolism and Endocrine Products. She is the recipient of the 2023 Health Public Service Visionary Award from the Society for Women's Health Research.

Dr. Vasisht is double board-certified in internal medicine and adult endocrinology, diabetes, and metabolism, and holds a Doctor of Pharmacy degree. She completed her internal medicine and fellowship training at the University of Chicago Hospitals. As a clinician, she cared for patients with diverse endocrine conditions and trained endocrinology fellows.

Kaveeta Vasisht, MD, PharmD (continued)

Dr. Vasisht received her medical degree from the University of Medicine and Dentistry of New Jersey Robert Wood Johnson Medical School. She combines her medical, scientific, and regulatory expertise to further advance FDA's public health mission.

Marcea B. Whitaker, MD

Senior Medical Officer, Division of Urology, Obstetrics, and Gynecology, Office of New Drugs, CDER, FDA

Speaker, Session III: General Considerations for Drug Approval/ Panelist, Panel I Discussion

Dr. Marcea B. Whitaker is a Senior Medical Officer in the Division of Urology, Obstetrics, and Gynecology (DUOG) within the FDA's Center for Drug Evaluation and Research (CDER). With more than 24 years of dedicated service at the FDA, Dr. Whitaker brings extensive regulatory expertise and a deep commitment to advancing drug evaluation standards that protect and promote public health. Dr. Whitaker earned her Doctor of Medicine from West Virginia University and completed specialty training in internal medicine at Christiana Medical Center in Delaware. Her clinical background informs a rigorous, evidence-based approach to the review and evaluation of drug products across her areas of focus.

A recognized expert in women's health, Dr. Whitaker has played a pivotal role in shaping FDA policy and guidance in this domain. She served as a co-author of the FDA's guidance on female sexual dysfunction, contributing to the agency's scientific and regulatory framework for this historically underserved therapeutic area. She has also represented the FDA as a speaker at public meetings, engaging with stakeholders, the medical community, and the public on critical issues in women's health and drug development. Throughout her career, Dr. Whitaker has demonstrated a sustained commitment to ensuring that drug therapies for women are evaluated with the scientific rigor and equity they deserve.

Margaret E. Wierman, MD

Professor of Medicine, Integrative Physiology and OBGYN, University of Colorado School of Medicine

Speaker, Session I: Physiological Roles of Testosterone Throughout a Woman's Life – What We Know and What We Don't/ Panelist, Panel I Discussion

Margaret E. Wierman MD, is a Professor of Medicine, Integrative Physiology and OBGYN at the University of Colorado School of Medicine. Dr. Wierman is a translational clinical scientist whose research interest has been in reproductive endocrinology and sex hormone action in women and men, as well as the molecular mechanisms of pituitary tumors and adrenal cancer. She currently is a member of the Colorado SCORE (PI W Kohrt) to understand the vascular and metabolic changes that occur at menopause. Her clinical efforts focus on expanding Reproductive Medicine training and directing the Pituitary and Adrenal Tumor Program at the University of Colorado. Her approach is to take the advances in the science of endocrine disorders back to the patient. Her efforts have resulted in a center of excellence recognized regionally and nationally. With each patient, Dr. Wierman is a "hormone detective" evaluating those with complex endocrine disorders and providing patient centered wholistic care. She is past Vice President Clinical Investigator for the Endocrine Society and led the clinical guidelines on the role of androgens in women.

She also participated in the International Guidelines on Testosterone in Women update. She is a past President of the International Society of Endocrinology and is passionate about its vision to provide endocrine science and education globally. She directs the Pre-R grant review panel for the Colorado Clinical Translational Science Institute to aid young faculty getting their first research grants. Maggie also directed the Program to Advance Gender Equity in the Department of Medicine and a midcareer women faculty leadership program. Dr. Wierman has a long track record in mentoring and pipeline development of academic clinicians and researchers. She received the Women in Endocrinology Mentor Award and the Endocrine Society Laureate Mentor Award.

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