FDA PUBLIC WORKSHOP · 17 SEPTEMBER 2026

Testosterone Use in Menopausal Women

Detailed summary

White Oak, Washington DC and virtual · 7h25m
Summary for Dr Louise Newson
Timecodes link to the FDA recording on YouTube at that moment.

0:04:49

Welcome and housekeeping

Dr Lakshmi Kannan (FDA Office of Women's Health, host)

Opens the workshop, co-hosted by the FDA Office of Women's Health and the Center for Drug Evaluation and Research (CDER), for the in-person audience at White Oak and thousands online. Covers housekeeping and explains how to take part:

- submit questions after each talk via the QR code
- a public docket for written comments is open until 19 October
- speakers' comments do not necessarily reflect FDA views
- the recording will be posted within two weeks.

0:09:00

Opening remarks

Dr Kaveeta Vasisht (Associate Commissioner for Women's Health; Director, FDA OWH)

Frames the workshop within the OWH mission of bridging knowledge and scientific gaps in women's health, on the principle that FDA-regulated products should reflect women's biology and that clinicians and patients deserve the best available science. Notes the scale: over a million US women enter menopause each year.

Recalls that in 2025 the FDA opened two public dockets on hormone therapy, and although they were not specifically about testosterone, many commenters asked for an FDA-approved testosterone formulation for women and described its role in managing their symptoms. States that off-label use has grown substantially and, with no approved formulation, key questions remain:

- long-term safety
- optimal dosing
- the right biomarkers and endpoints for different indications.

Sets the goal of a shared understanding of the science, the guidelines, the evidence gaps, and the efficacy and safety considerations.

0:12:36

Opening remarks

Dr Christina Chang (Division Director, Urology, Obstetrics and Gynecology, CDER)

Introduces herself and thanks the clinical experts and the patient representative, Susan Amanda Swain Lake. Lays out the day: the morning covers testosterone physiology, the challenge of measuring and interpreting blood levels, and current and potential clinical uses; the afternoon covers the regulatory considerations for the efficacy and safety package needed to support a marketing application.

Notes that although many estrogen and progestogen products are approved for menopausal symptoms, there are no FDA-approved testosterone therapies for menopausal women. Names the knowledge gaps:

- context of use
- dosage and dosing regimen
- safety.

Says the aim is to narrow them and to signal that the FDA is open and ready to engage to support product development.

0:19:03

Keynote

Admiral Brian Christine (Assistant Secretary for Health, HHS)

Speaks as a urologist of about 35 years, the last 25 focused on men, and frames the past year as a landmark for women's health, citing the FDA's November 2025 removal of the broad black box warning from menopause hormone therapy products. Says the administration is listening to women on hormonal health across the lifespan.

Argues that testosterone in women is the next hormone issue to address, and states his commitment to advancing women's health, noting he has seen the importance of testosterone replacement in both men and women.

0:27:28

Keynote

Dr Dorothy Fink (Deputy Director, NICHD, NIH)

An endocrinologist who trained just after the Women's Health Initiative abruptly curtailed hormone therapy. Describes how the black box warnings made it hard to care for women, who would return frightened by the package insert even when benefits outweighed risks, and welcomes the recent update to those warnings as recognition that women deserve accurate, up-to-date, evidence-based information.

Recounts that a testosterone patch designed for women was reviewed by the FDA in 2004 for HSDD and ultimately not approved in 2006, with additional long-term safety data among the concerns, all within a post-WHI climate of caution. Notes that 20 years on there is more research, more clinical experience, and more women willing to speak. Observes that physicians are trained to worry about high testosterone (for example in PCOS) far more than about low testosterone, and shares a patient with an undetectable level, low energy and low libido.

0:34:48

Session I, Physiological roles of testosterone

Dr Margaret Wierman (University of Colorado)

Calls herself a hormone detective and reviews testosterone physiology in women across the menstrual cycle, menopause and ageing. Walks through steroid synthesis from cholesterol, explaining that DHEA and androstenedione are prohormones that must be converted to testosterone (and then DHT) or to estradiol to act, and that aromatase is very active in the brain, fat and liver.

Presents data that adrenal androgen levels such as DHEA fall with age. Emphasises what the data do not show: in the studies she cites, testosterone levels did not correlate with cognition or with muscle mass and strength, with only a limited androgen effect on trabecular bone. Frames testosterone as a therapy rather than a straightforward replacement given current evidence, and raises the open scientific question of whether its effects are dose and level dependent or independent of levels. Closes on what has not been studied and should be.

0:52:42

Session I, Measuring and assessing testosterone levels

Dr James Simon (George Washington University)

Notes that he last appeared before the FDA at the 2004 Intrinsa patch advisory committee and published his first paper on testosterone in women in 2000. Argues the evidence base (randomised trials, systematic reviews, consensus documents and decades of experience) supports physiologic testosterone for appropriately selected women, yet there is still no approved US product.

Focuses on the difficulty of measurement: results must be interpreted against age, ovarian status, sex hormone binding globulin, estrogen route, timing, illness and exogenous exposure. Assays are unreliable, especially at the low concentrations seen in women, so more precise measurement in defined populations is needed to establish anything like a normal range. His practical message: treat the individual as her own control and treat symptoms rather than a lab value.

1:10:13

Session II, Clinical guidelines

Dr Rajita Patil (UCLA Comprehensive Menopause Program)

Reviews the 2019 Global Consensus Position Statement and the ISSWSH clinical practice guideline. The consensus supports considering testosterone for postmenopausal women with HSDD, defined as persistent low desire with clinically meaningful distress, using roughly one tenth of the male dose to keep levels in the physiologic premenopausal range. Its practical recommendations:

- transdermal delivery
- informed consent about off-label use and limited long-term data
- total testosterone measured at baseline and at 3 to 6 weeks
- efficacy judged clinically rather than by a lab number, with benefit by 4 to 12 weeks and a stop point at 6 months.

Stresses the limits: the evidence did not support benefit for general well-being or mood, and a Level 1, Grade A conclusion that testosterone should not be prescribed for musculoskeletal health (no consistent bone density, lean mass or strength benefit). Short-term breast data are reassuring but long-term data are insufficient, and cardiovascular data are insufficient to draw conclusions. Lists the evidence gaps:

- formulation and dose variability
- long-term safety data (cardiovascular, thromboembolic, breast)
- broader real world populations
- better outcome measures focused on distress and quality of life.

Concludes the major unmet need is access to regulated, female-specific formulations plus the evidence to characterise benefit and risk.

1:32:34

Session II, Benefit-risk and dosing

Dr Pelin Batur (Cleveland Clinic)

Talks about real world dosing, noting prescribing has roughly tripled in about five years. Frames three practical hurdles:

- following the guideline and using the FDA-approved male product effectively hands the patient a 10 to 20 month supply, which she finds uneasy without follow-up
- compounding raises purity and potency concerns: batch testing has found anywhere from no testosterone to five times the labelled potency, plus recalls for mould and insects and one fatal hypersensitivity case
- testosterone is a controlled substance, which creates legal and logistical friction.

Explains the dosing maths (about one tenth, possibly moving to one twentieth, of the male dose, with roughly one tenth absorbed and absorption enhancers that vary, citing UK misdosing reports), and calls for standardisation, better side effect reporting and predictable cost, which currently ranges from about 15 to 3,000 dollars. Argues an approved product would level cost, standardise delivery and ease the legal burden.

1:50:08

Session II, Clinician perspective

Dr Rachel Rubin (Georgetown University)

A urologist and sexual medicine specialist. Argues that the central problem is the lack of an FDA-approved female product, which costs patients legitimacy, ease of prescribing, insurance coverage and research. Illustrates with a 52-year-old patient whose quality of life was transformed, and notes the VA standardised testosterone approval for symptomatic peri- and postmenopausal women in 2025.

Details the day-to-day obstacles created by off-label, controlled substance status:

- hunting coupon codes by zip code
- sachets that are hard to dose
- pharmacists refusing prescriptions, one telling a patient testosterone is only for men, despite approval in Australia, the UK, South Africa and New Zealand. Reviews emerging real world evidence and argues testosterone matters well beyond libido (pelvic floor, vulvar tissue, bladder, even a dry eye trial).

She cites a large menopause clinic in England (Newson Clinic) that has treated over 40,000 women with an approved testosterone formulation and published improvements in mood, genitourinary symptoms, cognition, energy, exercise capacity and sexual health, plus presented signals of reduced opioid use, SSRI prescriptions and suicidal thoughts, and similar findings from a US telehealth platform.

Calls for an FDA priority review pathway and encourages the public to submit comments to the FDA docket by 19 October.

2:11:13

Session II, Patient perspective

Susan Amanda Swain Lake (patient)

Tells her story. From 2015, aged 50, she had severe hot flashes (peeling down to a tank top in construction meetings), sudden joint pain, brain fog and insomnia, and her libido fell to what she calls a negative 3 as a newlywed. Her GP, OB-GYN, an arthritis specialist and a neurologist all told her the results were normal or that it was her age, and an MRI was read as a beautiful brain for a woman her age.

By 2020, aged 55, she no longer recognised her body or mind, was severely depressed, found antidepressants ineffective and reached a point of not wanting to live that way. She persisted for about five years until a therapist put her in touch with a sexual therapist, who referred her to Dr Rachel Rubin, the urologist who spoke earlier in the session. She says of her that to say that woman saved my life is an understatement, describes a first hour long appointment and full hormone testing, and says she is now an educator herself so that her friends and family do not have to suffer as she did.

2:39:05

Panel I, Discussion and Q&A on Sessions I and II (moderator: Christine Pham Nguyen)

The panelists debate whether testosterone levels correlate with symptoms (largely not, so treat the woman as her own control), how to interpret lab values (treat symptoms, not numbers), and the limited dose-response data, with Dr James Simon pointing back to the old patch dose ranging studies. There is repeated agreement that trials need larger samples, better endpoints and the right, more inclusive populations, and that the placebo effect in sexual medicine is unusually large.

Other threads:

- how clinicians should handle the gap between guidelines and what patients want
- real world and off-label prescribing
- physician education and CME
- the cautionary history of failed testosterone products, including BioSante, where a high placebo effect and an unvalidated endpoint sank the result.

In a closing round each panelist names a top priority, from more and better science to more time with patients and funding.

4:39:16

Session III, General considerations for drug approval

Dr Marcea Whitaker (CDER)

Sets out the regulatory scale, using 2024 data: 1,855 investigational new drug applications and 50 novel approvals. Walks through the clinical development pipeline:

- Phase 1 for safety and pharmacokinetics
- Phase 2 for proof of concept and dose finding
- Phase 3 as the pivotal studies tested against placebo or standard of care
- Phase 4 after approval.

Explains the two criteria that must both be met:

- substantial evidence of effectiveness
- benefit outweighing risk.

Stresses that studies must be properly controlled to separate the drug effect from placebo and bias, that safety data must be sufficient for the intended duration of use, and that combination products require a design (for example a factorial trial with each drug, the combination and placebo) showing that each component contributes.

4:54:15

Session III, Efficacy considerations

Dr Anandi Kotak (CDER)

Explains that a drug and its indication go together: the FDA approves a drug for a specific indication, so studies must be designed with that indication in mind, and each symptomatic condition (sexual dysfunction, musculoskeletal, cognition, mood) is best studied individually to keep the data interpretable. Stresses clinically meaningful endpoints and the benefit-risk balance, where tolerated risk scales with the severity of the condition and the size of the treatment effect.

Gives the FDA definition of HSDD (acquired, generalized, at least 6 months) and says the agency would consider applications for other indications based on the data presented. Raises open questions the FDA needs answered:

- whether levels must be measured
- what signals should prompt backing off therapy

- whether testosterone should be given alone or with estrogen and progestogen, in which case each component's contribution to efficacy and safety must be demonstrated. Later names the lowest effective dose per indication as the highest-priority gap.

5:17:41

Session III, Clinical outcome assessments

Dr Selena Daniels (CDER, Division of Clinical Outcome Assessment)

Explains that clinical outcome assessments (COAs) are the tools and questionnaires that capture what patients actually experience: their symptoms, functioning and daily impact. Describes the COA types (such as patient-reported outcomes) and notes wearables and digital tools are a growing source of data.

Stresses that a COA is only as good as its design: it must be valid, reliable and fit for purpose, meaning validated for the specific population (menopausal women) and condition, because using a COA outside the population it was developed in risks misleading results. Points sponsors to FDA guidance and a roadmap, and urges them to:

- look for existing COAs first
- document their rationale
- be upfront about gaps
- engage the FDA early on measurement strategy. Frames COAs as the bridge between lived patient experience and regulatory decision-making.

5:37:43

Session III, Safety considerations

Dr Linda Jaffe (CDER)

Reviews safety data from trials, observational cohorts, claims studies and the roughly 20-year-old patch application, grouping concerns into androgenic effects, metabolic effects and long-term risks. Notes an exposure-response relationship between free testosterone and acne and hirsutism, hair loss related to treatment duration, and, in the patch application, shifts toward higher triglycerides and increases in blood pressure versus placebo.

On long-term risks, short-term trials (generally 6 to 24 months) show no strong cardiovascular signal, but claims studies are limited by healthy user bias and the data are insufficient to characterise cardiovascular risk. For breast cancer she cites the Aphrodite study (4 cases in the testosterone arms versus none on placebo over 52 weeks) and the limits of observational studies, concluding it needs further investigation. Highlights the study-design challenges:

- long latency for cancers and cardiovascular disease
- the need for adequate duration
- a representative, heterogeneous population
- endometrial biopsy
- accounting for concurrent estrogen and progestin.

6:16:40

Session III, Role of testosterone concentration and PK

Dr Doanh Tran (CDER, Office of Clinical Pharmacology)

Grounds the audience in exposure-response analysis and why dose finding is critical to choosing the Phase 3 dose. Uses the patch data as an example:

- 150 micrograms had little effect
- 300 micrograms showed benefit over placebo
- 450 micrograms added none.

This is why 300 was selected.

Argues very little is known about the exposure-response relationship in female indications, which is both a large gap and an opportunity. Discusses total versus free testosterone (free is likely the value to rely on) and the difficulty of measuring low female concentrations accurately with immunoassays, suggests examining the interplay with estradiol and progestins, and proposes exploring a wide dose range in Phase 2, provided there is enough safety data.

6:35:51

Panel II, Discussion and Q&A on Session III (moderator: Christina Chang)

FDA reviewers discuss what makes a drug approvable (knowing what is being treated, the population and the formulation, and why a placebo-controlled trial is needed given the high placebo effect), and what would be needed to support indications beyond HSDD, including specific proposals with defined baselines and improvements.

The closing questions, which the reviewers were pressed on, focus on the data the FDA most wants:

- the most consequential safety gaps, namely cardiovascular and breast cancer risk
- the pharmacokinetic and pharmacodynamic gaps, and how to address them through trial design
- each reviewer's single highest priority. Answers include the lowest effective dose per indication, better exploration of dose-response, sponsors and payers stepping up, and, from the chair, high-quality data so the FDA can work with manufacturers toward an approved product.

7:21:45

Closing remarks

Dr Kaveeta Vasisht (FDA OWH)

Closes the workshop, thanks the speakers, panelists and audience, and reiterates that women deserve the data needed to support an approved product.

Abbreviations

CDER	Center for Drug Evaluation and Research
CME	Continuing Medical Education
COA	Clinical Outcome Assessment
DHEA	Dehydroepiandrosterone
DHT	Dihydrotestosterone
FDA	US Food and Drug Administration
HHS	US Department of Health and Human Services
HSDD	Hypoactive Sexual Desire Disorder
ISSWSH	International Society for the Study of Women's Sexual Health
MRI	Magnetic Resonance Imaging
NICHD	Eunice Kennedy Shriver National Institute of Child Health and Human Development
NIH	National Institutes of Health
OB-GYN	Obstetrician-Gynaecologist
OWH	Office of Women's Health
PCOS	Polycystic Ovary Syndrome
PK	Pharmacokinetics
SSRI	Selective Serotonin Reuptake Inhibitor
VA	US Department of Veterans Affairs