



October 19, 2026

**Comments Regarding the Food and Drug Administration's
Public Workshop on Testosterone Use in Menopausal Women
Docket No. FDA-2026-N-5479**

Submitted electronically

Public Citizen, a national nonprofit consumer advocacy organization with over one million members and supporters nationwide, submits the following comments to the docket for the Food and Drug Administration's (FDA's) September 17, 2026, public workshop on testosterone use in menopausal women. The workshop examined scientific evidence about testosterone use and gaps in knowledge about sexual function, cognition, mood, musculoskeletal health, testosterone measurement, and long-term cardiovascular and breast cancer safety.^{1,2} These comments were prepared by Deborah Fadoju, M.D., a fellow with Public Citizen's Health Research Group.

No testosterone product is currently FDA-approved for menopausal women in the United States.^{3,4} The FDA stated that the workshop was intended to examine the current scientific evidence and critical knowledge gaps in order to inform future research and potential drug development.⁵ In clinical practice, clinicians have nonetheless prescribed testosterone off-label to women for a variety of symptoms, including low sexual desire. Moreover, off-label use in women nearing or after menopause has increased over the past decade.^{6,7} Because there are no approved testosterone

¹ Food and Drug Administration. Testosterone Use in Menopausal Women; Public Workshop; Request for Comments. 91 Fed. Reg. 53417 (Aug. 18, 2026). <https://www.federalregister.gov/documents/2026/08/18/2026-16829/testosterone-use-in-menopausal-women-public-workshop-request-for-comments>. Accessed October 19, 2026.

² *Ibid.*

³ *Ibid.*

⁴ Parish SJ, Simon JA, Davis SR, et al. International Society for the Study of Women's Sexual Health Clinical Practice Guideline for the Use of Systemic Testosterone for Hypoactive Sexual Desire Disorder in Women. *J Sex Med.* 2021;18:849–867.

⁵ Food and Drug Administration. Testosterone Use in Menopausal Women; Public Workshop; Request for Comments. 91 Fed. Reg. 53417 (Aug. 18, 2026). <https://www.federalregister.gov/documents/2026/08/18/2026-16829/testosterone-use-in-menopausal-women-public-workshop-request-for-comments>. Accessed October 19, 2026.

⁶ Davis SR, Baber R, Panay N, et al. Global Consensus Position Statement on the Use of Testosterone Therapy for Women. *J Clin Endocrinol Metab.* 2019;104:4660–4666.

⁷ Food and Drug Administration. Testosterone Use in Menopausal Women; Public Workshop; Request for Comments. 91 Fed. Reg. 53417 (Aug. 18, 2026). <https://www.federalregister.gov/documents/2026/08/18/2026-16829/testosterone-use-in-menopausal-women-public-workshop-request-for-comments>. Accessed October 19, 2026.

products for women, clinicians generally use products approved for men, with dose modification, or compounded formulations; neither are FDA-approved for this use.^{8,9}

Public Citizen agrees with the FDA that menopausal women deserve effective, evidence-based options for symptoms that affect their quality of life. Currently, however, randomized trials support at most a modest benefit of testosterone for sexual function in postmenopausal women with HSDD.¹⁰ There are no adequate data supporting testosterone use for cognition, mood, or musculoskeletal health in menopausal women. Long-term cardiovascular and breast cancer safety have not been established for any use.¹¹

Before approving any testosterone product for women, we urge the FDA to require the following: (1) evidence of clinically meaningful benefit for a specific, defined indication; (2) adequate long-term safety data, particularly for cardiovascular and breast cancer outcomes; (3) separate evidence for each proposed indication; and (4) product-specific dosing, exposure, and monitoring data. We discuss our recommendations in more detail below.

1. Evidence of Benefit for Testosterone Is Limited to Sexual Function in Postmenopausal Women with HSDD, and That Benefit Is Modest

The only outcome for which randomized trials show a benefit of testosterone is sexual function, and only in postmenopausal women with HSDD, a condition characterized by low sexual desire accompanied by personal distress.^{12,13} This is a narrower population than menopausal women in general.

⁸ Davis SR, Baber R, Panay N, et al. Global Consensus Position Statement on the Use of Testosterone Therapy for Women. *J Clin Endocrinol Metab.* 2019;104:4660–4666.

⁹ Parish SJ, Simon JA, Davis SR, et al. International Society for the Study of Women's Sexual Health Clinical Practice Guideline for the Use of Systemic Testosterone for Hypoactive Sexual Desire Disorder in Women. *J Sex Med.* 2021;18:849–867.

¹⁰ Islam RM, Bell RJ, Green S, Page MJ, Davis SR. Safety and efficacy of testosterone for women: a systematic review and meta-analysis of randomised controlled trial data. *Lancet Diabetes Endocrinol.* 2019;7:754–766.

¹¹ Davis SR, Baber R, Panay N, et al. Global Consensus Position Statement on the Use of Testosterone Therapy for Women. *J Clin Endocrinol Metab.* 2019;104:4660–4666.

¹² Parish SJ, Simon JA, Davis SR, et al. International Society for the Study of Women's Sexual Health Clinical Practice Guideline for the Use of Systemic Testosterone for Hypoactive Sexual Desire Disorder in Women. *J Sex Med.* 2021;18:849–867.

¹³ Davis SR, Baber R, Panay N, et al. Global Consensus Position Statement on the Use of Testosterone Therapy for Women. *J Clin Endocrinol Metab.* 2019;104:4660–4666.

In 2019, Islam and colleagues published a systematic review and meta-analysis of 36 randomized controlled trials involving 8,480 women.¹⁴ The trials evaluated different testosterone formulations, doses, and patient populations, comparing testosterone against placebo or, in some trials, a comparator such as estrogen with or without progestogen. Only 13 of the 36 trials specifically recruited women with low sexual function. Among postmenopausal women, testosterone use was associated with an average of 0.85 additional satisfying sexual events per month compared with control, as well as improvements in sexual desire and reductions in sexual distress.¹⁵ Although statistically significant, the difference between testosterone and control represents fewer than one additional satisfying sexual event per month. Because the trials included different populations, formulations, and doses, these findings should not be generalized to all menopausal women or assumed to apply equally to every testosterone formulation.

One of the largest trials included in the Islam et al. review, APHRODITE, illustrates the magnitude of benefit. The trial enrolled 814 postmenopausal women with HSDD who were not receiving estrogen therapy and randomized them to transdermal testosterone patches delivering 150 or 300 micrograms per day or placebo.¹⁶ At 24 weeks, women receiving 300 micrograms of testosterone per day reported a statistically significant increase of 2.1 satisfying sexual episodes over four weeks, compared with 0.7 increase in such episodes in the placebo group. In the 150-microgram group, a statistically significant increase in satisfying sexual episodes was not found.

The Islam et al. review also included three small trials in premenopausal women, which showed no benefit over placebo or a comparator for satisfying sexual events or any other sexual function domain.¹⁷ Neither the pooled findings nor the results of the APHRODITE trial should be generalized to women without HSDD or to menopausal women more broadly.¹⁸

If the FDA were to receive a new drug application for a testosterone product for HSDD, the clinical trials supporting the application should assess not only the frequency of satisfying sexual episodes but also changes in desire, associated distress, and the proportion of women reporting meaningful improvement.

¹⁴ Islam RM, Bell RJ, Green S, Page MJ, Davis SR. Safety and efficacy of testosterone for women: a systematic review and meta-analysis of randomised controlled trial data. *Lancet Diabetes Endocrinol.* 2019;7:754–766.

¹⁵ *Ibid.*

¹⁶ Davis SR, Moreau M, Kroll R, et al. Testosterone for low libido in postmenopausal women not taking estrogen. *N Engl J Med.* 2008;359:2005–2017.

¹⁷ Islam RM, Bell RJ, Green S, Page MJ, Davis SR. Safety and efficacy of testosterone for women: a systematic review and meta-analysis of randomised controlled trial data. *Lancet Diabetes Endocrinol.* 2019;7:754–766.

¹⁸ Davis SR, Baber R, Panay N, et al. Global Consensus Position Statement on the Use of Testosterone Therapy for Women. *J Clin Endocrinol Metab.* 2019;104:4660–4666.

2. The Long-Term Safety of Testosterone Products for Women Must Be Established Before Approval

Testosterone treatment is associated with adverse effects that may vary by formulation. Long-term cardiovascular and breast cancer safety has yet to be established.

The Islam et al. study identified increased acne and hair growth with testosterone. Oral testosterone, but not other formulations, adversely affected lipid measures. These findings support formulation-specific evaluation rather than considering different testosterone products as interchangeable.¹⁹

In the APHRODITE study, there were four breast cancer diagnoses in testosterone-treated participants and none in the placebo group.²⁰ Safety was assessed for 52 weeks, with a subgroup of participants followed for a second year. The authors acknowledged that the study was neither large enough nor long enough to establish long-term safety.²¹

The 2019 Global Consensus Position Statement on the Use of Testosterone Therapy for Women reviewed evidence on testosterone therapy in premenopausal and postmenopausal women.²² On safety, the review found that (1) available trials were too limited to assess long-term breast cancer risk; (2) women at elevated cardiometabolic risk were generally excluded from trials; and (3) there were no safety data for testosterone use beyond 24 months.²³

These concerns are not new. In 2004, an FDA advisory committee reviewed a testosterone patch proposed for use by women with HSDD following surgical menopause who were receiving estrogen.²⁴ The committee voted 14 to 3 that the efficacy benefit was clinically meaningful but unanimously recommended against approval of the patch because its long-term safety had not been adequately established. Although additional studies have been conducted since 2004, the available evidence remains insufficient to resolve the safety concerns.

Before approving any testosterone product for women, the FDA should require safety evidence that adequately represents the intended treatment population, including women with typical cardiovascular risk factors, and provides sufficient follow-up to assess risks associated with the

¹⁹ Islam RM, Bell RJ, Green S, Page MJ, Davis SR. Safety and efficacy of testosterone for women: a systematic review and meta-analysis of randomised controlled trial data. *Lancet Diabetes Endocrinol*. 2019;7:754–766.

²⁰ Davis SR, Moreau M, Kroll R, et al. Testosterone for low libido in postmenopausal women not taking estrogen. *N Engl J Med*. 2008;359:2005–2017.

²¹ *Ibid*.

²² Davis SR, Baber R, Panay N, et al. Global Consensus Position Statement on the Use of Testosterone Therapy for Women. *J Clin Endocrinol Metab*. 2019;104:4660–4666.

²³ *Ibid*.

²⁴ Moynihan R. FDA panel rejects testosterone patch for women on safety grounds. *BMJ*. 2004;329:1363.

expected duration of treatment. Postmarketing studies should supplement, not replace, essential preapproval safety evidence.

3. There Are No Adequate Data Supporting Testosterone Use in Women for Cognition, Mood, or Musculoskeletal Health

The FDA workshop identified cognition, mood, and musculoskeletal health, alongside sexual function, among the topics for evidence review.²⁵ Adequate evidence of clinically meaningful benefit has not been established for cognition, mood, or musculoskeletal health.

The Islam et al. study did not establish a benefit for cognitive function, musculoskeletal outcomes, or depressive mood; the evidence for these outcomes was limited.²⁶ Similarly, the Global Consensus Position Statement concluded that evidence was insufficient to support testosterone for cognition, mood, general well-being, or bone and muscle health.²⁷

Data from studies of women with HSDD should not be used to support testosterone treatment for unrelated menopausal symptoms. The FDA should require adequate and well-controlled clinical trials of testosterone for each specific indication that fully assess safety and whether any benefit is clinically meaningful.

4. Product-Specific Dosing and Monitoring

Testosterone formulations differ in dosing, absorption, and systemic exposure. Evidence from one formulation should not be assumed to establish the safety or efficacy of another formulation. The FDA should require product-specific data demonstrating consistent dosing, bioavailability, and physiologic testosterone levels, together with monitoring to avoid androgen-related adverse effects.²⁸

²⁵ Food and Drug Administration. FDA Public Meeting: Testosterone Use in Menopausal Women, September 17, 2026. <https://www.fda.gov/consumers/womens-health-events/fda-public-meeting-testosterone-use-menopausal-women-09172026>. Accessed October 19, 2026.

²⁶ Islam RM, Bell RJ, Green S, Page MJ, Davis SR. Safety and efficacy of testosterone for women: a systematic review and meta-analysis of randomised controlled trial data. *Lancet Diabetes Endocrinol.* 2019;7:754–766.

²⁷ Davis SR, Baber R, Panay N, et al. Global Consensus Position Statement on the Use of Testosterone Therapy for Women. *J Clin Endocrinol Metab.* 2019;104:4660–4666.

²⁸ Parish SJ, Simon JA, Davis SR, et al. International Society for the Study of Women's Sexual Health Clinical Practice Guideline for the Use of Systemic Testosterone for Hypoactive Sexual Desire Disorder in Women. *J Sex Med.* 2021;18:849–867.

Conclusion

Menopausal women deserve effective, evidence-based treatments for symptoms that affect their quality of life. Current evidence supports, at most, a modest benefit of testosterone for sexual function in postmenopausal women with HSDD. Long-term cardiovascular and breast cancer safety remain inadequately established. There are no adequate data supporting testosterone use for cognition, mood, musculoskeletal health, or other menopausal symptoms. Public Citizen urges the FDA not to approve any testosterone product for women without evidence of clinically meaningful benefit for a specific indication and adequate long-term safety data.

Thank you for your consideration of our comments on this important topic for women's health.