



FORMAL COMMENTS TO THE U.S. FOOD AND DRUG ADMINISTRATION

Re: [Docket No. FDA-2026-N-5479] – Testosterone Use in Menopausal Women; Public Workshop; Request for Comments

Submitted electronically via Regulations.gov

Date: October 19, 2026

Organizations: Alliance for Pharmacy Compounding and National Community Pharmacists Association

The Alliance for Pharmacy Compounding and the National Community Pharmacists Association submit these comments to the U.S. Food and Drug Administration (FDA) in response to the Agency's August 18, 2026, notice and September 17, 2026, public workshop on testosterone use in menopausal women. APC is the national trade association representing the pharmacy compounding industry, including 503A compounding pharmacies, 503B outsourcing facilities, pharmacists, pharmacy technicians, prescribers, educators, researchers, and suppliers. NCPA represents America's community pharmacists, including 18,900 independent community pharmacies. Our members are small business owners who are among America's most accessible healthcare providers.

We provide an evidence-based perspective on the clinical use of testosterone in women and on the role of patient-specific compounding in meeting needs that no FDA-approved product currently addresses.

FDA acknowledges in its workshop notice that there are no FDA-approved indications for testosterone therapy for menopausal women, even as off-label use among women nearing or after menopause has increased over the past decade. For these women, compounded testosterone is not an alternative to an approved product. It is often the only preparation available in a strength and dosage form designed for them.

I. EXECUTIVE SUMMARY

- **Access to Compounded Therapy:** With no FDA-approved testosterone product for women, patient-specific compounded preparations allow prescribers to order strengths and dosage forms that commercially available male products do not provide. FDA should recognize the legitimate role of 503A compounding and preserve patient access while the evidence base develops.
- **Path to an Approved Product:** APC and NCPA support development of an FDA-approved testosterone product for women and urges FDA to actively facilitate it,

beginning with postmenopausal HSDD, by updating its development guidance, defining long-term safety expectations in advance, and engaging sponsors of products already approved in other countries [1, 2].

- **Clinical Benefit:** The strongest evidence supports testosterone for postmenopausal women with hypoactive sexual desire disorder (HSDD), improving satisfying sexual events, desire, arousal, and distress [1, 2, 3, 4].
- **Emerging Evidence:** Evidence on bone, body composition, mood, and cognition is limited and should be answered with data rather than settled by assumption in either direction [1, 5].
- **Safety and Monitoring:** Short-term trials show a favorable tolerability profile, and long-term data remain limited. The guideline-based monitoring framework applies whether a patient's testosterone comes from a fractionated male product or a compounded preparation [1, 2].
- **Regulatory Recommendations:** FDA should distinguish lawful pharmacy compounding from unlawfully marketed unapproved drugs, keep drug-approval standards separate from individualized prescribing decisions, study testosterone as it is actually used by women, and work with DEA to reassess testosterone's Schedule III status.

II. NARRATIVE CLINICAL PERSPECTIVE

Testosterone is a normal physiologic hormone in women, and levels decline with age. FDA's own notice observes that levels in the late 40s are approximately half those in the early 20s. HSDD affects an estimated 6–19% of women, depending on population and study methods [6], and it is the best-supported indication for testosterone therapy in women [1].

When a prescriber decides that testosterone is appropriate for a woman, the practical question is how to deliver an accurate, physiologic dose. Every commercially available testosterone product in the United States was developed and dosed for men. That is the gap patient-specific compounding fills, and it is why APC urges FDA to keep compounded therapy available to the women who rely on it.

III. CLINICAL NECESSITY OF COMPOUNDED TESTOSTERONE THERAPY FOR WOMEN

Women's therapeutic testosterone doses are a small fraction of men's. In the absence of an approved female product, clinical guidance directs clinicians to divide male products: the 2026 VA/DoD Guideline's own dosing table describes using one-tenth of a 50 mg tube of 1% testosterone gel per day, or roughly 0.5 mL [2]. Asking patients to estimate a tenth of a tube or packet at home is an imprecise way to deliver a hormone whose guideline-recommended target is the physiologic premenopausal range [1].

Compounded transdermal preparations address this directly. Pharmacies prepare creams in concentrations that allow women to measure and apply small, consistent doses, often in

metered dispensers, rather than adapting a product designed for men. Compounding also allows alternative bases for women who experience skin irritation or sensitivity to the excipients in commercial gels, and other dosage forms when a prescriber determines that a different route is appropriate because of poor absorption, intolerance, or adherence challenges.

We recognize that the 2019 Global Consensus and the 2026 VA/DoD Guideline both prefer FDA-approved products over compounded testosterone [1, 2]. In the United States, however, no such product exists for women. Presently, the practical alternative to a patient-specific compounded preparation is not an approved female product. It is a male product divided into fractional doses at home. A compounded preparation prescribed and prepared for an individual patient, with the assessment and monitoring these guidelines describe, is a reasonable way to deliver individualized care.

Compounded testosterone preparations, when prescribed for an identified individual patient pursuant to a valid prescription and compounded in compliance with section 503A of the Federal Food, Drug, and Cosmetic Act and applicable USP standards, serve an important clinical role for women whose needs cannot be met by commercially available products.

We urge FDA to recognize the legitimate and medically necessary role of pharmacy compounding in testosterone therapy for women, particularly where commercially available products are not clinically appropriate because of dosing limitations, route-of-administration constraints, or patient-specific tolerability issues.

IV. CLINICAL AND SCIENTIFIC CONSIDERATIONS

A. Sexual Function and HSDD

Across meta-analyses of placebo-controlled trials, physiologic-dose transdermal testosterone adds about one satisfying sexual event per month (Islam: MD 0.85, 95% CI 0.52–1.18; Achilli: MD 0.92, 95% CI 0.65–1.19) and improves desire, arousal, orgasm, pleasure, responsiveness, and self-image while reducing distress [3, 4]. The 2019 Global Consensus, endorsed by 11 international societies, identifies postmenopausal HSDD as the only evidence-based indication (Level I, Grade A) [1], and the 2026 VA/DoD Guideline suggests transdermal testosterone for sexual dysfunction in menopause, particularly low interest, desire, or arousal [2].

Evidence in premenopausal women is promising but not yet sufficient. A 2026 systematic review found improvements in libido, satisfying sexual events, and satisfaction across small trials, but too few trials to support a formal recommendation [7]. This finding is consistent with the Global Consensus position that premenopausal evidence remains insufficient for a formal evidence-based recommendation [1].

B. Bone, Body Composition, Mood, and Cognition

Observational studies associate endogenous testosterone with bone mineral density in women [8, 9]. In a randomized dose-response trial in hysterectomized women, higher

testosterone doses increased lean mass, chest-press strength, and stair-climb power compared to lower doses and placebo [10]. The mechanistic basis for these anabolic effects – including androgen receptor-mediated myogenic differentiation and upregulation of protein synthesis – has been reviewed primarily in the context of male physiology, with mechanisms broadly applicable to both sexes [11]. Trials adding testosterone to estrogen have produced mixed bone results, with some showing increased spine or hip bone mineral density and others no benefit over estrogen alone, and a transdermal testosterone patch added to estradiol and progestin in women with primary ovarian insufficiency did not improve bone mineral density [12].

The Endocrine Society guideline similarly recommends against testosterone for bone health in women with androgen deficiency, citing insufficient evidence [5]. At physiologic doses, however, the Global Consensus found no significant effect on bone mineral density, lean mass, muscle strength, wellbeing, or depressed mood, and no trial has reported fracture outcomes [1, 12]. An 8-week randomized trial of adjunctive transdermal testosterone in women with antidepressant-resistant depression found no benefit over placebo [13]. A 510-woman retrospective pilot (Glynne et al. 2025 [14]) reported self-reported improvements in mood (47%) and cognition (39%) in women also using estradiol. A larger 920-woman retrospective cohort (Glynne et al. 2026 [15]) and significant overall improvement in validated depression scores with body-identical MHT, but no statistically significant incremental benefit from adding testosterone to estradiol and progestin ($p=0.47$) – a finding consistent with the position stated in Section IV.B and Recommendation 7 that testosterone should not be positioned as a primary treatment for mood disorders. We agree that testosterone should not be positioned as a primary treatment for depressed mood or cognitive decline; improvements in these areas may occur as secondary benefits in some women and merit further study.

C. Safety

In trials of physiologic-dose transdermal testosterone, the most common adverse effects were mild acne and increased facial or body hair. Alopecia, clitoromegaly, and voice changes were not significantly increased, although these trials were not designed to detect uncommon or long-term harms [1, 16]. Oral testosterone is associated with adverse lipid effects [1, 17]. No trial in women has been powered for cardiovascular outcomes, and available trials were not large or long enough to assess breast or endometrial cancer risk [1]. FDA's workshop notice recognizes that long-term safety data beyond 24 months are limited.

Because most controlled data involve transdermal delivery, evidence for the other routes and dosage forms in current use is limited. That evidence should be developed rather than presumed, and concerns about specific dosage forms, particularly testosterone pellets, have been raised in the medical literature because currently available pellet products have been associated with sustained androgen levels above the premenopausal physiologic range and cannot be readily reversed if adverse events occur [1,2]. APC's position is that the regulatory concern is supraphysiologic dosing, not the dosage form per se. A compounded pellet prescribed at a physiologic dose, with appropriate pre-implant serum

testosterone testing and post-implant monitoring confirming levels remain within the premenopausal reference range, directly addresses the specific concern the guidelines identify. FDA should therefore require evidence-based dosing standards and monitoring requirements for pellets rather than a categorical prohibition on the dosage form.

D. Patient Selection and Monitoring

No validated biochemical threshold exists for androgen deficiency in women, and female reference ranges vary by assay [1, 5]. The Global Consensus recommends diagnosing HSDD through a biopsychosocial assessment, measuring total testosterone at baseline and again 3–6 weeks after initiation, and discontinuing therapy if there is no benefit at 6 months. It and the VA/DoD Guideline both call for ongoing serum monitoring to keep levels within the physiologic premenopausal range [1, 2,]. Davis et al, 2024 [17] recommends confirming levels at 3 months; the 3–6-week timeframe is specific to the Global Consensus [1] and VA/DoD Guideline [2]. We support this framework. It applies whether a patient's testosterone is a fractionated male product or a compounded preparation, and pharmacists, including compounding pharmacists, are well positioned to support it alongside prescribers.

Concerns about supraphysiologic testosterone exposure in women are best addressed through individualized dosing and monitoring rather than through presumptions about particular routes or dosage forms. Whether a patient's levels exceed the physiologic range is a question answered by her measured serum concentrations, interpreted in light of the assay variability FDA has recognized. Patient-specific compounding supports this goal: it allows prescribers to order small, precise doses and adjust them in response to monitoring, which a fractionated male product cannot reliably provide. We support titration to physiologic premenopausal targets for every patient, whatever the source of her therapy.

E. Women with Hypopituitarism

Women with hypopituitarism, particularly those with combined gonadotropin deficiency and secondary adrenal insufficiency, have the most profound androgen deficiency of any female population because both ovarian and adrenal androgen sources are lost [18, 19]. In the only randomized trial in this group, 51 women treated for 12 months with a 300 µg/day transdermal patch showed increased hip and radius bone mineral density, increased fat-free mass and thigh muscle area, and improved mood and sexual function compared with placebo, with no change in cognition [20]. The 2014 Endocrine Society guideline nonetheless recommends against routine treatment, citing reliance on that single trial and the absence of long-term data [5].

We recommend that FDA recognize hypopituitary women with genuine androgen deficiency as a distinct population meriting targeted study, and consider whether a supervised, individualized trial of physiologic testosterone, with monitoring as for HSDD and discontinuation if no benefit is observed, may be appropriate for carefully selected women whose quality of life and sexual function remain impaired despite full optimization of other pituitary hormone replacement [18, 19, 20].

V. REGULATORY AND POLICY CONSIDERATIONS

A. FDA Should Actively Facilitate an Approved Testosterone Product for Women

APC and NCPA strongly support development of an FDA-approved testosterone product for women and urges FDA to take an active role in making one possible. The evidence for postmenopausal HSDD carries the highest grade in international guidance [3], testosterone is already approved for HSDD in women in Australia, New Zealand, the United Kingdom, and South Africa, and FDA's own notice recognizes that off-label use among U.S. women has grown over the past decade [2]. Women should not have to rely on male products divided at home, and prescribers should have an approved option with labeling, dosing, and monitoring information developed for women.

FDA has tools to move this forward. We encourage the Agency to:

- Finalize and update its 2016 draft guidance on developing drugs for low sexual interest, desire, and arousal in women to address testosterone specifically, including acceptable primary endpoints, target populations, and dose-finding expectations [1];
- Define clearly and in advance the long-term safety data it will expect, including whether cardiovascular and breast outcomes can be addressed in part through postmarketing studies or a national registry rather than solely through premarket trials of a size and duration that could make development impractical;
- Engage sponsors of testosterone products approved for women in other countries, and consider how existing foreign clinical and postmarketing data could support a U.S. application;
- Use pre-IND, end-of-phase 2, and other existing meeting mechanisms to give sponsors early and consistent advice; and
- Encourage development in strengths and dosage forms suited to women, so that an approved product meets as many patients' needs as possible.

An approved product and patient-specific compounding are complementary. Under section 503A, a compounded preparation that produces a significant difference for an individual patient, as determined by the prescribing practitioner, is not essentially a copy of a commercially available drug product. We therefore ask FDA to pursue an approved female product as an addition to, not a replacement for, the individualized therapy that compounding provides.

B. Drug Approval and Individualized Patient Care Are Distinct Questions

APC and NCPA support FDA's efforts to identify the evidence necessary to support approval of testosterone products specifically indicated for women. At the same time, the evidentiary standards necessary to establish safety and effectiveness for an FDA-approved indication should not be conflated with the individualized clinical decision-making of a licensed prescriber treating a particular patient. The absence of an FDA-approved testosterone product for menopausal women does not, standing alone, answer whether testosterone therapy may be clinically appropriate for an individual patient. Nor should it be

interpreted as rendering inappropriate the lawful preparation of a compounded medication pursuant to a patient-specific prescription when the requirements of federal and state law are satisfied.

C. Distinguishing Lawful Pharmacy Compounding from Unlawfully Marketed Unapproved Drugs

We encourage FDA to use precision when discussing “unapproved” testosterone products. A drug product commercially marketed without required FDA approval presents a fundamentally different regulatory circumstance from a medication compounded by a state-licensed pharmacy under section 503A for an individually identified patient based on a valid prescription or order. Failing to distinguish between these categories can confuse patients, prescribers, pharmacists, state regulators, and the public, and can incorrectly suggest that a lawfully compounded prescription is equivalent to an unlawfully marketed unapproved drug product.

D. Preserving Patient Access as the Evidence Base Develops

The development of additional evidence and FDA-approved therapeutic options should not disrupt access for women currently receiving lawfully prescribed compounded testosterone. FDA’s goals of examining existing evidence, identifying knowledge gaps, and charting a path toward research and drug development can be pursued without prejudging the clinical decisions of prescribers or limiting access to patient-specific compounded preparations.

Even if FDA-approved products for women become available, patient-specific needs will remain that a commercial product cannot meet. Future product development should take into account the reasons prescribers currently rely on compounded preparations, because a product without appropriate strengths, useful dosage forms, or sufficient dosing flexibility will leave many of those needs unaddressed. Section 503A should continue to govern the circumstances in which a prescriber determines that a compounded testosterone preparation is necessary for an individual patient.

E. Reassessing Testosterone’s Schedule III Status

Testosterone’s classification as a Schedule III controlled substance burdens women’s therapy as well as men’s. It requires prescriber registration, limits prescriptions to five refills within six months, and imposes storage, recordkeeping, and dispensing obligations on pharmacies. These barriers are particularly disproportionate for women, whose therapeutic doses are a small fraction of those used in men.

In comments submitted to Docket No. FDA-2025-N-6743, APC and NCPA urged FDA to work with the Drug Enforcement Administration to reassess testosterone’s scheduling, and members of FDA’s expert panel on testosterone therapy in men expressed support for removing the Schedule III designation [21]. We encourage FDA to ensure that women’s therapy is considered as part of that reassessment.

VI. RESEARCH PRIORITIES

We agree with FDA that significant knowledge gaps remain regarding testosterone measurement, clinical outcomes, and long-term safety in women. That research should address testosterone as it is actually prescribed and used, including the strengths, doses, routes of administration, dosage forms, treatment duration, and monitoring practices in clinical care, rather than relying primarily on products and dosing regimens developed for men. Our priorities are:

- Comparative data on the routes and dosage forms women currently use, including compounded preparations, so that clinical guidance rests on evidence;
- A national outcomes registry for women, with harmonized data elements, capturing formulation, dose, route, duration, and monitoring alongside sexual function, cardiovascular, bone and fracture, oncologic, and metabolic outcomes [1, 2];
- Long-term (more than two years) randomized data on cardiovascular, breast, and endometrial outcomes [1, 2];
- Standardized, validated female-specific testosterone assays and outcome measures [1, 5];
- Adequately powered trials in populations underrepresented in existing research, including premenopausal women with sexual dysfunction and women with androgen deficiency from hypopituitarism, bilateral oophorectomy, or primary ovarian insufficiency [7, 18]; and
- Hypothesis-driven study of potential uses beyond HSDD, including the two areas described below.

Two such areas merit particular attention. In genitourinary syndrome of menopause, an ISSWSH expert consensus review notes that genitourinary tissues, including the clitoris, vestibule, urethra, anterior vaginal wall, and pelvic floor, are androgen-responsive. Vaginal DHEA improves dyspareunia, and limited data suggest systemic or vaginal testosterone may improve vaginal epithelial health and blood flow, making vaginal testosterone a promising but not yet established treatment [22]. In metabolic health, physiologic-range testosterone in androgen-deficient women has been linked to increased lean mass, decreased fat mass, improved insulin sensitivity, and reduced inflammation, and testosterone is an obligatory precursor for extragonadal estradiol synthesis [23]. These hypothesis-generating findings warrant prospective study.

Compounding pharmacists can contribute a practical perspective to this work. Their experience preparing patient-specific testosterone prescriptions can help identify challenges with low-dose formulations, dose measurement, routes of administration, and monitoring. We encourage FDA to include compounding pharmacists, alongside prescribers, researchers, and patients, in these discussions, and to consider whether early sponsor engagement, guidance on clinically meaningful endpoints, or public-private partnerships might enable the larger, longer-term studies these questions require.

VII. RECOMMENDATIONS

Based on the current evidence base and clinical practice guidelines, APC and NCPA respectfully recommend that FDA:

1. Recognize in its policies, guidance, and communications the legitimate and medically necessary role of pharmacy compounding under section 503A for women whose needs cannot be met by commercially available testosterone products, including situations involving individualized dosing, alternative routes of administration, or tolerability concerns, as discussed in Section III;
2. Actively facilitate development of an FDA-approved testosterone product for women, beginning with postmenopausal HSDD, by finalizing and updating its 2016 draft guidance to address testosterone, defining long-term safety expectations in advance, engaging sponsors of products approved in other countries, and encouraging strengths and dosage forms suited to women, as discussed in Section V.A;
3. Clearly distinguish in its communications between unlawfully marketed unapproved drug products and medications lawfully compounded pursuant to section 503A;
4. Keep the evidentiary standards for drug approval separate from individualized prescribing decisions, and preserve access to patient-specific compounded preparations both while the evidence base develops and after approved products become available;
5. Recognize biopsychosocially confirmed postmenopausal HSDD as the primary evidence-based indication for testosterone therapy in women [1, 2];
6. Ensure that communications reflect the consistent sexual function benefit in postmenopausal HSDD and the limits of current data on uncommon and long-term harms, and that statements about particular routes, dosage forms, or compounded preparations rest evidence-based dosing and monitoring standards, recognizing that the concerns about specific dosage forms such as pellets identified in published guidelines [1,2] related specifically to supraphysiologic dosing, a concern that patient-specific compounding with appropriate monitoring is uniquely positioned to address.
7. Support clinical guidance that includes biopsychosocial assessment, baseline and follow-up serum testosterone monitoring with validated assays, and discontinuation if no benefit is observed at 6 months [1, 2, 17];
8. Clarify that testosterone is not a first-line treatment for depressed mood or cognitive symptoms, while acknowledging possible secondary improvements in some women [1, 13];
9. Support a national outcomes registry and long-term research that includes the routes and dosage forms women currently use, including compounded preparations, with compounding pharmacists participating, and encourage development of FDA-approved products in strengths and dosage forms that meet the range of patient needs; and

10. Work with the Drug Enforcement Administration to reassess testosterone's classification as a Schedule III controlled substance, including its effect on women's therapy, as discussed in Section V.D.APC and NCPA appreciate the opportunity to provide these comments and would be pleased to engage further with FDA and other stakeholders on testosterone therapy in women.

VIII. REFERENCES

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