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Editorial

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Is It Time to Revisit Menopausal Hormone Replacement Therapy After Updated Labeling by the FDA?

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For over 20 years, the shadow of the 2002 and 2024 reports from the Women's Health Initiative (WHI) studies has negatively affected the hormonal therapies for menopausal women. These reports, which linked hormone replacement therapy (HRT) with cardiovascular events and breast cancer risks, caused a massive global wave of fear, leading millions of women to abandon treatment (1, 2). However, officially, the U.S. Food and Drug Administration (FDA) has signaled a paradigm shift by moving to remove or significantly modify the "Boxed Warning"—the agency's most stringent safety label—from many HRT products in November 2025 (3).

The primary driver behind this regulatory change is the scientific consensus on the window of opportunity. The FDA's previous warnings were primarily based on data from an older cohort (average age 63) who were many years post-menopause (1,2).

Modern clinical data consistently show that for symptomatic healthy women who are below 60, or within 10 years after the menopausal onset, the benefits from HRT typically far outweigh the risks. This distinction between "early-start" and "late-start" therapy is the cornerstone of the FDA's new perspective (4-6).

The FDA's 2025 evaluation introduces three critical changes to the clinical landscape. Firstly, the FDA has finally acknowledged that vaginal low-dose estrogens, used for genitourinary symptoms of menopause, do not carry the same systemic risks as oral or transdermal therapies, recommending the removal of cardiovascular warnings for these specific products. Secondly, the long-standing practice advice of administering the lowest HRT dosage for the shortest duration is being replaced. The new guidance supports individualized duration, recognizing that many women require longer-term therapy to manage bone density and quality-of-life symptoms. Thirdly, by differentiating data by age and time since menopause, the FDA is allowing labels to reflect that HRT may actually have a cardioprotective effect when initiated at the appropriate time (3).

This re-evaluation is more than a labeling change; it is a restoration of agency to women and their physicians. The removal of the "Black Box" status for specific cohorts reduces the "stigma of prescription," allowing for a more delicate discussion on bone health, cognitive function, and metabolic benefits. However, the FDA remains transparent about the necessity of progestogens to prevent hyperplasia of the endometrium in women with an intact uterus, and the need for caution in patients diagnosed with a hormone-sensitive cancer (3).

In conclusion, the FDA's latest stand marks a victory of longitudinal evidence over reactionary fear. By updating these guidelines, the medical community can finally move toward a model of Precision Menopause Medicine, ensuring that a woman's "second act" is defined by her health potential rather than outdated statistics.

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Competing Interests

None declared.

Ethical Issues

Not applicable.

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References

1. Anderson GL, Limacher M, Assaf AR, et al. Effects of conjugated equine estrogen in postmenopausal women with hysterectomy: the Women's Health Initiative randomized controlled trial. JAMA. 2004;291:1701–12. doi: 10.1001/jama.291.14.1701
2. Rossouw JE, Anderson GL, Prentice RL, et al. Risks and benefits of estrogen plus progestin in healthy postmenopausal women: principal results From the Women's Health Initiative randomized controlled trial. JAMA. 2002;288:321–33. doi: 10.1001/jama.288.3.321
3. Makary MA, Nguyen CP, Høeg TB, Tidmarsh GF. Updated Labeling for Menopausal Hormone Therapy. JAMA. 2026;335(2):117-118. doi:10.1001/jama.2025.22259
4. Chlebowski RT, Anderson GL, Aragaki AK, et al. Association of Menopausal Hormone Therapy With Breast Cancer Incidence and Mortality During Long-term Follow-up of the Women's Health Initiative Randomized Clinical Trials. JAMA. 2020;324(4):369-380. doi:10.1001/jama.2020.9482
5. Manson JE, Chlebowski RT, Stefanick ML, et al. Menopausal hormone therapy and health outcomes during the intervention and extended poststopping phases of the Women's Health Initiative randomized trials. JAMA. 2013;310(13):1353-1368. doi:10.1001/jama.2013.278040
6. Kim JE, Chang JH, Jeong MJ, et al. A systematic review and meta-analysis of effects of menopausal hormone therapy on cardiovascular diseases. Sci Rep. 2020;10(1):20631. Published 2020 Nov 26. doi:10.1038/s41598-020-77534-9