



FOR IMMEDIATE RELEASE

November 10, 2025

Major Victory for Women’s Health: FDA Removes Black Box Warning from Estrogen-Containing Products

SEATTLE, WA – The **Washington State Urology Society (WSUS)** proudly announces a historic advancement in women’s health: the **U.S. Food and Drug Administration (FDA)** has removed the broad “black box” warnings from many **estrogen-containing products** used for **Menopause Hormone Therapy (MHT)** and the **Genitourinary Syndrome of Menopause (GSM)**.

This decision represents a landmark step in reducing unnecessary fear surrounding these therapies and will greatly enhance care for women suffering from menopause-related symptoms and GSM. The FDA is collaborating with drug manufacturers to update labeling that previously cited increased risks of cardiovascular disease, breast cancer, and dementia—risks that modern data no longer support for low-dose, localized estrogen therapies. This update aims to align product information with current science and promote informed, individualized discussions between patients and healthcare providers.

Urologic Leadership and Evidence-Based Advocacy

The removal of the black box warning is the culmination of sustained, evidence-based advocacy led by the **American Urological Association (AUA)**, **Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU)**, and many other medical organizations—supported by patients, clinicians, and members of WSUS.

The **AUA GSM Guideline Panel** presented compelling evidence to the FDA confirming the **safety and efficacy of low-dose vaginal estrogen therapy**, particularly for localized urological symptoms of menopause. These efforts underscore the essential role of collaborative leadership in advancing women’s health.

Positive Impact on Patient Care and GSM Management

For years, the presence of the black box warning discouraged both physicians and patients from pursuing effective treatments, despite minimal systemic absorption and strong safety data. GSM symptoms—including **urinary frequency, urgency, recurrent urinary tract infections (UTIs)**, and **painful intercourse (dyspareunia)**—significantly affect quality of life.

The **AUA/SUFU/AUGS Guideline on Genitourinary Syndrome of Menopause (2025)** provides the latest evidence for diagnosis and management, reaffirming that **localized, low-dose estrogen therapy** remains a cornerstone of treatment, backed by numerous high-quality studies and long-term follow-up data.

Washington State Leadership Recognized

Washington urologists played key roles in this milestone achievement:

- **Rachel Rubin, MD**, urologist and sexual health expert, represented the AUA at the **FDA and Health and Human Services press conference** on November 10.
- **Kelly Casperson, MD**, Washington State urologist, podcaster, and author, shared powerful testimony on the impact this change will have on GSM diagnosis and treatment.
- **Una Lee, MD**, WSUS Past President and Women’s Health Committee Chair, serves as **Vice Chair of the AUA GSM Guideline Panel** and has led patient-centered advocacy and research in this area.
- **Sabrina Stair, MD, Cristi Palmer, MD, and Van Ginger, MD** presented expert clinical guidance on GSM at the **2025 WSUS Annual Meeting**.
- **Suzette Sutherland, MD**, Past President of the Society of Women in Urology, has been a vocal advocate for this change, including on the **BackTable Urology Podcast**.

Many other WSUS members across Washington continue to empower patients through education, advocacy, and evidence-based treatment of GSM.

Learn More

- **FDA/HHS Press Conference:** [Watch here](#)
- **FDA Podcast:**
 - *FDA Direct: Removing Black Box Warnings for HRT (Part 1)*
 - *FDA Direct: Removing Black Box Warnings for HRT (Part 2)*

About the Washington State Urology Society (WSUS)

The **Washington State Urology Society** represents urologists throughout Washington State, promoting excellence in urological care through education, advocacy, and collaboration. WSUS remains committed to advancing women’s health, supporting its members, and advocating at local, regional, and national levels to improve patient outcomes.

For more information, visit www.wsus.org.

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