

Let's Talk Menopause and National Menopause Working Group Launch 'Unboxing Menopause' Campaign

Campaign to Remove Outdated and Misleading FDA Boxed Warning on Local Vaginal Estrogen Products

NEW YORK, NY, UNITED STATES, September 17, 2024 / EINPresswire.com/ -- Let's Talk Menopause (LTM) and the Menopause Advocacy Working Group, a coalition of leaders in medicine, advocacy, and communication, announced today the launch of their latest joint advocacy campaign to remove the outdated FDAmandated boxed warning from local vaginal estrogen products used to treat Genitourinary Syndrome of Menopause (GSM).

GSM affects up to 84% of menopausal women, with symptoms like vaginal dryness, urinary urgency, and recurrent UTIs. Despite local vaginal estrogen's proven effectiveness, an



outdated boxed warning prevents many women from accessing this treatment.

"Genitourinary Syndrome of Menopause isn't just a minor inconvenience—it's a chronic and progressive condition that worsens over time if left untreated," said Dr Sharon Malone, OBGYN, Menopause Advocacy Working Group, NYT-bestselling author, and LTM Medical Advisory Board member. "Women deserve to know that there are safe, effective treatments like local vaginal estrogen available to help them regain their comfort and quality of life."

Outdated Warnings, Real Consequences The boxed warning (formerly known as the Black Box Warning), the highest level of caution issued by the FDA, stems from findings of the Women's Health Initiative (WHI) study, which primarily investigated the risks of systemic Menopause Hormone Therapy (MHT). The study's findings were inaccurately applied to local vaginal estrogen, which has minimal absorption and does not carry the same risks as systemic hormones.

"The WHI study changed the conversation about hormones, but applying its findings to vaginal estrogen is outdated," said Dr Kelly Casperson, Urologist, LTM's Medical Advisory Board, and Menopause Advocacy Working Group member. "We need to update our thinking—and our warnings—to reflect today's science."

The Real Cost of the Boxed Warning

For millions of women suffering from GSM, the boxed warning on local vaginal estrogen has created unnecessary fear and confusion. This barrier to treatment has resulted in higher healthcare costs, multiple doctor visits, and persistent discomfort.

"The boxed warning poses a massive economic burden on women — and on society," said Jen Weiss-Wolf, Let's Talk Menopause Board Member, author, and ED at Birnbaum Women's Leadership Center. "Untreated GSM leads to higher healthcare costs, lost productivity, and unnecessary suffering."

Advocating for Change

Let's Talk Menopause and the Menopause Advocacy Working Group are calling on women and healthcare providers to join the movement and demand that the FDA remove the boxed warning from local vaginal estrogen products.

"Vaginal estrogen is the gold standard treatment for GSM," said Dr. Robin Noble, OBGYN, Let's Talk Menopause's Chief Medical Advisor. "It targets the problem at the source, helping women regain their comfort, their sexual function and their quality of life with minimal risk."

"Fear shouldn't dictate our health choices," remarked Tamsen Fadal, author, journalist, filmmaker, and LTM Ambassador and board member. "The black box warning is costing us our well-being and our money."

Join the Campaign

Let's Talk Menopause and the Menopause Advocacy Working Group urge women and providers to advocate for removing the outdated boxed warning to make local vaginal estrogen more accessible.

For more information on how to get involved or to learn more about GSM and local vaginal estrogen, visit the <u>Unboxing Menopause campaign</u> website and sign the <u>consumer advocacy</u> <u>letter</u> to the FDA.

About Let's Talk Menopause

Let's Talk Menopause is a nonprofit organization dedicated to providing education, support, and advocacy for women navigating menopause. Through public education, research, and policy reform, LTM aims to empower women to take control of their health during this critical stage of life.

The Menopause Advocacy Working Group

The Menopause Advocacy Working Group unites leaders from medical, advocacy, and communication fields, committed to enhancing awareness and access to menopause-related healthcare. Through collaboration, the group seeks to break the stigma surrounding menopause and advocate for critical policy reforms, including ongoing work to support the Menopause Research & Equity Act of 2023.

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