

Menopause Advocacy Working Group

Marie Capozzi, Chief Operating Officer,
Let's Talk Menopause (LTM)

Kelly Casperson, MD, Urologist

Samara Daly, Co-Founder & Board Chair, Let's
Talk Menopause

Tamsen Fadal, Journalist; Author; Menopause
Advocate; LTM Board Member & Ambassador

Claire Gilli, Founder, National Menopause
Foundation; CEO, Bone Health & Osteoporosis
Foundation

Sally Greenberg, JD; CEO of The National
Consumers League

Alicia Jackson, PhD; CEO & Founder, Evernow

Cathy Rought-Jacobson, CEO & President of
Integritas Public Affairs; LTM board member

Sheryl Kingsberg, PhD; Chief of Behavioral
Medicine, University Hospital Cleveland Medical
Center; Advocacy Chair of The International
Society for the Study of Women's Sexual Health
(ISSWSH)

Donna Klassen, LCSW; Co-Founder & CEO,
Let's Talk Menopause

Lisa Larkin, MD, FACP, MSCP; Founder & CEO,
Ms. Medicine

Jessica Levin, JD; Chief Program Officer,
Let's Talk Menopause

Sharon Malone, MD, OB/GYN; Chief Medical
Advisor to Alloy Women's Health

Mary Jane Minkin, MD, OB/GYN; Clinical Professor,
Yale Medical School

Robin Noble, MD, MHCDS, MSCP; Medical Director,
Intermed; LTM Chief Medical Advisor

Rachel Rubin, MD, Urologist; Sexual Medicine
Specialist; Education Chair for The International
Society for the Study of Women's Sexual Health
(ISSWSH)

Omisade Burney-Scott, Creator and Chief
Curatorial Officer, Black Girl's Guide to Surviving
Menopause

Jennifer Weiss-Wolf, JD; Executive Director of
NYU's Law's Birnbaum Women's Leadership
Center; author/advocate

July 17, 2025

**Marty Makary, M.D., M.P.H., Commissioner, U.S. Food & Drug
Administration**

**Sara Brenner, M.D., M.P.H., Principal Deputy Commissioner, U.S. Food
& Drug Administration**

Dear Doctors Makary and Brenner,

For the past two years, the **Menopause Advocacy Working Group**—a coalition of leading physicians, researchers, and nonprofit leaders—has worked to improve the lives of millions of women experiencing menopause. Members include Dr. Sharon Malone, OB-GYN and women's health advocate; Dr. Lisa Larkin, Founder and CEO of Ms. Medicine; Dr. Sheryl Kingsberg, Past President of the International Study of Women's Sexual Health (ISSWSH); and Dr. Rachel Rubin, Director-at-Large on the Board of ISSWSH (see Appendix A for full list).

Millions of postmenopausal women experience **Genitourinary Syndrome of Menopause (GSM)**—a more accurate and inclusive term than “vulvovaginal atrophy,” endorsed by the Menopause Society and ISSWSH. The drop in estrogen after menopause causes genital (dryness, burning, irritation), sexual (pain, impaired function), and urinary (urgency, dysuria, recurrent UTIs) symptoms. Unlike hot flashes, GSM is a **chronic, progressive condition**, affecting 50–90% of postmenopausal women. Yet fewer than 25% of women discuss their symptoms with a provider, and even fewer receive treatment. UTIs alone account for 7 million hospital visits annually, 25% of infections in older adults, and nearly one-third of related Medicare spending.

Despite clear evidence that **Local Vaginal Estrogen is safe**, with minimal systemic absorption, the FDA-required boxed warning mirrors that of systemic estrogen products. It cites risks—cardiovascular disease, stroke, and breast cancer—based on systemic hormone therapy data, which do not apply to Local Vaginal Estrogen. This warning misleads both patients and providers, creating unnecessary fear and undermining appropriate care.

Recent research and clinical guidelines reaffirm the safety and effectiveness of local vaginal estrogen for treating genitourinary syndrome of menopause (GSM). Clinical trials and observational studies consistently show minimal to no systemic absorption, with estradiol levels remaining within the

postmenopausal range. A large [JAMA study](#) of 50,000 women with breast cancer found no increase in early breast cancer-specific mortality among

those using vaginal estrogen. Similarly, another study reported no increased risk of breast cancer recurrence within five years in women with a personal history of breast cancer treated with vaginal estrogen. Long-term data include an 18-year follow-up from the Women's Health Initiative demonstrating no increased risk of chronic disease outcomes, a 2017 randomized, double-blind, placebo-controlled phase 3 trial across 89 sites showing significant improvement in GSM symptoms without elevating serum estradiol levels, and a 2019 systematic review of low-dose estrogen (without progestin) finding no increased risk of endometrial hyperplasia or cancer. There is also no evidence of increased risk for thromboembolic events or stroke.

Major medical societies strongly support the use of Local Vaginal Estrogen, even in women with a history of breast cancer when nonhormonal options fail. Endorsements come from The Menopause Society, the American College of Obstetricians and Gynecologists (ACOG), the American Society of Clinical Oncology (ASCO), the American Urological Association (AUA), The International Society for the Study of Women's Sexual Health (ISSWSH) and the Endocrine Society, all of which recognize its effectiveness and safety.

The boxed warning on Local Vaginal Estrogen has serious clinical and psychosocial consequences. Women are often denied therapy by physicians unwilling to prescribe it, and many stop treatment out of fear after reading the warning. As a result, millions suffer unnecessarily from avoidable UTIs, pain, and sexual dysfunction that could be effectively treated.

We urge the FDA to remove the boxed warning from Local Vaginal Estrogen products, distinguish local from systemic estrogen therapies in labeling, and update patient and provider education materials accordingly. The current warning reflects outdated data from systemic estrogen studies and does not align with decades of evidence supporting the safety of Local Vaginal Estrogen. Removing the boxed warning will empower women and clinicians to make informed, evidence-based decisions and significantly improve the quality of life for millions of women and their families.

In addition, we request an update to the FDA's most recent guidance on estrogen, which has not been revised since 2003. The 2003 guidance predates the recognition of genitourinary syndrome of menopause (GSM) as a comprehensive diagnosis and appears to overlook the unique safety and risk profile of Local Vaginal Estrogen. Updating this guidance is critical to align regulatory language with current scientific evidence and clinical practice.

Thank you for your time and consideration.

Sincerely,

The Menopause Advocacy Working Group

Appendix A

The Menopause Advocacy Working Group

Marie Capozzi, Chief Operating Officer, Let's Talk Menopause (LTM)

Kelly Casperson, MD, Urologist

Samara Daly, Co-Founder & Board Chair, Let's Talk Menopause (LTM)

Tamsen Fadal, Journalist; Author; Menopause Advocate; LTM Board Member & Ambassador

Sally Greenberg, JD; CEO of The National Consumers League

Alessandra Henderson, Senior Program Advisor, LTM, Co-founder & Board Member at Elektra Health; Inc.

Claire Gill, Founder, National Menopause Foundation; CEO, Bone Health & Osteoporosis Foundation

Jill Herzig, Midi Health Chief Brand Officer

Cathy Rought Jacobson, CEO & President of Integritas Public Affairs; LTM board member

Alicia Jackson, PhD; CEO & Founder, Evernow

Sheryl Kingsberg, PhD; Chief of Behavioral Medicine, University Hospital Cleveland Medical Center; Past President of ISSWSH

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Sharon Malone, MD, OB/GYN; Chief Medical Advisor to Alloy Women's Health

Corinne Menn, DO, MSCP; Director of Clinical Education and Education, Alloy Women's Health

[Mary Jane Minkin](#), MD, OB/GYN; Clinical Professor, Yale Medical School

[Robin Noble](#), MD, MHCD, MSCP; Medical Director, Intermed; Chief Medical Advisor, LTM

[JoAnn Pinkerton](#), MD; Professor ObGyn and Director Midlife Health at University of Virginia

[Charles Powell](#), MD; Urologist, IU Health Physicians Urology

[Rachel Rubin](#), MD, Urologist; Sexual Medicine Specialist; Assistant Clinical Professor, Georgetown University; Director-at-Large on the Board of ISSWSH

[Kathryn Schubert](#), President and CEO, Society for Women's Health Research (SWHR)

[Omisade Burney-Scott](#), Creator and Chief Curatorial Officer, Black Girl's Guide to Surviving Menopause

[Rebecca Thurston](#), PhD, FABMR, FSBSM; Assistant Dean for Women's Health Research University of Pittsburgh, Pittsburgh Foundation Chair in Women's Health and Dementia

[Jennifer Weiss-Wolf](#), JD; Executive Director of NYU's Law's Birnbaum Women's Leadership Center; Author/Advocate

Organizations

American Association of Clinical Urologists (AACU)

Black Girl's Guide to Surviving Menopause

The International Society for the Study of Women's Sexual Health (ISSWSH)

Let's Talk Menopause

National Menopause Foundation

Society for Women's Health Research