



January 15, 2026

The Honorable Marty Makary
Commissioner
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

The Honorable Robert F. Kennedy
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue
SW Washington, D.C. 20201

Dear Commissioner Makary and Secretary Kennedy:

As members of the Democratic Women's Caucus, we write to acknowledge the Food and Drug Administration (FDA) for its recent decision to remove the black box warning from hormone therapy. This step demonstrates a commitment to science-based regulation and the health of women nationwide. Menopause is a natural but often challenging life stage that profoundly affects physical and emotional well-being. Yet, too many women continue to face barriers to care due to lack of adequate information and evidence-based treatment options. This action offers a timely opportunity for the FDA and the Department of Health and Human Services (HHS) to lead a broader effort to strengthen education and support equitable access to menopause care. It is imperative that women are empowered with the information and resources they need to make informed decisions about their health throughout all stages of their lives.

We urge HHS and the FDA to continue advancing rigorous research on hormone therapy's safety and effectiveness, particularly as your agencies update product labeling and risk communication. It is important to emphasize that menopause research is not just important as it relates to women's symptoms but necessary to address their health as they age. It should continue to be the priority of the agencies to empower clinicians to treat patients based on their unique risk factors and individualized treatment objectives. They are necessary safeguards to ensure all patients across age, race, gender identity, socioeconomic status, and health status can benefit from these therapies without avoidable harm. Continued research into nonhormonal therapies for individuals with contraindication to hormone therapy or preference not to take them is also necessary. By advancing rigorous research, your agencies will lay the groundwork for a more robust evidence base and fairer standards of care.

We are currently in a moment that underscores the broader importance of women's health research across the lifespan, including menopause. Sustained investment in women's health science has been shown to improve quality of care when women's health concerns are no longer treated as niche or secondary concerns. Defunding or weakening women's health research initiatives, particularly those focused on menopause, would reverse recent progress and perpetuate the pattern in which women's symptoms are neglected. This dynamic has especially serious consequences for women of color, who already face higher burdens of disease and greater barriers to care.

To build on the progress already made, we urge the FDA and HHS to:

- Support large, diverse longitudinal studies and comparative research on hormone therapy safety;
- Increase federal resources for the National Institute of Child Health and Human Development (NICHD) Menopause Research Program and establish a dedicated, well-resourced menopause research division within NICHD with clear authority to drive this work;
- Implement targeted education initiatives to ensure prescribers, patients, and caregivers clearly understand the guidelines, their implications, and how to apply them effectively from each perspective; and
- Ensure robust post-marketing surveillance and regularly updated guidelines and labeling to maintain public trust and transparency.

Thank you for your attention to these vital efforts. We look forward to working together to advance the health and well-being of all who rely on the effectiveness and efficiency of your agencies.

Sincerely,



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Co-Chair
Reproductive Health Care Task
Force
Democratic Women's Caucus



Ayanna Pressley
Co-Chair
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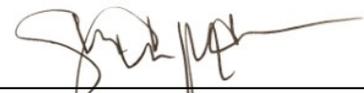
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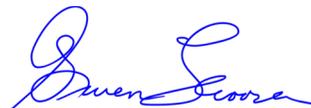

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