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U.S. DEPARTMENT OF
HEALTH AND HUMAN SERVICES

FOR IMMEDIATE RELEASE
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HHS Advances Women's Health, Removes Misleading FDA Warnings on Hormone Replacement Therapy

WASHINGTON, NOV. 10, 2025—The U.S. Department of Health and Human Services (HHS) today announced historic action to restore gold-standard science to women's health. After more than two decades of fear and misinformation surrounding hormone replacement therapy (HRT), the U.S. Food and Drug Administration (FDA) is initiating the removal of broad "black box" warnings from HRT products for menopause.

Health and Human Services Secretary Robert F. Kennedy Jr. and FDA Commissioner Marty Makary, M.D., M.P.H. made the announcement at a press conference </live/live-1/index.html#12215> at HHS with more than 200 people in attendance, including Second Lady of the United States Usha Vance and Secretary of Labor Lori Chavez-DeRemer.

Women have used HRT products for decades to relieve menopausal symptoms. However, their use plummeted in the early 2000s when the FDA applied boxed warnings following a Women's Health Initiative study that found a statistically non-significant increase in the risk of breast cancer diagnosis. The average age of women in the study was 63 years — over a decade past the average age of a woman experiencing menopause — and study participants were given a hormone formulation no longer in common use.

The FDA is initiating removal of the boxed warnings following a comprehensive review of the scientific literature, an expert panel <https://www.fda.gov/patients/fda-expert-panels/fda-expert-panel-menopause-and-hormone-replacement-therapy-women-07172025> in July, and a public comment period. The agency is working with companies to update language in product labeling to remove references to risks of cardiovascular disease, breast cancer, and probable dementia. The FDA is not seeking to remove the boxed warning for endometrial cancer for systemic estrogen-alone products.

"Today, we are standing up for every woman who has symptoms of menopause and is looking to know her options and receive potentially life-changing treatment," said **Secretary Kennedy.** "For more than two decades, bad science and bureaucratic inertia have resulted in women and physicians having an incomplete view of HRT. We are returning to evidence-based medicine and giving women control over their health again."

"Tragically, tens of millions of women have been denied the life-changing and long-term health benefits of hormone replacement therapy because of a medical dogma rooted in a distortion of risk," said **FDA Commissioner Makary.** "For too long, issues of women's health have been underrecognized. Women and their physicians should make decisions based on data, not fear."

As women go through menopause, the ovaries produce less estrogen and progesterone. FDA-approved HRT containing estrogen and progesterone (or estrogen alone as indicated for postmenopausal women without a uterus) can restore these declining hormones, and relieve symptoms such as hot flashes, night sweats, sleep disturbances, and bone loss.

"Estrogen is a key hormone for women's health. Every single part of a woman's body depends on estrogen to operate at its best—including the brain, bones, heart, and muscles," said **Advanced Research Projects Agency for Health Director Alicia Jackson, Ph.D. "**The removal of the black box warning, based on the best science and data, is an incredible step forward to empower millions of women to live longer, healthier lives."

"Someday, science will help us slow or reverse all the damage of aging," said **Health and Human Services Deputy Secretary Jim O'Neill**. "A good safe way to address estrogen depletion already exists, and today Secretary Kennedy and Commissioner Makary are removing a barrier on this treatment. Many more women can reduce their risk of fracture, heart disease, and immune and cognitive decline while extending their vigor."

Randomized studies show that women who initiate HRT within 10 years of the onset of menopause (generally before age 60) have a reduction in all-cause mortality and fractures. Women may also reduce their risk of cardiovascular diseases by as much as 50% <https://pubmed.ncbi.nlm.nih.gov/2005736/>, Alzheimer's disease by 35%,

<https://pubmed.ncbi.nlm.nih.gov/8885820/> and bone fractures by 50 to 60% <https://www.nejm.org/doi/full/10.1056/nejm198011203032102>. Though the starting time of HRT and duration of use are decisions made between the prescriber and the individual patient, the FDA's labeled recommendation will be to start HRT within 10 years of menopause onset or before 60 years of age for systemic HRT.

In addition to the removal of boxed warnings, the FDA is also approving two new drugs to expand treatment options for menopausal symptoms. The first is the approval of a generic version of Premarin (conjugated estrogens), the first such approval in more than 30 years for this widely used hormone replacement therapy. The new generic product is expected to improve affordability and access while maintaining the same quality, safety, and effectiveness as the brand-name drug.

The second approval is for a non-hormonal treatment for moderate to severe vasomotor symptoms, such as hot flashes, associated with menopause. This option provides relief for women who cannot or choose not to use hormone therapy.

See FACT SHEET: FDA Initiates Removal of "Black Box" Warnings from Menopausal Hormone Replacement Therapy Products </press-room/fact-sheet-fda-initiates-removal-of-black-box-warnings-from-menopausal-hormone-replacement-therapy-products.html>.

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