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FDA Calls for Removal of Hormone-Replacement Therapy Warnings

The agency says clinical trials show no association with increased breast cancer risk

By Joseph De Avila Follow

Updated Nov. 10, 2025 at 1:53 pm ET

The FDA's commissioner cited several studies showing some health benefits associated with the drugs. JIM LO SCALZO/EPA/SHUTTERSTOCK

The Food and Drug Administration said manufacturers should remove black box warnings on hormone-replacement therapy drugs, citing clinical trials showing no association with increased breast cancer risk.

The black box warnings may have kept many women away from what could be life-changing treatment, the head of the FDA said Monday in an opinion piece published

A study published in 2002 called the Women's Health Initiative found an additional 1 in 1,000 women receiving the drugs was identified to have a nonfatal breast cancer diagnosis compared with a control group, wrote Dr. Marty Makary, commissioner of the FDA.

He said the finding wasn't statistically significant. The increased risk could be attributed to a particular hormonal medication used in the study that doctors have since moved away from, he wrote.

The risks of breast cancer and other complications apply to women who start the hormone drugs after the age of 60, he said. Medical professionals recommend that women begin the drug treatment within 10 years of the onset of menopause.

Hormone-replacement therapy, which consists of estrogen and progesterone, alleviates short-term symptoms of menopause. That includes hot flashes, night sweats, mood swings and weight gain.

Makary cited several studies that showed some health benefits associated with the drugs, including reducing the risk of heart disease and slowing cognitive decline.

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