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US FDA to drop black box warnings from menopause hormone therapies

WASHINGTON (Reuters) -The U.S. Food and Drug Administration said on Monday it would remove the strictest "black box" warnings from hormone therapies used to treat menopause symptoms, a move that may boost access to treatments long shunned by patients and doctors over safety fears.

FDA Commissioner Marty Makary said the decision follows an extensive review of scientific literature, input from an expert panel in July, and a public comment period.

"After 23 years of dogma, the FDA today is announcing that we are going to stop the fear machine steering women away from this life-changing, even life-saving treatment," Makary said during a press conference.

"We are listening to women who have been challenging the paternalism of medicine. We are listening to female medical students that have demanded more menopause education in the curricula," he added.

The agency is also approving two new drugs for the treatment of menopausal symptoms, he said, including a generic version of Pfizer's Premarin and a non-hormonal treatment for moderate to severe vasomotor symptoms, such as hot flashes, associated with menopause.

The agency said it was working with drug manufacturers to update language in product labeling to remove references to risks of cardiovascular disease, breast cancer, and probable dementia.

Hormone replacement therapy, or HRT, was widely prescribed, including to protect women from chronic diseases, especially heart disease, for decades. But its use plunged after a 2002 Women's Health Initiative study found it could raise the risk not only of breast and ovarian cancer but also of strokes and other serious conditions.

"That study was misrepresented and created a fear machine that lingers to this day," Makary said on Monday, adding it showed no statistical significance in the increase in breast cancer.

The American College of Obstetricians and Gynecologists welcomed the move, which it said it had long advocated for.

"By discouraging clinicians from prescribing low-dose vaginal estrogen, the current warning label harms patients by making inaccessible an effective treatment for symptoms that can significantly decrease health-related quality of life," said ACOG President Steven Fleischman.

The move was also welcomed by Claire Gill, founder and president of the National Menopause Foundation, who called it an important first step in addressing access to therapies for women suffering from menopausal symptoms.

Makary said drugmakers welcomed the move. "The companies are generally speaking, very excited when the FDA tells them you can remove a scary warning on your product," he said.

Digital health firms, including Hims & Hers Health, WeightWatchers International and Noom, have rolled out programs designed to support women experiencing a shift in hormone levels during menopause, citing a link between the cessation of menstrual cycles and weight gain.

Hims in an October announcement said the offering would help drive the company toward $1 billion in yearly revenue by 2026.Hormone replacement therapy for menopause replenishes the hormones, primarily estrogen, that decline with menopause to relieve symptoms like hot flashes and vaginal dryness.

All menopause treatments containing estrogen carry a warning that it increases the risk of strokes, blood clots and perhaps dementia. It also warns of the possibility of breast cancer.A black box warning is the most severe the FDA can place for a prescription medication, indicating serious or potentially fatal side effects.