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FDA reviewing safety of Essure birth control implant

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Federal health regulators are reviewing the safety of an implantable contraception device after receiving reports of unusual side effects from patients, including fatigue, depression and weight gain.

The Food and Drug Administration says those problems have not been established in studies of the device and are not listed on the product label. But the agency scheduled a September 24 public meeting to consult outside experts about the overall safety of the Essure implant, which is marketed by Bayer.

The coil-like device is implanted by a doctor in the fallopian tubes, where tissue gradually grows and eventually blocks sperm from reaching a woman's eggs. The device was first approved by the FDA in 2002.

The product's labeling currently includes a number of warnings, including long-term risks such as chronic pelvic pain and the possibility of the device slipping out of position into the lower abdomen. The device is made of a nickel-titanium alloy and can cause allergic reactions—such as itching and hives—in some patients.

Regulators said late Wednesday that their review of two follow-up studies conducted by Bayer "found no conclusive evidence" of new or widespread complications "definitely associated" with the device. The company studies were designed to evaluate the safety of the procedure used to implant Essure, the device's safety after implantation and its effectiveness in preventing pregnancy.

Despite those findings, the FDA says it has continued to receive reports of complications from patients. A review of the agency's complaint database turned up more than 5,000 reports of problems linked to Essure. The problems most commonly reported by patients included abdominal pain, menstrual irregularities, headache and weight fluctuations. The agency stressed that patient reports are voluntarily submitted, and have a number of scientific limitations, including "incomplete, inaccurate, untimely, unverified, or biased data."

"FDA will continue to monitor the safety of Essure to ensure it does not pose an increased risk to public health and that its benefits continue to outweigh the risks," the agency said in a posting to its website.

A Bayer spokeswoman said the company "looks forward to an open and transparent discussion" about its device at the FDA panel meeting in September.

"Essure is supported by more than a decade of science and real world clinical experience," she said.

Bayer is headquartered in Germany with U.S. health operations in Whippany, New Jersey.

Diana Zuckerman, president of the National Center for Health Research, said she is pleased the FDA is looking into concerns about Essure.

"Our center is studying more than 900 women who have had problems with Essure permanent birth control, including chronic debilitating pain, abnormal bleeding, and pregnancy," Zuckerman said in an emailed statement.

Calls to Bayer were not returned immediately Thursday.