Women urge FDA to pull contraceptive device linked to pain

September 25 2015, byMatthew Perrone

This product image provided by Bayer Healthcare Pharmaceuticals, Inc. shows the birth control implant called Essure. Federal medical experts on Monday, Sept. 21, 2015 said it will take a closer look at a host of problems reported with Essure, including chronic pain, bleeding, headaches and allergic reactions. (Bayer Healthcare Pharmaceuticals, Inc. via AP)

More than a dozen women who received a metallic birth control implant are urging health regulators to pull the device from the market, citing problems including severe pain, irregular bleeding and weight gain.

The Essure implant has been sold for more than a decade and is frequently pitched to women as the only non-surgical option for permanent birth control. Manufacturer Bayer estimates 750,000 women have received the device since 2002.

But since 2013, the Food and Drug Administration has received thousands of complaints about the device from women and doctors. While the product's label warns about pelvic pain and bleeding immediately after the procedure, many women say these problems persisted and were so severe they required invasive surgery to remove the device.

The FDA convened a panel of outside experts Thursday to review the device's safety and effectiveness.

In often emotional prepared remarks, women from throughout the U.S. described debilitating symptoms which they attribute to Essure.

Elena Mendez received her implant in February 2008 at the recommendation of her doctor. An emergency room nurse in New York, Mendez said she liked the idea that she could return to work after a quick, in-office procedure.

But soon afterward Mendez began experiencing severe, constant pain, especially during sex.

"Pain became my norm every day," Mendez said. "This negatively impacted my marriage and I could not be the mother my children deserved."

Essure consists of two metallic coils inserted into the fallopian tubes, where they are intended to spur scar tissue that eventually blocks sperm. Bayer sells the device as an alternative to traditional procedures used to

"tie the tubes," via incision or other methods.

Essure's warning labeling lists a number of potential risks, including that the device can slip out of position or puncture the uterus, requiring surgery to remove. Additionally, Essure is made of a nickel-titanium alloy that can cause allergic reactions—such as itching and hives—in some patients.

But thousands of women have attributed more severe problems to the implant, including chronic pain, headaches, mood disorders, hair loss and irregular bleeding. Many of those complaints have been shared through social media, including a Facebook page called Essure Problems, which has over 20,000 members.

Later today the FDA will ask its panel of experts to discuss whether use of the device should be restricted to certain women. The panel's recommendations are not binding.

The dilemma confronting the FDA is not a new one when it comes to medical devices.

Short-term studies used to approve the device initially suggested it was safe and effective. But real-world experience from thousands of women suggests Essure can cause troubling side effects and may be less reliable at preventing pregnancy than advertised.

Three years ago a similar FDA panel convened to review unforeseen problems with metal-on-metal hip replacements. Those devices were thought to be more durable than older ceramic models. But the panel said real-world data showed the devices actually break down earlier than older implants, exposing patients to tiny, metallic shards.

In the case of Essure, the original company studies suggested the implant

prevented pregnancy in 97 percent of cases. But the studies only tracked 85 percent of women out to a year and only 25 percent of women were followed for two years. Researchers from Yale University said this drop-out rate "limited the evaluation of adverse events and device safety," in an op-ed in this week's *New England Journal of Medicine*.

"I think we could do better for women by getting better information," said Dr. Aileen Gariepy of Yale School of Medicine, in an interview with The Associated Press.