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Bayer to phase out Essure birth control device in U.S.

NEW YORK (Reuters) - Life sciences company Bayer AG said on Friday it would discontinue the sale of its birth control product Essure in the United States, citing a decline in sales of the implantable device that made the business no longer sustainable.

The decision followed an announcement by the company in September 2017 that it would discontinue the sale of the

contentious sterilization device in all countries outside the United States.

Bayer said in a statement that the decision was not related to safety concerns. The company, based in Leverkusen, Germany, is facing some 16,000 U.S. lawsuits over Essure, and it said it was expecting more.

“The benefit-risk profile of Essure has not changed, and we continue to stand behind the product’s safety and efficacy, which are demonstrated by an extensive body of research,” Bayer said.

It said it had informed the U.S. Food and Drug Administration of its decision and would update healthcare providers.

Essure will be gradually phased out and U.S. sales halted by the end of this year. Doctors will be able to perform Essure procedures until the end of next year when they will be asked to return unused devices.

FDA Commissioner Scott Gottlieb said in a statement that the agency would continue to monitor Essure’s safety, and added, “We expect Bayer to meet its postmarket obligations concerning this device.”

Early in 2016, the FDA put its strongest safety warning label on the device after thousands of complaints and asked the drugmaker to conduct a post-market study.

The agency said it received nearly 12,000 reports in 2017 related to Essure.

Bayer said extensive research by the company and independent medical researchers showed Essure was safe.

Women have claimed in lawsuits that Essure, which is implanted in a woman's fallopian tubes to permanently block the passage of eggs to the uterus, could pierce the tubes, and that metal parts of the device could become dislodged and migrate to other parts of the body, causing pain, injuries and severe bleeding.

They also claimed that the device failed to prevent unwanted pregnancies and led to nickel allergies and depression.

Bayer has been accused in lawsuits of knowing the risks associated with Essure and failing to warn sellers, doctors and regulators.

Marcus Susen, a Florida-based lawyer representing a number of women who have sued the company, called its decision long overdue, and said it would be up to a jury to decide if Bayer stopped the sale of Essure for commercial or safety reasons.

Bayer spokesman Steven Immergut said the company had sold roughly one million Essure devices worldwide since the product came on the market in 2002.

The majority of those sales were in the United States, he said, where the company has seen an average 40 percent annual sales decline in the device since its introduction.

In April, the FDA said some women were not being properly informed of the risks associated with Essure before getting

implanted and it limited its sale to healthcare facilities providing full information about its risks and benefits.

Bayer said in a statement that the decline in sales was due to an overall decrease of permanent contraception in the United States, a growing reliance on other birth control methods and “inaccurate and misleading publicity about the device.”