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Bayer's sale of its Contraception Device Essure Faces New FDA Restrictions

By Colette Gulick, J.D. Candidate 2018 | April 24, 2018

On April 9, the United States Food and Drug Administration placed restrictions on Bayer's implantable, contraception device Essure. The FDA's order specifies that Bayer must restrict the sale and distribution of its contraceptive implant to "only health care providers and facilities that provide information to the patient about the risks and benefits of this device." These new restrictions stem from a history of rising complaints that the agency has received about the device and the concern that women were not being apprised of its risks adequately.

Essure is a permanent, implantable birth control device made up of two small coils that operates via placement into the fallopian tubes to create scar tissue by triggering an inflammatory response. This resultant scar tissue created by the inflammatory response creates a physical barrier that isolates the eggs and prevents contact with sperm. Essure is a non-hormonal and non-surgical form of birth control. It is estimated that 750,000 Essure devices have been sold throughout the world with a majority of devices being sold in the United States.

In 2016, due to thousands of complaints regarding the use of the device, the FDA ordered Bayer to place the most serious health advisory warning on the label of Essure, warning that the device could cause certain injuries or health problems. The agency also ordered that Bayer conduct a new safety study. The concerns and complaints raised about the use of the device include depression, rash, hair loss, hives, fatigue, weight loss, perforation of the uterus or fallopian tubes, debilitating pain, and more. Many of the patients who complained suffered from more than one condition possibly caused by the device, and other serious problems reported include "deaths, pregnancy loss, and ectopic pregnancies." In 2017, the FDA received almost 12,000 medical reports related to Essure. In addition to complaints filed with the FDA, Bayer itself has received about 10,600 U.S. lawsuits alleging Bayer gave insufficient warning to providers and regulators regarding the risks of the device.

Under the FDA's order, before implantation of the device, an acceptance of risk form needs to contain the signatures of both the patient and the health care provider. The form can only be signed after the health care provider has discussed all the potential risks with the patient by reviewing a brochure together.

The burden lies with Bayer to ensure that medical providers follow the restrictions imposed by the FDA. If Bayer fails to implement the restrictions properly, and fails to ensure that physicians comply with the restrictions, the FDA has said that it will "take appropriate action against Bayer," which can include criminal and civil penalties.

Essure entered the market in 2002. After the FDA required the most serious warning label to be placed on Essure's box and ordered Bayer to conduct a new safety study in 2016, the sales of the contraceptive device have declined approximately 70% in the United States.

In light of these developments, Bayer maintains that the device's "benefit or risk profile has not changed."