Safety Concerns Arise Over FDA-Approved Medical Devices After Thousands Of Patient Complaints

Essure Risks Lead To New Legislation

(NAPSA)—Since being brought to market in 2002, over 10,000 complaints have been reported to the Food and Drug Administration (FDA) by women who have had Essure® coils placed for permanent birth control. The device became the standard of care for women no longer interested in conceiving children in recent years because it can be placed in a nonsurgical setting. To date, nearly 30,000 women have joined Essure Problems, an online support network for women who have been negatively affected by the device. The site lists over 100 side effects, including conditions related to gynecological, gastrointestinal and neurological systems, as well as autoimmune disorders.

There are more than 6,000 self-reported adverse events by medical professionals included in a June 2015 report from the FDA Manufacture and User Facility Device Experience (MAUDE) database showing that in addition to the device breaking, doctors need better training on placement and understanding the potential risks.

Republican Congressman Mike Fitzpatrick (Pennsylvania) and Democratic Congresswoman Louise Slaughter (New York) introduced new legislation aimed at strengthening the FDA's medical device review process and increasing accountability for dangerous products.

Ariel Grace's Law corrects an existing law that prevents thousands of people harmed by medical devices from having their voices heard in court. The Medical Device Guardians Act aims to reform the FDA process, adding doctors into the list of entities that are required to report unsafe devices.

Essure Coils Must Be Removed By A GYN Specialist

Women who experience negative reactions to Essure need to have the coils removed by a GYN specialist.

"Incorrect removal can cause permanent damage to reproductive organs," said Paul MacKoul, MD, The Center for Innovative GYN Care. "Depending on the location of the coils at the time of removal, it may be necessary to perform additional procedures."

Specialists and legislators have come up with ways to help women who've been harmed by a birth control device.

These procedures include hysterectomy (removal of the uterus), salpingectomy (removal of fallopian tubes) or salpingo-oophorectomy (removal of fallopian tubes and ovaries).

Having a laparoscopic hysterectomy, or other minimally invasive procedure performed by a GYN specialist who is familiar with the risks, is important for women who are planning legal action. The fallopian tubes, uterus and ovaries (depending on whether or not the tubes have migrated) need to be removed intact.

"For women who have been negatively affected by Essure, it is essential that the surgeon understand the protocol for removal of the organs so that they can be documented appropriately," said Natalya Danilyants, MD.

"We chose to only offer surgical sterilization procedures at our facility," said Dr. Paul MacKoul. "The goal is to reduce the overall risk, and our procedures are performed with 5mm incisions in an outpatient setting so patients go home the same day and are back at work in two days, without a high-risk device placed in their tubes."