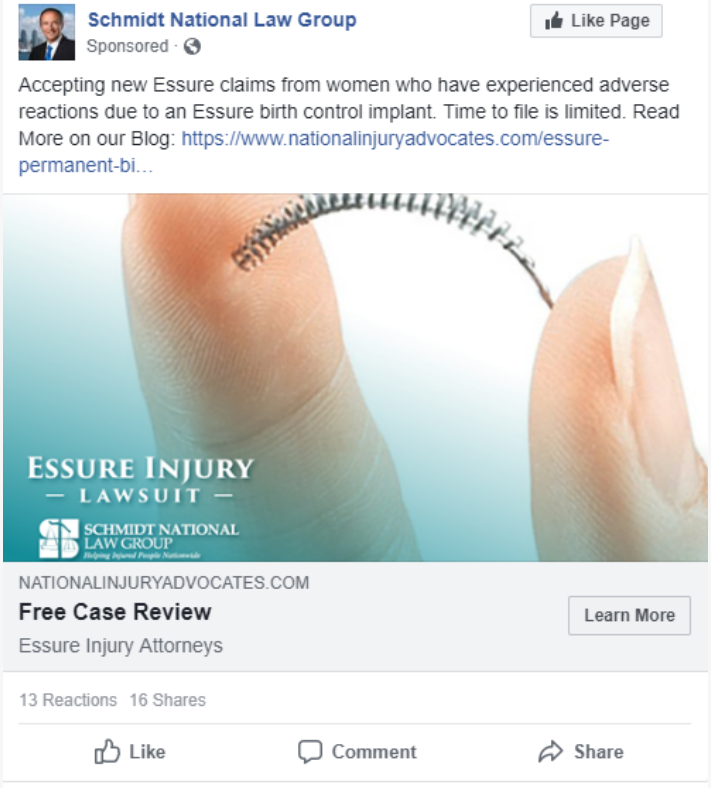
The FDA Moves to Restrict Sale of Bayer's Essure® Birth Control Device as Sales Continue to Decline

The FDA is taking this step after becoming aware that some women were not being adequately informed of Essure's risks before getting the device implanted



Essure on Facebook

SAN DIEGO, CALLIFORNIA, UNITED STATES, June 21, 2018 /EINPresswire.com/ -- Sales of Bayer's permanent birth control device Essure® are down 70 percent in the United States, according to the U.S. Food and Drug Administration (FDA). Those sales could continue to drop after the agency announced it would restrict sales of the device in the U.S.

The FDA announced in early April it would begin restricting sales of Essure® in the U.S. because women were still getting the potentially dangerous device without being fully informed of its risks.

"The FDA is aware that some women have received the Essure® device without being adequately informed of Essure's risks," reads the FDA's announcement on its website. The regulatory agency said it would restrict sales of Essure® to only those healthcare providers who agreed to review and sign a patient-doctor checklist before implanting the device.

The FDA required Bayer, the maker of Essure®, to provide a patient-doctor checklist in 2016 after thousands of complaints poured into the FDA's adverse events database regarding potential risks of the contraceptive device.

Risks of Essure® include severe abdominal pain, migration of the device, device breakage, perforation of organs by the device, and unintended pregnancy, among dozens of others.

On April 9, the FDA said only those healthcare providers who provide and sign the checklist will be able to sell Essure®.

"The FDA is taking this step after becoming aware that some women were not being adequately informed of Essure's risks before getting the device implanted, despite previous significant efforts to educate patients and doctors about the risks associated with this device," reads a press release issued by the FDA.

> The FDA doesn't provide any remedy whatsoever for the person who was harmed... The only person who can help them is an attorney experienced in dealing with potentially harmful medical devices."
>
> *Martin Schmidt*

These "significant efforts" included implementing the patient-doctor checklist and adding a Black Box Warning—the FDA's strongest warning short of a device recall—in 2016. The agency also required Bayer conduct post-market studies on Essure® to ensure the device was indeed as safe and effective as the manufacturer claimed.

According to the FDA, there has been about a 70 percent decline in sales of Essure® in the U.S. since the agency ordered the post-market studies and added the black box warning and patient-doctor checklist more than two years ago.

Will these sales decline even further when a new documentary about the unchecked power of the medical device industry and featuring Essure is available for millions of Americans to view this summer?

Attorney Martin Schmidt filed one of the first Essure® lawsuit in the state of California in 2015, spearheading the fight to get Bayer's permanent birth control device off the market. Schmidt says filing an Essure® lawsuit is the only way to hold Bayer accountable and to help women exposed to Essure's risks seek justice.

"The FDA doesn't provide any remedy whatsoever for the person who was harmed by a drug or medical device that failed. The only person who can really help them is a plaintiff attorney who is experienced in dealing with potentially harmful medical devices and drugs," says Schmidt.

Call Schmidt National Law Group toll free at 800-631-5656 or visit National Injury Advocates on the web.

About Schmidt National Law Group: In his 30 years as a trial attorney, Martin Schmidt has represented many victims of defective drugs as well as those injured by defective products and personal injury accidents. Martin Schmidt has been recognized as a leading personal injury attorney, having been chosen as one of the "Top 100 Trial Lawyers" for the state. Schmidt National Law Group is a personal injury firm located in San Diego, California, and its attorneys represent victims of all types of injuries.

Martin Schmidt
Schmidt National Law Group
800-631-5656
email us here
