‘Essure Problems’: A Contraceptive Device Creates an E-Sisterhood of Suffering

Women banded together to force a pharmaceutical company to reckon with the devastating side effects of its controversial product.

Since 2002, Essure has been marketed as a permanent birth control method for women that is convenient and can be performed in their own doctor’s office.

The procedure is simple: A 4-centimeter metal coil is inserted through the cervix and placed into each fallopian tube, where scar tissue builds and eventually blocks sperm from
reaching an egg. Resembling the spring of a ballpoint pen, the medical device requires no incision or invasive surgery, and offers women an alternative to a hysterectomy. Women can even go back to work the very next day. So far, the device remains the only FDA-approved, non-incisional form of permanent birth control.

But this July, Bayer Pharmaceuticals announced it would stop selling the device by the end of 2018, citing declining sales. However, the roughly 17,000 lawsuits filed against Bayer by women who have used Essure as well as a damning Netflix documentary that spotlighted the medical device industry may also have been factors.

A Facebook group, “Essure Problems,” a sisterhood of women sharing their experiences of debilitating pain and a diverse range of physical and emotional side effects, has grown to 38,000 members since Angie Firalino of Tannsersville, New York, first created it in 2011. Firalino suffers from an autoimmune disorder as a result of her Essure implant and wanted to warn her friends.

The group operates as an online support system for the self-styled “E-sisters” to educate one another on the risks, and also act as a resource for legal action. It shows women how to file an “adverse event report” to the FDA if they are experiencing negative side effects, as well as how to use social media to speak publicly about their experiences, contact their state representatives, and educate themselves regarding proper removal of the device.

“We’re still working on advocacy and supporting women,” says Amanda Rusmisell, the group’s legislative liaison. “We’re still very focused on holding Bayer accountable.”

Rusmisell’s doctor did not initially believe Essure was to blame for her symptoms. “They’ve done to you what they’ve done to women for thousands of years,” she says. “[They say] ‘You’re hysterical, you’re overacting … your body’s failing you.’”
Rusmisell was finally forced to undergo a hysterectomy after experiencing severe pain during the insertion procedure and for weeks afterward. After seeing a news story about other women reporting similar side effects, she discovered the Facebook group and immediately got involved. Rusmisell recalls saying to her husband, “I’m not the only one.”

“Something always compelled me to be in this movement,” she says. “You see all these women joining, and it’s the same story just different versions, over and over. It’s like waves.”

Rusmisell and her E-sisters have several major goals. They are seeking compensation for all the women who have been harmed by the device, and they are working to change federal and state laws regarding medical device approvals and regulation.

But most of all, they want Essure gone for good.

Attorney Marcus Susen decided to take up Essure cases after learning that many women had been struggling for years to find legal representation. He is the lead counsel of the Essure Plaintiffs Steering Committee that represents the common interests of all plaintiffs. He now represents about 2,000 women in a mass tort lawsuit against Bayer.

While individual plaintiffs can file a lawsuit based on a unique set of damages, a mass tort allows numerous plaintiffs to join forces to seek damages from a company when they have experienced similar injuries from the same product. “We want to get these women some compensation for what they’ve been through,” Susen says. “It’s solely against Bayer and Bayer entities.”

The April release of *The Bleeding Edge*, a Netflix documentary on the $400 billion medical device industry, helped raise the profile of Essure sufferers, and E-sisters have also traveled to Capitol Hill, lobbying Congress to back a bill that would offer stronger legal protections for women harmed by the device. That proposal, the Medical Device Safety Act, would essentially restore patients’ rights to pursue litigation. Due to FDA preemption, which bars lawsuits against certain medical devices, Bayer claims this makes the company *immune* to injury lawsuits. The proposal would change the law to make it
“retroactively effective and apply to pending civil actions.” But with the 115th Congress winding down its business before the midterms, the measure would likely have to be reintroduced in the next session.

Amanda Dykeman of Orion, Illinois, one of the administrators for the Facebook group, says it didn’t take long for her to realize she was not alone in her own suffering and contacted her state representatives to persuade them to help change the laws.

She told the Prospect that women are struggling to find physicians willing to remove the device because procedural protocol for removal is often unclear. Extracting the device without getting a full hysterectomy can be dangerous. Small fragments of the device could break off or migrate elsewhere in the body.

Oftentimes, women have difficulties convincing their doctors that they are having a serious problem, a disparity not uncommon in medicine in which women’s pain is dismissed or not taken seriously. “Hopefully, this is a game changer and lives are saved,” says Dykeman. “I think it’s pretty sad that [Bayer is] trying to discredit thousands and thousands of women. ... They’re just making themselves look unethical.”

In 2016, the FDA issued a black box warning—the agency’s strongest—about the device. In addition to the 26,733 complaints it received through the years, eight adult deaths have been reported. In September 2017, Bayer halted all international sales of Essure, but the medical device will remain available in the United States until the end of 2018.