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### When Birth Control Hurts You: An Essure Investigation

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## When Birth Control Hurts You

The FDA severely undercounts injuries related to Essure, according to victims and experts

By Mia Garchitorea

The Essure device is supposed to be an easy and safe way to prevent pregnancy. But that's often not the case.

Lisa Saenz endured cramps, chronic discomfort, and menstrual periods that lasted for as long as 15 days. She later discovered one of the Essure coils had perforated her uterus.

Janie Garcia had the Essure device implanted and then bled uncontrollably for six months. She tried to get the device removed, but a chunk of the metal and surgical clips were left inside her. The problem had to be resolved by removing the 31-year-old's uterus.

Cecilia Bogle's Essure coils broke into pieces when doctors tried to remove them after they perforated her uterus and migrated into her stomach. She now has about five and a half centimeters of metal still in her body.

They're not alone.

Thousands of women report having suffered from injuries and malfunctions related to Essure, including chronic pain, heavy bleeding, migration, or perforation. Many of these women also claim that Essure has caused nickel allergies, hair loss, bloating, rashes, unintended pregnancies, and death. What was promised to be an easy solution has become a life-altering problem.

As patient complaints have increased, experts have gone back and studied the science behind the approval of the Essure device. Their findings are startling: There were flaws with the studies that supported the Food and Drug Administration's approval of the device, the experts claim. Furthermore, the FDA, which is now puzzling out what to do about the problem, may be grossly underestimating the magnitude of the problem. In the meantime, doctors continue implanting the devices.

Dr. Charles Monteith of North Carolina has removed the Essure coils from about 250 women who reported complications. "We are running an uncontrolled trial on American women as a result of the decisions that were made when the device was approved," he said.

### **A Life-Altering Device**

Saenz felt immediate regret when she got Essure in 2008. Her lower abdomen twisted in pain as she walked out of Montefiore Centennial Women's Center in the Bronx.

“I thought to myself, ‘I shouldn’t have done this,’” she said.

The draw for Saenz was how convenient it was to get Essure.

Essure is a non-hormonal permanent birth control method that is not supposed to require any surgery or downtime. The product is essentially a metal coil that’s inserted into each of a woman’s two fallopian tubes. Scar tissue naturally forms around the coils until the tubes are completely closed off. When this happens, sperm can’t reach any eggs, making it impossible to get pregnant. It’s estimated that the device has been implanted about 750,000 times since it was approved in 2002.

Bayer stands behind its device and says patient safety is its top priority. “The safety and efficacy of Essure is supported by more than a decade of science and real world clinical experience,” said Tara DiFlumeri, the company spokeswoman.

Saenz said that a friend told her that getting Essure was so easy she could do it on her lunch break. As a social work intern, a part-time graduate student, and a working mother of three, she didn’t have time for a break. Unfortunately, from the day she had the device implanted, Saenz started suffering from extreme fatigue, constant cramps, and menstrual periods that lasted half a month. She later found out that one of the coils had perforated her uterus. The pain went on for two years until she had a hysterectomy.

Janie Garcia said getting Essure was more painful than naturally delivering her twins. She got the Essure coils in 2012 after deciding that it was considerably cheaper than a tubal ligation. Afterward she bled so heavily she had to change her pads every hour for six months. A year and many ER visits later, she decided to remove the device and her fallopian tubes. Five and half weeks later, she found out that a portion of Essure and surgical clips had been left behind inside of her. She had a hysterectomy but suffered from an infection and an inflammatory response from the PET fibers found in Essure. She even wore a drain bag to drain an abscess that developed.

"The pain, the agony, and the frustration...when you go to a doctor they make you feel you're an addict to pain pills or you're just crazy," she said.

Three months after Cecilia Bogle had the two metal coils inserted into her fallopian tubes she found out she was pregnant.

“Having made the decision to not have any more children and then to find out I was pregnant and having a child was very hard for me,” Bogle said.

She was also shocked to learn that the two coils, which were supposed to permanently prevent pregnancy, had dislodged from her tubes, perforated through her uterus, and migrated into her stomach.

Doctors tried to remove the coils after she delivered her daughter, Summer, but in the process, one of the coils broke into pieces. They removed only two and half centimeters of the first coil and couldn't find the second one. They decided to leave the rest inside of her body. She had multiple surgeries over the next few years. Her sex life with her husband was strained. And along the way, she developed a nickel allergy.

Because of the complications of Essure, she ended up getting a hysterectomy in hopes that her symptoms would subside. They didn't. To this day, she still has several centimeters of the two metal coils embedded somewhere in her ascending colon and lower abdomen. She continues to suffer from nausea, bloating, severe stomach, back and joint pain and migraines.

"I am in pain everyday. Some days are worse than others that have prevented me from being able to get up at times," she said.

Soon after Essure was introduced to the market, women started reporting problems. They found, in general, that their doctors were not responsive to their complaints. So they turned to each other for understanding, finding each other online and in 2011 starting the Essure Problems Facebook group. The group has now grown to almost 25,000 members, with dozens of posts and comments every day. They've developed their own lingo, calling themselves the "E-Sisters" and after they've had the devices removed saying they are "E-Free."

The Facebook group has also helped women quantify how many have reported problems with Essure. Bogle documents the group members' reported pregnancies and miscarriages. When women post these incidents to the Facebook group she jots them down into a database.

As of September, she tallied 650 pregnancies from the Facebook group. Of that total, 273 ended in miscarriage, 15 were ectopic pregnancies, and eight babies did not survive past the 24<sup>th</sup> week of pregnancy. The 177 live births were reported including eight sets of twins and one set of triplets. Eight abortions occurred "involving health related risks," she said. Forty-two of these pregnancies had an unknown outcome and 111 women were pregnant at that time.

Another of the members of the Facebook group, Krystal Donahue, co-authored a study that was published in *Pharmaceutical Medicine*. It outlined the number of voluntary Essure reports made over a seven-month period through the MedWatcher app, produced by Boston Children's Hospital and Epidemico. Out of the 1,349 submissions, 77% of women reported serious events, including hospitalization, disability, and permanent damage, the study found.

Donahue, 39, said she also suffered from the device. The Essure coils caused her extreme pain, heavy bleeding and a trip to the emergency room. "It felt like something was

stabbing me from my stomach to my lower back,” Donahue said. “I would stand up and it felt like something snapped.”

Essure made Donahue feel so lethargic that she would sleep for days on end. She stopped doing yoga, her favorite exercise, because of the abdominal pain. She couldn't spend quality time with her three children. She went back and forth between doctors for two years before finding one who could remove her coils. She had them removed on her 37<sup>th</sup> birthday.

“It was a birthday gift to myself,” Donahue said.

At 5:39 a.m. on Sept. 24, Donahue steered her blue Ford Flex through the mist of the Maryland White Marsh Mall parking lot. This was a day she and other members of the Essure Problems Facebook group had been demanding for a long time: The first hearing on Essure at the FDA headquarters in Silver Spring, Maryland. Donahue would be one of the women to speak. She felt a combination of stage fright, anger – and a concern that despite the hearing the agency wouldn't take any meaningful action to protect women.

The women who reported problems with Essure were demanding a ban on the device, and they even had some medical providers and researchers who shared their concerns about its safety. Hundreds of attendees, including physicians and women with Essure, came in from across the country to see what was to become of the potentially harmful permanent birth control.

On the way to the FDA hearing Donahue picked up fellow E-Sister and Syracuse resident, Sheila Pitt. She had Essure for nine years before experiencing hair loss and dementia-like symptoms. It was the first time they had ever met in person, but the two women embraced in the parking lot.

“I don't know if I have any tears left,” Pitt said.

Unlike most of the women at the FDA hearing, Donahue wasn't hopeful about whether the FDA was going to recall Essure. She was too realistic about the political realities that could keep the device on the market. A lot of powerful people are making a lot of money from the device, she said.

Inside, hundreds of people were gathered in a large conference hall. Two security guards and a long, red nylon rope separated the attendees from the FDA and Bayer panelists. The hearing began at 8 a.m. and for three hours, the FDA and Bayer representatives explained their findings from the pre- and post-approval studies conducted through Conceptus, the company that owned the device until Bayer acquired it in 2013.

By 11:10 a.m., speakers from the public could present their speeches. Donahue had practiced her speech for an hour the night before. She was supposed to speak third but the panel startled her by calling her second. As she spoke her breathing was irregular and her voice and body shook. She talked about the time when her pain was so sharp and intense

it caused her to spasm on a doctor's exam table, and how she suffered from abdominal pain, painful sex, extreme fatigue, joint pain, rashes, and abdominal swelling.

"I am not an extreme case," she told the panel. "I did not get pregnant, develop life-threatening complications, or get cancer. My coils did not migrate or perforate. I did, however, endure physical pain and mental anguish for two years after being implanted with Essure.

"Despite the thousands of women harmed and despite all the data presented here today, Bayer and the FDA have difficulty seeing the causal relationship between Essure and our health due to limited data."

Donahue took her seat to rigorous applause from those who sided with her. The faces of the Bayer and FDA officials did not register any response.

Many more women – 22 out of 43 speakers in all – testified at the hearing. Tears rolled down many of the attendees' faces as they presented their Essure experiences to the panel. One woman named Sharilyn Ervin told the panel that she experienced a loss of bowel control after getting implanted by Essure and was hospitalized for 17 weeks.

"My 12-year-old was my caretaker. She had no life at 12. She changed my diapers. She took me to the potty. She bathed me. She had no childhood. She would not leave my side for fear of death," she said.

The entire room of attendees broke out in audible sniffles. Even Dr. Cheryl Iglesia, the chair of the panel, shed a few tears.

Around 2 p.m., Donahue had to leave early to pick up her daughter from middle school. She said as she got into her car that she didn't think Essure would be recalled. There's just too many politics involved.

"I'm probably going to take a break from the Essure Problems Facebook page," she said.

Now, she says that she just wants to focus on her kids.

"I'm living my life. When I was sick, I put so much effort into the group. Now that I'm healthy, I'm putting my focus into my kids."

After the hearing, DiFlumeri, the Bayer spokeswoman, said that the company looks forward to working closely with the FDA as it considers how to proceed after the meeting. An FDA official said a public announcement is expected in February about action related to the meeting.

## **Incomplete Data**

The FDA approved the Essure device in 2002 based on the findings in two studies. But according to experts, both studies contained flaws that undermine their findings. For example, there wasn't consistent follow up with patients who dropped out of the studies, and there wasn't a control group.

One of the post-approval studies recruited 39 newly trained physicians to insert Essure coils. Conceptus, the company that owned Essure at the time, was supposed to enroll 800 women, but instead only enrolled 514, according to the FDA website.

There were no patient follow-ups other than a test three months after the insertion of the device to see if the coils had properly blocked the fallopian tubes.

The study results showed that 27 women experienced a total of 38 malfunctions. Nine of the cases dealt with a bent distal tip. The FDA website states that there were 13 adverse events that included perforation, pelvic pain, and bleeding. Conceptus did not consider these to be malfunctions.

Experts who have analyzed the two pre-approval studies said that they only tested for how well Essure could prevent pregnancies. They did not track possible complications related to the device. Since no pregnancies occurred during the study or at the five-year follow-up, the FDA deemed Essure as a success and approved it for the market.

Neither of the studies had a control group to compare the rate of complications with Essure and its surgical counterpart, the tubal ligation.

Dr. Charles Monteith, medical director of Personal Choice Tubal Reversal Center in North Carolina, said that using a small number of women with no high-risk health problems in a controlled setting could make a device seem great. But he points out that women who experienced complications during the study or dropped out altogether were excluded from the results.

Many women have traveled to Monteith's office in Raleigh, North Carolina, to have their Essures removed or reversed. He said that since 2008, women have requested to have their Essure coils removed because of complications they've experienced. Others want to get pregnant again.

Monteith said that the pre-approval studies for Essure only tested for pregnancy rates. Since no pregnancies occurred in the first study and at the five-year follow-up, Essure was deemed a successful preventative permanent birth control and was approved by the FDA. That means, however, that any complications that occurred after the five-year follow up were left unknown.

Dr. Sanket Dhruva of Yale University, who recently published a study on Essure, said that the studies excluded women who dropped out and there was no follow up with many more. Of the 745 women included in the studies that led to the approval of Essure, only 197 were followed after two years, he said. Without accounting for every person in the

studies, the medical community has a difficult time assessing the true risks and benefits associated with Essure, he said.

“Once enrolled, you always follow. That’s an obligation taught in medical school,” Dhruva said.

He points out that the two pre-approval studies should have had a control group in order to compare complication rates between Essure and a tubal ligation. An ideal study, Dhruva said, would take a tubal ligation group and an Essure group, follow them for at least five years, and compare the endpoint results (bleeding, unintended pregnancies, hysterectomies etc.).

The limited data on Essure’s effectiveness points to “inflated success rates and deflated failure rates,” said Yale researcher Aileen Gariepy, who worked on the study with Dhruva.

### **Tracking the Harm**

The FDA has been gathering reports about Essure-related problems for more than a decade through its Manufacturer and User Facility Device Experience database – MAUDE, for short.

Women have become pregnant and miscarried. Essure coils have perforated amniotic sacs and induced early labor. Two women died of blood clots, one after having a hysterectomy and the other after doctors attempted to insert her Essure coils.

Some of the MAUDE reports contain tragic narratives. According to a September 2015 report, a woman found out she was six weeks pregnant after she got her Essure implanted in 2012. Worried about the health of her baby, she consulted her doctor about the risks. She was told that the coils would “bend out of the way and they would not cause any harm to my pregnancy”.

At 22 weeks she got up to go the restroom and heard a loud popping sound, “like a balloon.” Water started trickling down her legs immediately afterwards. She went to the emergency room and found out that she was leaking amniotic fluid.

While in the ER, the doctors attempted to stitch her cervix closed, which is known as a cerclage procedure, to try to save the pregnancy.

The patient stated in the report that her doctor stopped the cerclage procedure when an Essure coil was found inside of her vaginal tract.

“What the (profanity) is an Essure coil doing in her vaginal tract?” the doctor reportedly said.

Apparently, the coil was never properly implanted in the fallopian tube and was floating around inside of her uterus during her entire pregnancy.

She had to deliver her baby on her own because she was too far along in the pregnancy. She delivered a baby, whom she and her husband named Daphne, and held her in their arms. Daphne died 15 minutes later.

“I had to bury my baby because of a coil,” the patient stated in the report. “I now suffer from PTSD because of the traumatizing nature in which this all happened.”

By the FDA’s count, between 2002 and May 2015 the MAUDE database contains 5,093 reported incidents related to the Essure device, including 11 deaths.

Many of the incidents are not investigated by Bayer or the FDA. If the patient or her physician doesn’t provide the actual coil, so it can be inspected, the cases are considered inconclusive. “It is not possible to determine if a device malfunctioned if the device is unavailable for inspection,” said DiFlumeri, the Bayer representative.

Physicians who support the Essure device downplay the complications and say they are often impossible to predict. “There are certain people that will have odd reactions to drugs or surgeries or an odd occurrence during surgery that’s not well documented,” said Dr. Cindy Basinski, an obstetrician-gynecologist in Indiana and Bayer consultant. “It doesn’t happen enough for us to understand how to predict it or even how to counsel patients about it.”

Basinski has performed over 1,100 Essure procedures at her practice in Newburgh, Indiana. She is paid \$35,364 by Bayer for Essure, according to ProPublica’s “Dollars for Docs”.

There are signs that the number of problems is actually much higher than what’s been reported by the FDA. A NYCity News Service analysis of the MAUDE reports found the number of reports has increased a great deal in recent months. Between June 2015 and November 2015 there were 4,042 reported injuries and 15 deaths related to Essure, the analysis found.

Dr. Julio Novoa, an obstetrician-gynecologist based in El Paso, Texas, spoke at the FDA hearing and said that the true number of adverse event reports could exceed over 25,000. He said that many women aren’t even aware of what the FDA MAUDE database is, so their complications potentially related to Essure won’t ever be reported.

Essure-related procedures to unblock or remove the fallopian tubes or remove the uterus now average over 100 cases per month, according to some estimates, he said at the meeting.

Novoa originally joined the Essure Problems Facebook group to defend Essure, but after three days of looking into the complaints, he changed his opinion.

“My change of heart happened very quickly.”

## **NEXT STEPS**

In June a new study was launched to investigate Essure’s effectiveness. The study enrolled 620 patients and will follow them for a decade. It also does not have a control group.

Proponents of Essure say the complaints should not undermine the device. Women should be aware of the risks and benefits of Essure and free to choose it, said Basinski. “My hope is that the FDA will support continued improvements in counseling to patients, that’s important,” she said.

The American Congress of Obstetricians and Gynecologists says there is a lack of evidence about Essure, and urged the FDA to obtain data about its safety that goes beyond anecdotal reports.

Meanwhile, there’s a push to ban the device. Rep. Mike Fitzpatrick, D-Penn., is leading a ban on Essure called the “E-Free Act.” The bill, introduced in November, would require the FDA to withdraw its approval for Essure. On Dec. 10, Fitzpatrick addressed Congress on behalf of the women harmed by Essure: “Their stories are real, their pain is real, and that their fight is real,” he said.