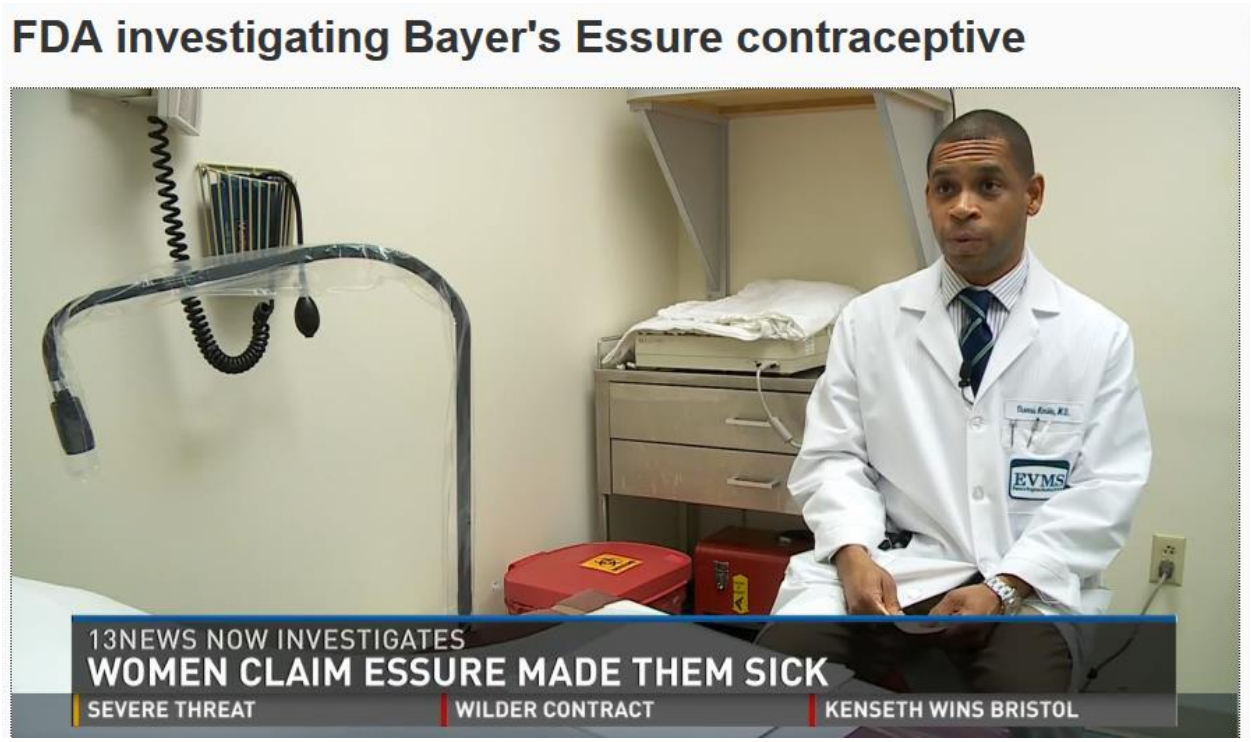
FDA investigating Bayer's Essure contraceptive

Women claim Essure made them sick

TV story contains interview with Thomas Kimble, MD. Original story found online at:
http://www.13newsnow.com/story/news/health/2015/04/20/fda-investigating-bayers-essure-contraceptive/26069323/

Lucy Bustamante, 13News Now 12:45 p.m. EDT June 26, 2015



(Photo: FDA)

CONNECTTWEETLINKEDIN 22 COMMENTEMAILMORE

NORFOLK, Va. (WVEC) -- The FDA has announced that it is having a meeting September 24 in front of the obstetrics and gynecology device panel.

They are inviting Essure victims to talk about their cases at that time. They are also posting all adverse events on their website. So far, they have posted that through May 2015 there have been more than 5,000 adverse events reported. They also highlight major adverse events like pregnancy, ectopic pregnancy, chronic pain, device migration, and nickel allergy rashes.

June Owens from Moyock, Wendi Headley from Chesapeake and Khristi Gurganus from Newport News hadn't met face-to-face, but they knew each other on social media and shared the same problem: they felt sick almost immediately after having Essure implanted.

They're among the 16,000 women on the Essure problems Facebook page talking about the problems they've had with the contraceptive.

They decided to talk with 13News Now, although Headley was hesitant because she didn't want people to see her teeth.

"I have black spots all along my teeth. I never imagined that at 31 years old, I was told I have to have dentures," she said.

Wendi is allergic to nickel, which is a main ingredient in Essure, according to Dr. Thomas Kimble at Eastern Virginia Medical School. He said he's not treating any of the women.

At the time Wendi had the device implanted, it wasn't marked for nickel allergies.

She says her teeth issue was just one of her symptoms. "I can feel it burning. I can feel it sizzling."

June, like Wendi, also reported excruciating pain.

"We all have what we call an Essure belly, where our stomach bloats," she says. "I was calling the ambulance to my house every single night. I was like what is wrong with me."

Khristi wondered the same thing when her doctor didn't implicate the device.

"The abdominal pain became chronic. My pain level was an 8 out of 10. I went back to the doctor. I was told that it couldn't be related to Essure because there are no side effects to Essure," Khristi said.

Khristi decided to check the Food and Drug Administration's webpage. She found about 850 women have reported problems with the product: everything from the coils puncturing their abdominal lining to failure in preventing pregnancy.

The device was first manufactured by the group Conceptus and pre-approved by the FDA before hitting the markets in 2002. In June 2014, Bayer bought Conceptus and has continued to manufacture and distribute Essure.Bayer Health Care. Bayer sent us a video statement. In it Edio Zampaglione, MD, FACOG, US Medical Affairs for Bayer Health Care, says he stands by the product's safety. Officials report 750,000 people have had it implanted to date with success.

However, after our affiliate ABC15 in Phoenix, Arizona interviewed a patient who claimed her Essure clinical trial documentation was falsified to make Essure look good in the face of the Food and Drug Administration, the FDA announced it was re-evaluating the clinical study.

One of the original testing sites was at the Jones Institute in Norfolk. EVMS was part of that five-year study. However, its number of participants is small. Only five women participated. Dr. David Archer reports all women reported 0 pregnancies after using. However, Dr. Thomas Kimble says he will be calling all five women to ensure they feel their results were accurately represented to the FDA by Conceptus.

Dr. Kimble will review the five patients followed here. Still, he says he reassures patients that Essure is a good product.

"In that study, there were no pregnancies reported. There was a low incidence of pain and bleeding and surgical complications that were reported," he notes.

He says out out of the dozens he's implanted, he's only removed one.

"This really has increased the opportunity for women to get contraception that is safe and easy has access to," he adds.

Owen, Headly and Gurganus are anxiously awaiting the re-evaluation.

"It's not a coincidence that there's more than 15,000 of us with the same side effects that we're dealing with everyday," Gurganus says.

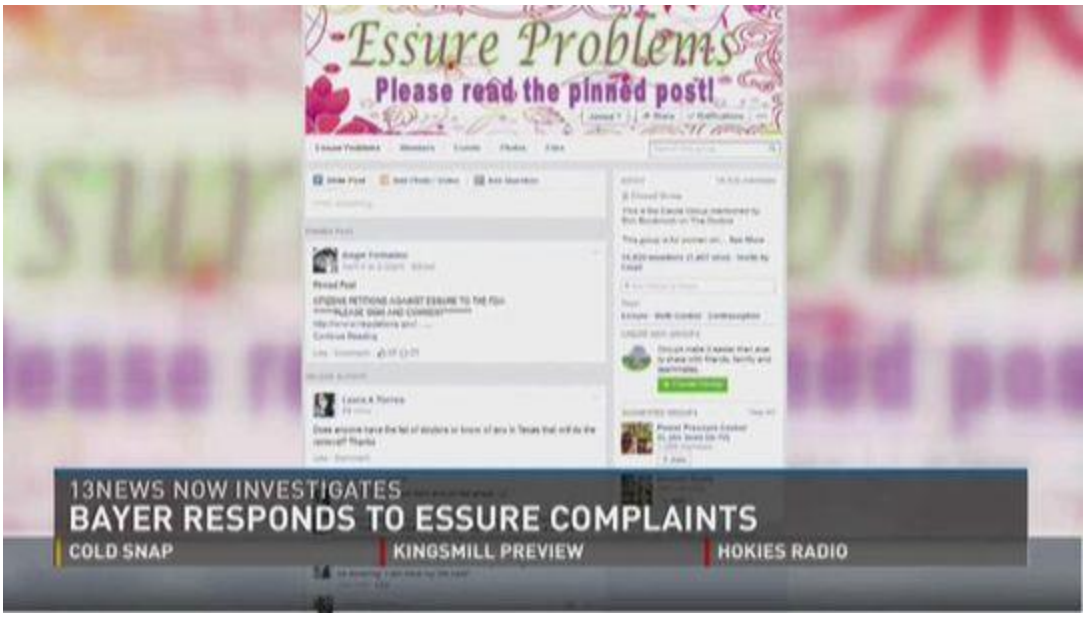
Khristi says it took two years of looking to find a doctor who would remove Essure through a full hysterectomy.

"I immediately woke up and felt better. The nurses were shocked at how well I was feeling after a full hysterectomy.
I said, 'You don't know the kind of pain I've been living in for the past two years.' I said 'this pain from the surgery is nothing compared to everyday pain that I've been dealing with,'" says Khristi.

Wendi also had a full hysterectomy and reported the same instant relief.

June is waiting on her insurance to kick in to have the surgery and hopes for the same outcome.

13News Now wanted more than Bayer's standard statement about their product. Officials agreed to do an interview Wednesday to talk more about the FDA's review. The results of that interview can be seen in the video below.



Bayer responds to Essure complaints

The entire raw interview with Bayer can be seen below. Due to technical issues, you can not hear Lucy's questions but we felt it was important to provide the response in its entirety.

Raw: Essure interview