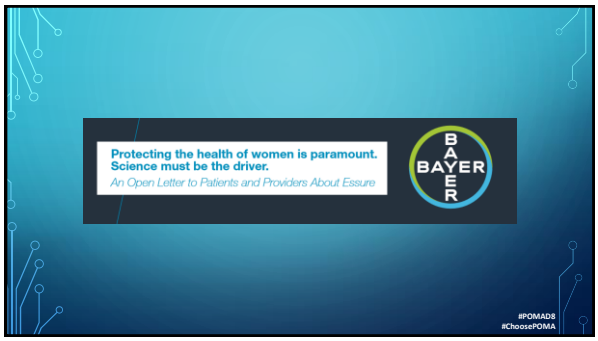
Protecting the health of women is paramount.
Science must be the driver.
An Open Letter to Patients and Providers About Essure
BAYER
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DISCLOSURES
• None
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ESSURE FAQS
1. Why did Bayer decide to stop the sales and distribution of Essure?
Bayer made a business decision to voluntarily discontinue sales and distribution of Essure in the United States after Dec. 31, 2018. This decision is based on a decline in U.S. sales of Essure in recent years and the conclusion that the Essure business is no longer sustainable. The benefit/risk profile for Essure has not changed, and we continue to stand behind the product's safety and efficacy, which are demonstrated by an extensive body of research, undertaken by Bayer and independent medical researchers, involving more than 200,000 women over the past two decades.
Several factors have contributed to declining patient interest in Essure in the U.S., including decreased use of permanent contraception overall, increased reliance on other birth control options such as long-acting reversible contraceptives (LARCs) and inaccurate and misleading publicity about the device.
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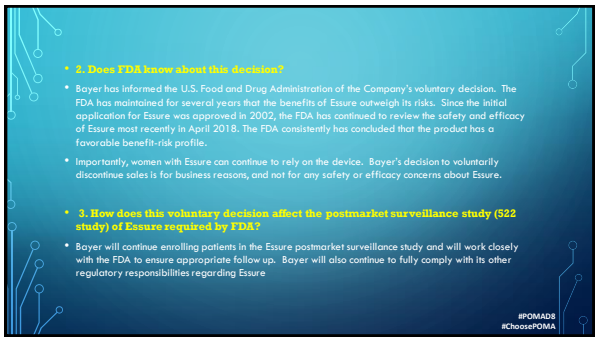
• 2. Does FDA know about this decision?
• Bayer has informed the U.S. Food and Drug Administration of the Company's voluntary decision. The FDA has maintained for several years that the benefits of Essure outweigh its risks. Since the initial application for Essure was approved in 2002, the FDA has continued to review the safety and efficacy of Essure most recently in April 2018. The FDA consistently has concluded that the product has a favorable benefit-risk profile.
• Importantly, women with Essure can continue to rely on the device. Bayer's decision to voluntarily discontinue sales is for business reasons, and not for any safety or efficacy concerns about Essure.
• 3. How does this voluntary decision affect the postmarket surveillance study (522 study) of Essure required by FDA?
• Bayer will continue enrolling patients in the Essure postmarket surveillance study and will work closely with the FDA to ensure appropriate follow up. Bayer will also continue to fully comply with its other regulatory responsibilities regarding Essure
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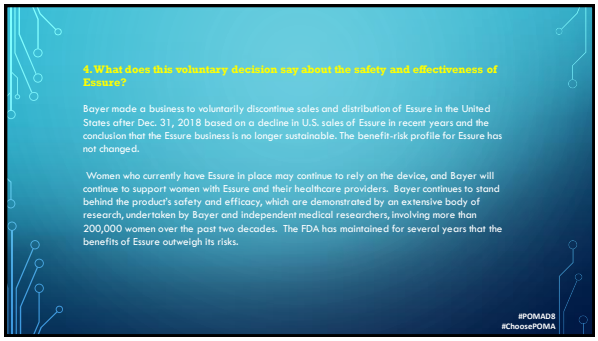
4. What does this voluntary decision say about the safety and effectiveness of Essure?
Bayer made a business to voluntarily discontinue sales and distribution of Essure in the United States after Dec. 31, 2018 based on a decline in U.S. sales of Essure in recent years and the conclusion that the Essure business is no longer sustainable. The benefit-risk profile for Essure has not changed.
Women who currently have Essure in place may continue to rely on the device, and Bayer will continue to support women with Essure and their healthcare providers. Bayer continues to stand behind the product's safety and efficacy, which are demonstrated by an extensive body of research, undertaken by Bayer and independent medical researchers, involving more than 200,000 women over the past two decades. The FDA has maintained for several years that the benefits of Essure outweigh its risks.
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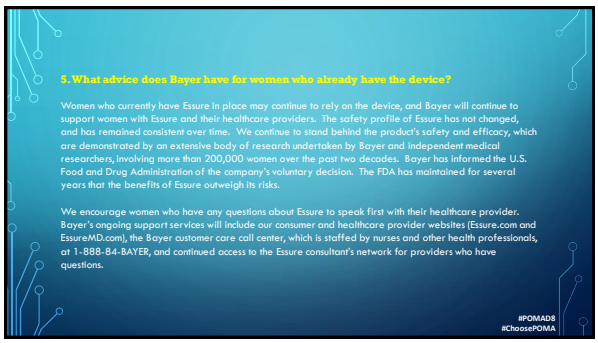
5. What advice does Bayer have for women who already have the device?
Women who currently have Essure in place may continue to rely on the device, and Bayer will continue to support women with Essure and their healthcare providers. The safety profile of Essure has not changed, and has remained consistent over time. We continue to stand behind the product's safety and efficacy, which are demonstrated by an extensive body of research undertaken by Bayer and independent medical researchers, involving more than 200,000 women over the past two decades. Bayer has informed the U.S. Food and Drug Administration of the company's voluntary decision. The FDA has maintained for several years that the benefits of Essure outweigh its risks.
We encourage women who have any questions about Essure to speak first with their healthcare provider. Bayer's ongoing support services will include our consumer and healthcare provider websites (Essure.com and EssureMD.com), the Bayer customer care call center, which is staffed by nurses and other health professionals, at 1-888-84-BAYER, and continued access to the Essure consultant's network for providers who have questions.
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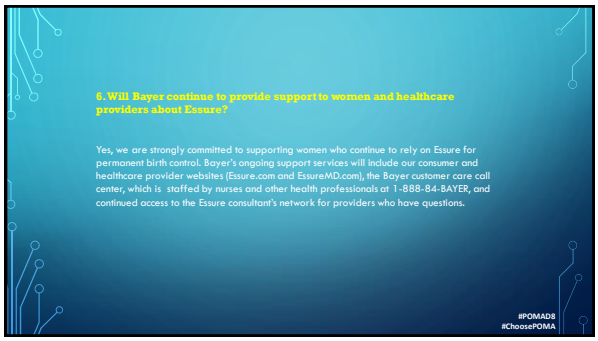
6. Will Bayer continue to provide support to women and healthcare providers about Essure?
Yes, we are strongly committed to supporting women who continue to rely on Essure for permanent birth control. Bayer's ongoing support services will include our consumer and healthcare provider websites (Essure.com and EssureMD.com), the Bayer customer care call center, which is staffed by nurses and other health professionals at 1-888-84-BAYER, and continued access to the Essure consultant's network for providers who have questions.
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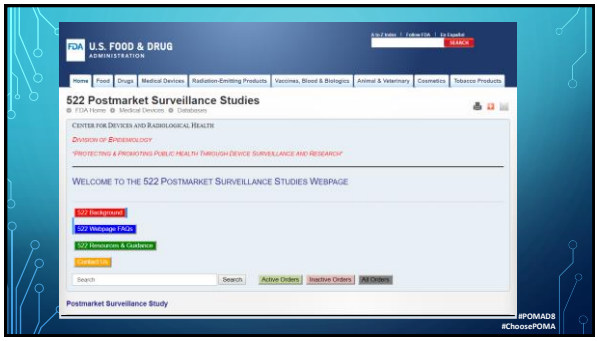
U.S. FOOD & DRUG
ADMINISTRATION
522 Postmarket Surveillance Studies
CENTER FOR DEVICES AND RADIOLOGICAL HEALTH
DIVISION OF EPIDEMIOLOGY
"PROTECTING & PROMOTING PUBLIC HEALTH THROUGH DEVICE SURVEILLANCE AND RESEARCH"
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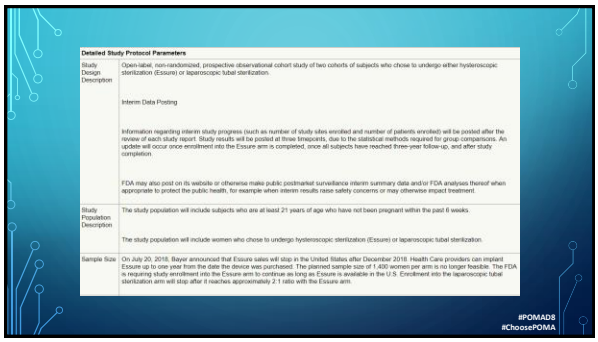
Detailed Study Protocol Parameters
Study Design Description
Open-label, non-randomized, prospective observational cohort study of two cohorts of subjects who chose to undergo either hysteroscopic sterilization (Essure) or laparoscopic tubal sterilization.
Interim Data Posting
Information regarding interim study progress (such as number of study sites enrolled and number of patients enrolled) will be posted after the review of each study report. Study results will be posted at three timepoints, due to the statistical methods required for group comparisons. An update will occur once enrollment into the Essure arm is completed, once all subjects have reached three-year follow-up, and after study completion.
FDA may also post on its website or otherwise make public postmarket surveillance interim summary data and/or FDA analyses thereof when appropriate to protect the public health, for example when interim results raise safety concerns or may otherwise impact treatment.
Study Population Description
The study population will include subjects who are at least 21 years of age who have not been pregnant within the past 6 weeks.
The study population will include women who chose to undergo hysteroscopic sterilization (Essure) or laparoscopic tubal sterilization.
Sample Size
On July 20, 2018, Bayer announced that Essure sales will stop in the United States after December 2018. Health Care providers can implant Essure up to one year from the date the device was purchased. The planned sample size of 1,400 women per arm is no longer feasible. The FDA is requiring study enrollment into the Essure arm to continue as long as Essure is available in the U.S. Enrollment into the laparoscopic tubal sterilization arm will stop after it reaches approximately 2:1 ratio with the Essure arm.
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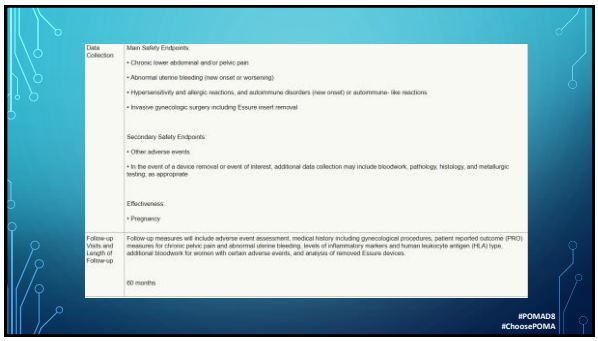

Data Collection	Main Safety Endpoints: • Chronic lower abdominal and/or pelvic pain • Abnormal uterine bleeding (new onset or worsening) • Hypersensitivity and allergic reactions, and autoimmune disorders (new onset) or autoimmune- like reactions • Invasive gynecologic surgery including Essure insert removal Secondary Safety Endpoints: • Other adverse events • In the event of a device removal or event of interest, additional data collection may include bloodwork, pathology, histology, and metallurgic testing, as appropriate Effectiveness: • Pregnancy
Follow-up Visits and Length of Follow-up	Follow-up measures will include adverse event assessment, medical history including gynecological procedures, patient reported outcome (PRO) measures for chronic pelvic pain and abnormal uterine bleeding, levels of inflammatory markers and human leukocyte antigen (HLA) type, additional bloodwork for women with certain adverse events, and analysis of removed Essure devices. 60 months

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