



Brief Summary of the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee Meeting – September 24, 2015

Introduction and Purpose of the Advisory Committee Meeting

The Obstetrics and Gynecology Devices Advisory Committee was convened on September 24, 2015 to hear expert scientific and clinical opinions on the benefits and risks of the Essure system, a form of permanent birth control (female sterilization), and to hear more from women who have used the device. Background material for this Committee meeting is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to September 24, 2015 for the advisory committee meeting link.

Summary

FDA Opening Remarks

Opening remarks were made by a representative from the FDA's Office of Women's Health.

Presentation by the Sponsor

Bayer HealthCare presented on several topics related to the Essure device, including the following:

- Essure product development and training
- Topics of interest regarding safety and effectiveness of Essure
- Real world experience of Essure, and the benefits and risks of Essure

Presentations by FDA staff

The FDA team presented information related to Essure, including summaries of the following:

- Pre-market review and clinical landscape
- Safety data pertaining to Essure, and
- Effectiveness data pertaining to Essure

Open Public Hearing (OPH)

Following presentations from Bayer HealthCare and the FDA, the panel heard presentations from Essure patients and family members, patient advocates, clinicians, non-profit organizations, and medical professional societies. A range of views on the benefits and risks of Essure were presented. Numerous patients spoke of adverse events experienced after having Essure implanted.

FDA Questions/Panel Deliberations

The panel was presented with six questions related to the safety and effectiveness of the Essure System. These questions were used to frame the panel's deliberations.

The panel was asked to discuss the clinical events that were presented and offer recommendations on ways to mitigate those potential risks. The panel discussed a range of events including persistent pain, perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, abnormal or irregular bleeding, allergy or hypersensitivity reaction, pregnancy and device removal

There was discussion of the desire to ensure that patients have access to health care services related to all steps of the Essure system, including access to confirmation tests and access to physicians trained in device removal. Support for informed decision-making by patients was another topic of interest. There was discussion of a need for better patient materials to support their decision-making process. Several recommendations for modifications to the patient labeling were provided by Committee members.

The Committee discussed the potential role and use of imaging modalities following device insertion to identify and/or evaluate certain adverse events. The panel discussed the need for additional physician training on topics including device removal and the situations in which the placement procedure should be aborted and alternative options pursued.

The panel expressed a general desire to see additional post-market data on the Essure system to better understand the adverse events that were discussed during the meeting. While it was suggested that a randomized controlled trial would be an ideal type of study, many panel members agreed that it would be impractical to conduct such a study at this point in time. It was suggested that ongoing trials be reviewed to determine if data could be collected to address some of the topics of concern. Several panelists suggested that a registry be considered to follow implanted patients and gather additional information related to the events discussed. The panel generally agreed that additional information regarding metal reactions/sensitivity is needed.

Finally, the panel discussed patient populations for whom the benefit-risk profile of Essure is acceptable and for those where it might be less favorable. The panel stated that hysteroscopic sterilization is an important option for women who are not good candidates for laparoscopic or general surgery (e.g., obese patients, patients who cannot tolerate general anesthesia) and who are well informed of the potential risks of the device. The panel suggested that patients with a known hypersensitivity to metal, autoimmune disease, history of pelvic inflammatory disease, and those with a history of abnormal uterine bleeding may be less suitable candidates for the Essure system.

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