215 Pennsylvania Avenue, SE • Washington, D.C. 20003 • 202/546-4996 • www.citizen.org

Essure Safety

Presentation by Sarah Sorscher, JD/MPH
Researcher, Public Citizen's Health Research Group,
before the Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee
September 24, 2015

(Slide 1)

Good morning, my name is Sarah Sorscher, I am a researcher with Public Citizen's Health Research Group.

(Slide 2)

Today's meeting was called in response to a large increase in adverse event reporting, driven largely by patients.[1,2] I won't dwell on these reports, because so many of those patients are here today.

(Slide 3)

Instead I will focus on safety issues in the two pre-market trials conducted by Conceptus, Essure's prior manufacturer.[3]

(Slide 4)

The total number of patients experiencing any adverse event related to pain in these trials was not reported. Pain severity was also not reported systematically.[4] Yet even these results show that nearly one in ten women experienced back pain in the first year, and severe pain occurred in at least a small but notable minority of women.[5]

---

[1] Food and Drug Administration. Essure Permanent Birth Control: FDA Activities. Last Updated 9/16/2015. http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm. Accessed September 20, 2015.

[2] Food and Drug Administration. FDA review document: Review of the Essure System for hysteroscopic sterilization. Prepared for the September 24, 2015 meeting of the Obstetrics and Gynecology Devices Advisory Panel. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM463486.pdf. Accessed September 22, 2015.

[3] *Ibid.* Page 11-12.

[4] *Ibid.* Page 44.

[5] *Ibid.* Page 44.

(Slide 5)

Strikingly, removal rates in the premarket trials were over 4 percent, and the main reasons for removal involved safety issues, including bleeding and pain.[6]

(Slide 6)

The manufacturer has made much of the apparently glowing patient satisfaction reports and lack of "persistent" pain in the 5-year follow-up study.[7]

(Slide 7)

Yet this extension study had many flaws. Endpoints involving "comfort wearing the device" and "satisfaction with the device," were vague and subject to biased interpretation.[8] The study was uncontrolled and severity of pain was not reported. Inexplicably, pain outside the pelvis, including low back and abdominal pain, was also not reported.[9,10] Finally, the definition of "persistent" pain — pain recorded at every visit — was too rigid, resulting in exclusion of patients with chronic, recurring pain.[11,12]

(Slide 8)

To illustrate some of these problems, I have data from a subject enrolled in the pivotal trial, Kim Hudak.[13] She is testifying today and has given permission to use her name.

(Slide 9)

Kim experienced long-term, debilitating pain and other symptoms that began soon after receiving the Essure implant and largely resolved after the device was removed via hysterectomy

---

[6] *Ibid.* Page 25.
[7] Chudnoff SG, Nichols JE, Levie M, Hysteroscopic Essure inserts for permanent contraception: extended follow-up results of a phase III multicenter international study. *J Minim Invasive Gynecol*. 2015;22(6):951-60.
[8] Food and Drug Administration. Essure Summary of Study Results extracted from PAS Study Status web page for the two PAS ordered in conjunction with original PMA approval. http://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/UCM452291.pdf. Accessed September 20, 2015.
[9] Chudnoff SG, Nichols JE, Levie M, Hysteroscopic Essure inserts for permanent contraception: extended follow-up results of a phase III multicenter international study. *J Minim Invasive Gynecol*. 2015;22(6):951-60.
[10] Food and Drug Administration. FDA review document: Review of the Essure System for hysteroscopic sterilization. Prepared for the September 24, 2015 meeting of the Obstetrics and Gynecology Devices Advisory Panel. Page 21. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM463486.pdf. Accessed September 22, 2015.
[11] *Ibid.*
[12] Chudnoff SG, Nichols JE, Levie M, Hysteroscopic Essure inserts for permanent contraception: extended follow-up results of a phase III multicenter international study. *J Minim Invasive Gynecol*. 2015;22(6):951-60.
[13] Conceptus medical forms: Kim Hudak. Data on file with author.

after the trial.[14] Kim reported this pain, yet her physicians insisted that it was unrelated to the device, and her forms were consistently marked with ratings of "excellent" and "very satisfied."

(Slide 10)

Here is a summary. Her comfort and satisfaction appeared uniformly high in spite of reports of severe pain. And because pain was not recorded at every visit, her long-term pain would not have been considered "persistent." Pain severity and other symptoms, such as 80-pound weight fluctuation, were not reported in published results.

(Slide 11)

Given this, can the Conceptus results be verified? Standard FDA records audits conducted prior to approval offer little insight,[15] as these would not have been designed to detect unrecorded symptoms or bias. Other "patient satisfaction studies identified by the FDA utilized similarly vague questions, and four were either funded by Conceptus or involved authors with declared conflicts of interest.[16,17,18,19]

(Slide 12)

The patient testimony today makes it clear that Kim's experience is not an isolated one. Yet even if such stories were rare, and we do not believe they are, a device that causes this level of debilitating long-term pain should not remain on the market.

Essure's benefits do not outweigh its risks, and it should be withdrawn.

---

[14] Email communication with Kim Hudak, September 21, 2015. Notes on file with author.
[15] FDA Review Document, Review of the Essure System for Hysteroscopic Sterilization. Prepared for the September 24, 2015 meeting of the Obstetrics and Gynecology Advisory Panel. Page 19. http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM463486.pdf. Accessed September 22, 2015.
[16] Grosdemouge I, Engrand JB, Dhainault C, et al. Essure implants for tubal sterilisation in France. Gynecologie, obstetrique & fertilite. 2009;37:389-395.
[17] Chudnoff SG, Nichols JE, Jr., Levie M. Hysteroscopic Essure Inserts for Permanent Contraception: Extended Follow-Up Results of a Phase III Multicenter International Study. Journal of minimally invasive gynecology. Apr 24 2015.
[18] Levie M, Weiss G, Kaiser B, Daif J, Chudnoff SG. Analysis of pain and satisfaction with office-based hysteroscopic sterilization. Fertility and sterility. 2010;94(4):1189-1194.
[19] Ploteau S, Haudebourg M, Philippe HJ, Lopes P. [Hysteroscopic sterilization among women older than forty years: what motivated the women?]. *Gynecologie, obstetrique & fertilite.* Oct 2009;37(10):775-779.