Essure Safety

Presentation by Sarah Sorscher, JD/MPH
Researcher, Public Citizen's Health Research Group

before the Ob/Gyn Devices Panel of the Medical Devices Advisory Committee

September 24, 2015

PUBLICCITIZEN

Adverse Event Reports

- 5,093 medical device reports
- Pain/abdominal pain (3,353)
- Menstrual irregularities (1,408)
- Headache (1,383)
- Fatigue (966)
- Weight fluctuations (936)
- Immunological reactions, device migration, breakage.
- 4 adult deaths

PUBLICCITIZEN

Safety Issues in the Conceptus Trials: Phase II Study, Pivotal Study

Pivotal Trial: Adverse Events at 1 Year

Adverse Events related to Pain	Number	Percent
Abdominal pain/abdominal cramps	18	3.8%
Back pain/low back pain	43	9.0%
Arm/leg pain	4	0.8%
Dysmenorrhea/menstrual cramps (severe)	14	2.9%
Pelvic/lower abdominal pain (severe)	12	2.5%
Dyspareunia	17	3.6%
Pain/discomfort - uncharacterized	14	2.9%

Device Removals: Phase II and Pivotal trial

- Device removals: 32 (4.7 %)
  - Unsatisfactory placement (9)
  - Abnormal bleeding (7)
  - Pain (5)
  - Heavy bleeding and pain (2)
  - Other (10)

5-year follow-up

- 99 % of women reported comfort wearing the device as “good” to “excellent”
- 97.9% of women reported overall satisfaction with the device as “somewhat satisfied” or “very satisfied”
- Zero “persistent” pain

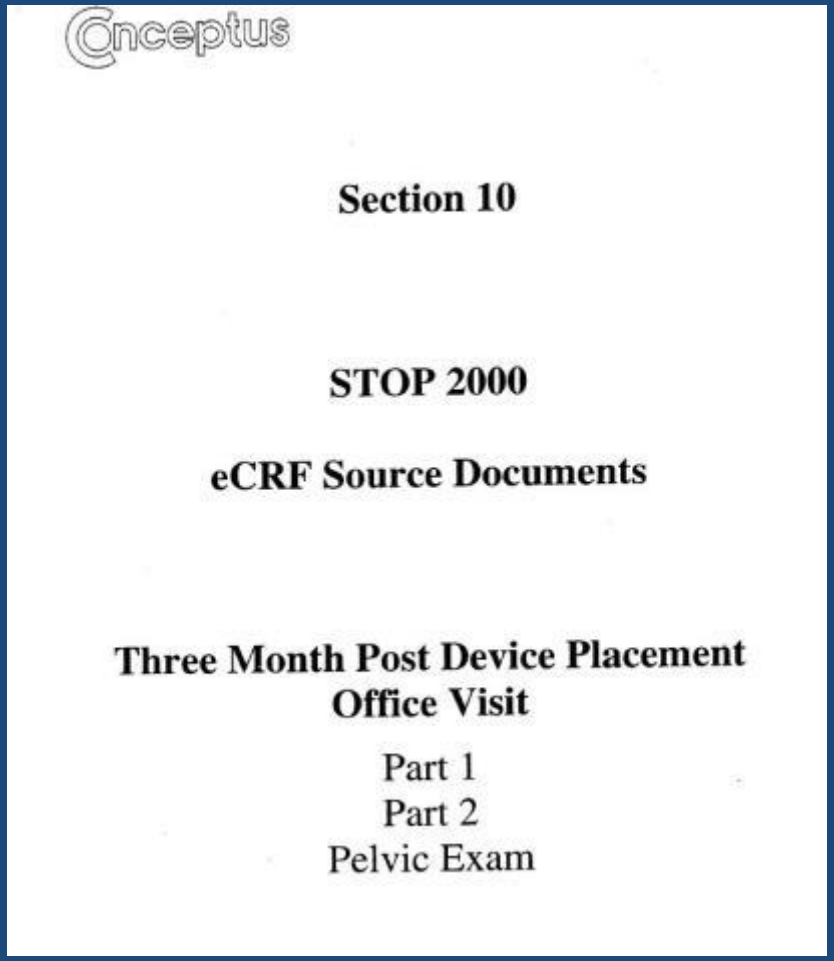
Source: Chudnoff SG, Nichols JE, Levie M, Hysteroscopic Essure inserts for permanent contraception: extended follow-up results of a Phase III multicenter international study. *Invasive Gynecol.* 2015.

PUBLICCITIZEN

Flaws in the Pivotal 5-Year Extension

- Poorly defined endpoints: comfort and satisfaction with the device
- Open-label, no control group
- Severity of pain not reported
- Non-pelvic pain (including low back pain) not reported
- “Persistent” pain defined narrowly as pain at *all* visits

Subject-Level Data: Kim Hudak*



Conceptus

Section 10

STOP 2000

eCRF Source Documents

Three Month Post Device Placement Office Visit

Part 1
Part 2
Pelvic Exam

* Name and medical information used with permission.

PUBLICCITIZEN

1-Year Visit

4. **Please describe the severity of the pain:** ☐ Mild ☐ Moderate ☒ Severe

Check ONE Answer – *Select the answer that best describes the patients pain*

5. **Please compare this pain to the pain the patient normally experiences during menses:**

Check ONE Answer - *Select the answer that best describes patients pain*

☐ Less ☐ Same ☐ A little more ☐ A lot more

☒ Pain is too different to compare, Please describe: nothing like pain during menses

8. **How does the patient rate the comfort of wearing the device:**

☒ Excellent ☐ Good ☐ Fair ☐ Very Good ☐ Poor

9. **How satisfied is the patient with the device overall ?**

☒ Very satisfied ☐ Neither satisfied or dissatisfied ☐ Somewhat dissatisfied

☐ Somewhat satisfied ☐ Very dissatisfied

PUBLICCITIZEN

Kim Hudak: Summary

Visit	Weight (lbs)	Narrative Adverse Event reported	Unusual pain?	Severity of pain	Pain location	Comfort wearing the device	Overall Satisfaction
Post-Placement Visit	160	pelvic cramping, pain, yeast infection, low back pain	no	-	-	Excellent	Very Satisfied
3 month	-	sore breasts, pelvic cramping	yes	mild	other	Excellent	Very Satisfied
6 month	-	-	no	-	-	Excellent	Very Satisfied
1 year	172	-	yes	severe	other	Excellent	Very Satisfied
1.5 year	-	-	yes	severe	other	Excellent	Very Satisfied
2 year	202	-	yes	severe	other	Excellent	Very Satisfied
3 year	-	-	no	-		Excellent	Very Satisfied
4 year	-	-	yes	severe	other	Excellent	Very Satisfied
5 year	240	-	yes	moderate	pelvic	Excellent	Very Satisfied
6 year	-	-	no	-		Excellent	Very Satisfied
7 year	190	amenorrhea, worsening PMS, MRSA, rash and generalized skin sensitivities, chronic pelvic pain, dyspareunia	yes	mild	pelvic	Excellent	Very Satisfied

Patient Satisfaction Evidence: Verifiable?

- Inspections are non-informative: Inspections of records carried out prior to any complaints would not detect unrecorded symptoms or biased interpretation of survey questions
- Other studies involving “patient satisfaction” also vaguely worded, some involved conflicts of interest:
  - Grosdemouge 2009 – Conceptus Funded
  - Chudnoff 2015 – Conceptus Funded (5-year follow-up to pivotal trial)
  - Levie 2010 – Lead author served on medical advisory board of Conceptus
  - Ploteau 2009 – Unspecified conflict of interest declared

Overall Risk-Benefit Profile

A device that causes debilitating, long-term pain should not remain on the market when other contraceptive methods are available.