Testimony Before the FDA's Obstetrics and Gynecology Devices Panel - Surgical Mesh for Transvaginal Repair of Pelvic Organ Prolapse in the Anterior Vaginal Compartment: *Removal of These Products from the Market is Long Overdue*

February 12, 2019

Michael Carome, M.D.
Director, Public Citizen's Health Research Group

(I have no financial conflicts of interest)

Public Citizen's Petition to the FDA

- In 2011 Public Citizen petitioned the FDA to ban and recall all non-absorbable surgical mesh products labeled for transvaginal repair of pelvic organ prolapse (POP) because these devices offer no clinically significant benefits in comparison with non-mesh repair of POP and have high rates of serious complications.
- The agency denied our petition in 2014.

Fundamental Deficiencies in FDA's Oversight of Medical Devices

- **Surgical mesh for transvaginal POP repair is a quintessential example of the fundamental deficiencies in the FDA's oversight of medical devices, particularly those that are permanently implanted.**
  - **2002-2011: Dozens of such mesh products were cleared for marketing under the 510(k) process without clinical testing**
  - **2011: FDA concluded that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare" [emphasis in original] and that it was "not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair."**
  - **2014: Proposed reclassification order, finalized 2016**
  - **2019: POP mesh products still marketed**

Transvaginal Mesh for POP: Benefit Assessment

- The assessment of the benefits of surgical POP repair procedures necessarily must focus on symptom relief rather than anatomic outcomes.
- The use of mesh in general does not provide better outcomes in terms of relief of prolapse symptoms and quality-of-life measures.
- The FDA stated that “when considering reoperation for either prolapse recurrence or mesh erosion/exposure, mesh patients had greater odds of reoperation.”

Transvaginal Mesh for POP: Risk Assessment

- **Mesh erosion, exposure, and/or extrusion are common significant adverse effects unique to the use of mesh in transvaginal POP repair in the anterior vaginal compartment, occurring in 3 to 15 percent of patients in the first three to five years post-surgery.**

Transvaginal Mesh for POP: Risk Assessment – FDA's Assessment

- "The FDA believes that the risk profile of surgical mesh placed in the anterior vaginal compartment is greater than that of native tissue repair. This is because mesh erosion/exposure, which can be serious and potentially debilitating, is associated only with surgical mesh and not native tissue repair. Management of mesh erosion may not be uncomplicated, may require multiple additional surgeries to address, and may remain unresolved despite treatment." [Emphasis added]

Transvaginal Mesh for POP: Risk Assessment – MAUDE Data

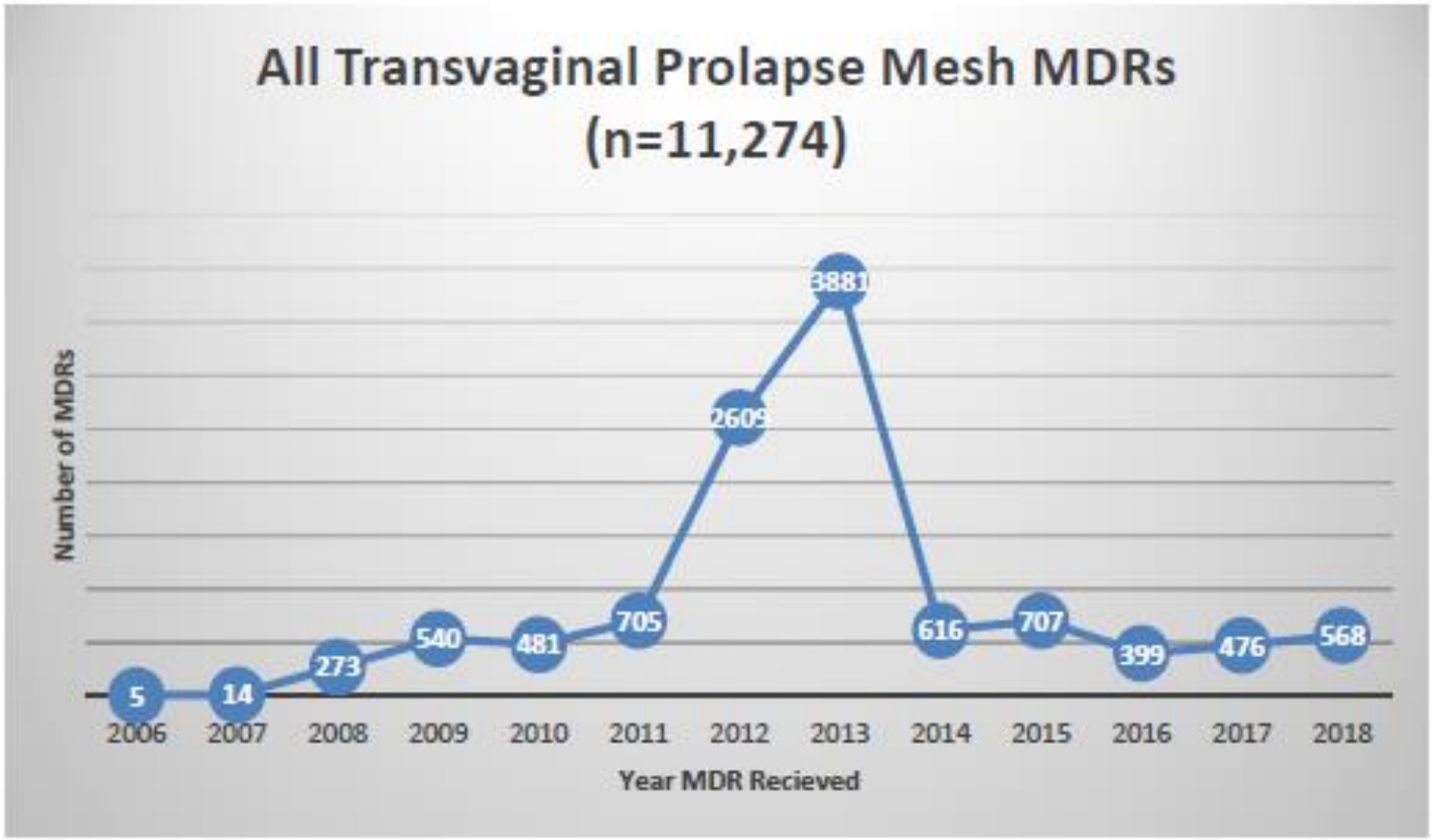

Figure 6 – *MDRs per year from January 2008 to October 2018.*

Transvaginal Mesh for POP: Risk Assessment – MAUDE Data

	Patient Problem	Count
1	Pain	3717
2	Erosion/Exposure	3509
3	Infection	1794
4	Injury	1701
5	Incontinence	814
6	Scar Tissue	761
7	Bleeding	475
8	Infection, Urinary Tract	371
9	Disability	339
10	Neurological Deficit/Dysfunction	272

Table 1 – *Top 10 patient problems for MDRs received from January 2008 to October 2018.*

Conclusions

Because of the FDA's recklessly inadequate actions regarding surgical mesh for transvaginal POP repair over nearly a decade, thousands of women have been unnecessarily harmed, many permanently. To prevent further harm to women, Public Citizen urges the FDA to reject the PMAs submitted for the three mesh products still on the market, thus effectively banning them.