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

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February 12, 2019**

I am Dr. Michael Carome, Director of Public Citizen’s Health Research Group. Public Citizen and I have no financial conflicts of interest.

In 2011 Public Citizen petitioned the Food and Drug Administration (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.¹ The agency denied our petition in 2014.²

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. From 2002 to 2011, dozens of such mesh products were cleared for marketing under the 510(k) process without clinical testing. By 2011, after thousands of women had been injured by these devices, the FDA had 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.”³ In May 2014 — nearly five years ago — the FDA issued a proposed order to reclassify these mesh products as class III devices, based in part on this panel’s conclusion that “a favorable benefit-risk profile for surgical mesh used for transvaginal POP repair has not been well established.”⁴ That order was finalized in January 2016.⁵ Nevertheless, the agency allowed these

¹ Public Citizen. Petition to ban the marketing of all currently available non-absorbable surgical mesh products specifically designed and labeled for transvaginal repair of pelvic organ prolapse. August 25, 2011. https://www.citizen.org/sites/default/files/petition_to_ban_surgical_mesh_for_transvaginal_repair_of_pelvic_organ_prolapse.pdf. Accessed February 9, 2019.

² Food and Drug Administration. Citizen Petition Denial Response from FDA CDRH to Public Citizen’s Health Research Group. May 1, 2014. <https://www.regulations.gov/document?D=FDA-2011-P-0641-0007>. Accessed February 9, 2019.

³ Food and Drug Administration. UPDATE on serious complications associated with transvaginal placement of surgical mesh for pelvic organ prolapse: FDA safety communication. July 13, 2011. <https://wayback.archive-it.org/7993/20170406003155/https://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>. Accessed February 9, 2019.

⁴ 79 FR 24634-24642.

⁵ 81 FR 354-361.

mesh products to remain on the market pending submission of premarket approval applications (PMAs), resulting in avoidable harm to many more women.

Benefit Assessment

Most women who have POP are asymptomatic and do not require treatment. For symptomatic women with this non-life-threatening condition, the goal of treatment is symptom relief. Thus, the assessment of the benefits of surgical POP repair procedures necessarily must focus on symptom relief rather than anatomic outcomes. We disagree with the FDA that “a combination of objective and subjective outcomes...is needed to adequately evaluate the effectiveness of surgical mesh placed in the anterior vaginal compartment against native tissue [POP] repair.”⁶

The FDA's review of the scientific literature reveals that although transvaginal POP repair in the anterior vaginal compartment with mesh results in lower rates of objectively documented prolapse in comparison with non-mesh procedures, the use of mesh in general does not provide better outcomes in terms of relief of prolapse symptoms and quality-of-life measures.⁷ Importantly, the FDA also stated that “when considering reoperation for either prolapse recurrence or mesh erosion/exposure, mesh patients had greater odds of reoperation.”⁸

Of note, the 522 clinical studies evaluating Boston Scientific's Uphold LITE and Xenform transvaginal mesh products — which were nonrandomized and unblinded, increasing the likelihood of bias — revealed that use of these products did not result in better subjective success rates than native tissue repair at one, two, and three years.⁹

Risk Assessment

On the other hand, a review of the scientific literature demonstrates that use of mesh leads to a high rate of serious complications, many of which require additional surgical intervention and some of which are not amenable to surgical correction and result in permanent life-altering harm to women.

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 three to

⁶ Food and Drug Administration. Surgical mesh for transvaginal repair of pelvic organ prolapse in the anterior vaginal compartment – FDA executive summary. Obstetrics and Gynecology Devices Panel. February 12, 2019. <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM630949.pdf>. Accessed February 9, 2019. Page 15.

⁷ *Ibid.* Pages 15-17.

⁸ *Ibid.* Page 17.

⁹ Boston Scientific Corporation. Uphold LITE Vaginal Support System (P180018) and Xenform Soft Tissue Repair System (P180021); prepared for Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee: Transvaginal mesh for anterior prolapse repair. February 12, 2019. <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM630952.pdf>. Accessed February 9, 2019. Pages 12-13.

15 percent of patients in the first three to five years post-surgery.¹⁰ The FDA highlighted the following regarding this adverse effect:

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.**¹¹ [Emphasis added]

The FDA's search of the MAUDE database also documented 11,274 reports over the past decade for all transvaginal POP mesh products, including 10,391 reports of serious injury and 77 reports of death (see figure below).¹²

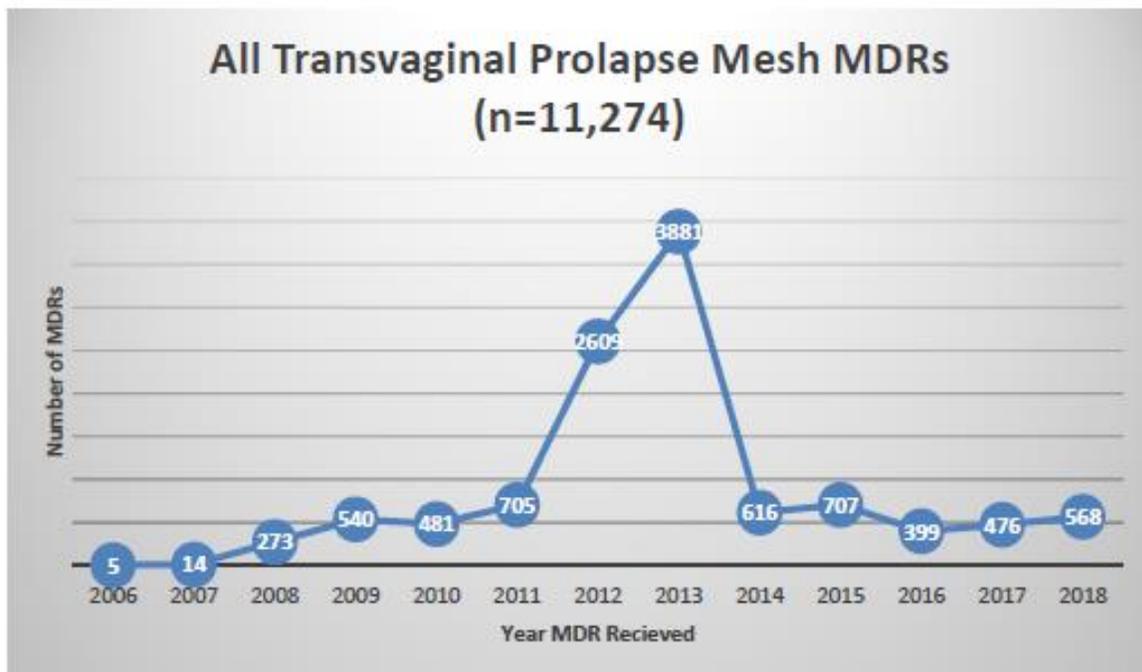


Figure 6 – MDRs per year from January 2008 to October 2018.

¹⁰ Food and Drug Administration. Surgical mesh for transvaginal repair of pelvic organ prolapse in the anterior vaginal compartment – FDA executive summary. Obstetrics and Gynecology Devices Panel. February 12, 2019. <https://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM630949.pdf>. Accessed February 9, 2019. Page 19.

¹¹ *Ibid.* Page 18.

¹² *Ibid.* Pages 25-26.

The top ten problems from the reports are listed in the table below.¹³

	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.

Many of these same adverse events also were reported for Boston Scientific's Uphold LITE and Xenform and Coloplast's Restorelle DirectFix Anterior transvaginal mesh products.¹⁴

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.

¹³ *Ibid.* Page 26.

¹⁴ *Ibid.* Pages 65-66.