

**Testimony to the FDA's Obstetrics and Gynecology Devices Panel of the  
Medical Devices Advisory Committee Regarding Non-Absorbable Synthetic  
Surgical Mesh for Transvaginal Repair of Pelvic Organ Prolapse**

**Michael A. Carome, M.D., and Sidney Wolfe, M.D., Public Citizen's Health Research Group  
Daniel S. Elliott, M.D., College of Medicine, Mayo Clinic  
L. Lewis Wall, M.D., D. Phil., M.Bioeth., School of Medicine, Washington University**

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My name is Dr. Michael Carome, Deputy Director of Public Citizen's Health Research Group. I am testifying on behalf of myself; Dr. Sidney Wolfe, Director of Public Citizen's Health Research Group; Dr. Daniel Elliott, a urologic surgeon specializing in female urology and pelvic organ prolapse (POP) at the Mayo Clinic; and Dr. L. Lewis Wall, Professor of Obstetrics and Gynecology and Professor of Anthropology at Washington University. We have no financial conflicts of interest related to the specific products being discussed today. Dr. Elliott is a paid consultant for Coloplast, serving as a resource for physicians trying to learn about the company's male incontinence sling (approximate income \$2000/year).

**Public Citizen's petition to ban non-absorbable surgical mesh for transvaginal POP repair**

On August 25, 2011, we petitioned the Food and Drug Administration (FDA) to immediately:<sup>1</sup>

- (1) ban the marketing of all currently available non-absorbable surgical mesh products specifically designed and labeled for transvaginal repair of POP because these devices (a) offer no clinically significant benefits in comparison to surgical repairs for POP performed without placement of surgical mesh; and (b) have high rates of serious complications;
- (2) order all manufacturers of these mesh products to recall them; and
- (3) require that any such mesh product that is proposed for marketing in the future be classified as a class III device and be approved for marketing only under a premarket approval application (PMA) that includes data from well-designed, prospective clinical trials that provide a reasonable assurance that the surgical mesh product is safe and effective.

**No clinically significant benefits are provided by non-absorbable surgical mesh for transvaginal POP repair in comparison to surgery without mesh**

Most women who have POP on pelvic examination are asymptomatic and do not require any treatment. For symptomatic women with POP, the goal of treatment is relief of symptoms. Therefore, the assessment of the benefits of surgical procedures for transvaginal POP repair necessarily must focus on symptom relief rather than anatomic outcomes.

A review of the scientific literature reveals that while transvaginal POP repair with mesh appears to result in less prolapse being detected on pelvic examination following surgery in comparison to non-mesh repair procedures, the use of mesh does not provide any better outcomes in terms of relief of symptoms and quality of life measures, which ultimately are the clinically significant indicators for measuring treatment success for this condition.

## **Safety assessment: the use of surgical mesh for transvaginal POP repair commonly causes serious complications, some of which are not seen in surgery without mesh**

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. These complications include:

- Mesh erosions (the most common complication, occurring in approximately 10% of patients)
- De novo urinary incontinence
- Dyspareunia and other types of pain
- Mesh contractions
- Intraoperative visceral injuries, including bladder perforations, ureteral injuries, and rectal injuries
- Infections, including pelvic abscesses
- Vesicovaginal and rectovaginal fistulae

The FDA, based on a review of medical device reports submitted to the agency reported that serious complications associated with surgical mesh for transvaginal repair of POP “are **not rare.**”

## **Overall risk-benefit assessment for transvaginal repair of POP with placement of non-absorbable surgical mesh**

Given the absence of evidence for clinically significant benefit and the overwhelming evidence of very serious, common risks, use of synthetic surgical mesh products for transvaginal repair of POP is not ethically justifiable.

## **Failure of the 510(k) process to ensure that non-absorbable surgical mesh for POP repair is safe and effective**

The experience with surgical mesh products for transvaginal POP repair provides a “poster-child” example of the fundamental failure of the 510(k) premarket notification process to protect the public’s health and welfare. Multiple mesh devices specifically designed for transvaginal POP repair were allowed by the FDA to come onto the U.S. market, based only on in vitro and animal testing data and a determination of substantial equivalence to other surgical mesh products already on the market. Despite a complete lack of clinical data demonstrating that invasive mesh devices were reasonably safe and effective for transvaginal repair of POP, these devices have been heavily promoted by industry and their highly paid physician consultants. As a result, tens of thousands of women have been seriously harmed, many permanently.

## **Excerpts from statement by co-petitioner Dr. Daniel Elliott<sup>2</sup>**

As a urologic surgeon specializing in female urology and [POP] at the Mayo Clinic, I have refused to use any transvaginal mesh kits for POP. But I am in direct daily contact with referral patients who have been previously treated with them. As a result, I am fully aware of the complications, the management of complications, and their potentially lifelong ramifications...

...The end result is oftentimes physically and psychologically devastating for the unsuspecting patient. Additionally, vast amounts of medical dollars are wasted on these

trocac-mesh kits, through repeat physician office visits for complications, and through repeat surgical repairs.

### **Excerpts from statement by co-petitioner Dr. L. Lewis Wall<sup>3</sup>**

Once a device has been approved for release into the marketplace by the FDA, device manufacturers will do everything they can to sell as many devices as possible, irrespective of whether or not the use of such devices is truly in the best interests of patients... Under these circumstances, the interests of patients are subordinated to the profit motive and the interests of company shareholders.

The Institute of Medicine has recently declared that the current 510(k) premarket notification process for medical devices...is fatally flawed. As presently structured, the 510(k) process cannot meet its stated goal and cannot ensure that non-absorbable mesh implants for transvaginal repair of POP are both safe and effective. Indeed, there is substantial evidence that such mesh is neither safer nor more effective than traditional native tissue repair operations for these conditions, without the use of synthetic mesh, and that the use of such mesh is associated with serious and sometimes irreversible harm to the patients in whom it is used. I commonly see patients who have been harmed by these mesh products in my own clinical practice.

### **Conclusion**

We endorse the FDA's belated proposal to reclassify non-absorbable surgical mesh products specifically designed and labeled for transvaginal repair of POP to class III and require PMA evaluations, but this action alone is insufficient. To properly protect the public health, the FDA also must immediately (1) ban all such mesh products currently available, and (2) require manufacturers to recall these dangerous and ineffective devices. A grace period allowing continued marketing of these devices would recklessly endanger women. Further clinical trials with current devices, as requested by the FDA, would be highly unethical.

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<sup>1</sup> Carome MA, Wolfe SM, Elliott DS, Wall LL. Petition to the FDA to ban non-absorbable surgical mesh products designed and labeled for transvaginal repair of pelvic organ prolapse. August 25, 2011. Available at [http://www.citizen.org/documents/Petition\\_to\\_Ban\\_Surgical\\_Mesh\\_for\\_Transvaginal\\_Repair\\_of\\_Pelvic\\_Organ\\_Prolapse.pdf](http://www.citizen.org/documents/Petition_to_Ban_Surgical_Mesh_for_Transvaginal_Repair_of_Pelvic_Organ_Prolapse.pdf). Accessed September 6, 2011.

<sup>2</sup> Elliott DS. Statement supporting Public Citizen's August 25, 2011 petition to the FDA to ban non-absorbable surgical mesh products designed and labeled for transvaginal repair of pelvic organ prolapse. August 19, 2011. Available at [http://www.citizen.org/documents/1963-Elliott\\_statement\\_in\\_support\\_of\\_HRG\\_petition.pdf](http://www.citizen.org/documents/1963-Elliott_statement_in_support_of_HRG_petition.pdf). Accessed September 6, 2011.

<sup>3</sup> Wall LL. Statement supporting Public Citizen's August 25, 2011 petition to the FDA to ban non-absorbable surgical mesh products designed and labeled for transvaginal repair of pelvic organ prolapse. Available at [http://www.citizen.org/documents/wall\\_statement\\_on\\_POP\\_mesh\\_petition.pdf](http://www.citizen.org/documents/wall_statement_on_POP_mesh_petition.pdf). Accessed September 6, 2011.