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POLICY & ACTION FROM CONSUMER REPORTS

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: [Docket No. FDA-2014-N-0297] Reclassification of Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair and Surgical Instrumentation for Urogynecologic Surgical Mesh Procedures and [Docket No. FDA–2014–N–0298] Effective Date of Requirement for Premarket Approval for Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair

To Whom It May Concern:

Consumers Union (CU), the policy and advocacy division of Consumer Reports, and the advocates in CU's patient safety network listed below, strongly supports the proposed order to change the classification for surgical mesh used to repair transvaginal Pelvic Organ Prolapse (POP) from Class II to Class III. This change will require any future mesh product for POP to provide much needed clinical evidence demonstrating it is a safe and effective device before it is marketed for use in patients. We also support reclassification of surgical instruments used for mesh insertion from Class I to Class II and the requirements for current mesh products to submit a Premarket Approval Application (PMA).

FDA delay in acting has harmed women.

The FDA Advisory Obstetrics and Gynecological Devices Panel (Expert Panel) met in September 2011 and now, almost three years later, a part of the panel's recommendations are being put forward in this proposed reclassification order. We strongly support this proposal. However, we cannot forget that during those three years, thousands of women reported harm to the FDA -- from January 1, 2011 to December 31, 2013, the FDA received 19,043 adverse event reports related to surgical mesh used for POP repair. According to the Institute for Safe Medication Practices (ISMP), less than 1% of all serious adverse events are reported directly to the FDA. So, these numbers reflect only a small portion of the patients who have been injured by surgical mesh.

It is likely that most of these women did not learn about the warnings issued by the Expert Panel of the benefits and risks of this procedure. They should have each been told exactly what was published in the May 1, 2014 Federal Register:

> *"Based on its review, FDA believes that the rate and severity of mesh-specific adverse events following vaginal POP repair with mesh calls into question the safety of these devices. Additionally, the available scientific literature does not provide evidence that surgical mesh used for vaginal POP repair offers a clear improvement in effectiveness when compared to traditional repair."*

But most consumers do not read the Federal Register and this information was not widely disseminated to the public and it is not being disseminated today from an official source, like the FDA. We urge the FDA to include public outreach with this reclassification order – this should begin now. Consumers Union is willing to help help get the word out in clear, consumer-

friendly language, however, the FDA issuing strong warning statements would go a long way towards giving the public a clear understanding of the risks and benefits of surgical mesh for POP.

When transvaginal mesh kits were originally marketed, after completion of cursory 510(k) reviews, as a way to achieve higher success rates for pelvic organ prolapse and incontinence repairs, no clinical evidence had been submitted demonstrating the effectiveness or safety of transvaginal mesh before it was widely used on unsuspecting women across the country. Further, the current definition of success for mesh use does not clearly consider adverse events that happen to women long after the mesh surgery. Over time, the mesh can break up and attach onto other parts of the body, including organs. No long term follow up and research based on anatomical measures rather than tapping into the real life experiences of women who had the mesh implanted turned into a recipe for disaster. The Expert Panel's consensus:

> *"was that premarket clinical data are needed for surgical mesh for transvaginal POP repair. The majority of panel members recommended that these devices be evaluated against a control arm of traditional "native-tissue" (nonmesh) repair to demonstrate a reasonable assurance of safety and effectiveness for the devices. Panel members also emphasized that these studies should evaluate both anatomic outcomes and patient satisfaction and that the duration of followup should be at least 1 year, with additional followup in a postmarket setting."*

Expand reclassification to include mesh for stress urinary incontinence.

Additionally, we are very concerned that the proposed order does not include mesh used to treat stress urinary incontinence (SUI). Since the use of surgical mesh for this purpose is also marketed after completing only a 510(k) review, there will continue to be no clinical evidence as to the safety and effectiveness of the mesh product used for this purpose. Requiring clinical evidence of effectiveness and safety for POP and not for urinary incontinence could result in off label use of the SUI product for both purposes, subverting the safety policies that this proposed order intends to put into place. The FDA's 2008 safety communication to health care providers (http://www.fda.gov/medicaldevices/safety/alertsandnotices/publichealthnotifications/ucm061976.htm) included the same warnings and recommendations for surgical mesh used for POP and for SUI. The most frequent complications noted were "erosion through vaginal epithelium, infection, pain, urinary problems, and recurrence of prolapse and/or incontinence." In other words, the mesh for both POP and SUI repairs harmed women and didn't fix the problems as intended.

Further, the FDA has received many adverse event reports of mesh for SUI complications from patients and physicians, including the mesh attaching to intestines, organs, nerves and blood vessels. The agency reported similar numbers of adverse events reported for both procedures during the three year period of 2008-2010: 1,503 reports were associated with POP repairs and 1,371 associated with SUI repairs (http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm. Just as with POP repairs, the complications of surgical mesh for SUI can be life altering for some women as mesh removal or excision may require multiple surgeries and a lifetime of pain and limited activities. Complete removal of all mesh that has broken up in the body is not always possible. Consumers Union has worked with women who have had multiple operations to remove the mesh but mesh remnants still remain in their bodies, causing continued pain and suffering.

The FDA should expand its order to include reclassification of mesh used for stress urinary incontinence as a Class III device. If this is not proposed, we respectfully request that in the

agency's public response to comments a thorough explanation be provided as to why mesh for treating SUI is not included, and how the agency plans to mitigate the loophole created by not doing so.

Informed consent – patients have a right to know.

This proposal allows for a current manufacturer of surgical mesh used for POP to continue marketing these products until the FDA completes its PMA process. Allowing this without even notifying patients that the product is being re-evaluated violates the trust that consumers place in the agency to ensure that implantable devices are safe to use. The safest path would be to temporarily suspend the use of a mesh product for POP until that product's Class III approval process is completed. This would motivate the companies to submit the required evidence of safety and effectiveness more quickly. Surely after all of these years, they have gathered some evidence about their products.

The FDA expert Panel specifically addressed this issue in its review, as indicated in the publication of the proposed order for reclassification:

> *"The Panel also emphasized that additional work should be focused on patient labeling and informed consent, including providing patients with benefit-risk information on available treatment options for POP—surgical and non-surgical options so patients understand long-term safety and effectiveness outcomes"*

Clearly there are other ways to address POP and SUI without the problematic use of a synthetic product that does the body does not absorb.

Short of suspending use until the PMA process is completed, the FDA should require that any surgical mesh marketed for POP during this "safety limbo" period come with an FDA-drafted notice to patients. This notice should include a discussion of known adverse events as well as safer alternative options for repair. Manufacturers should require their mesh kits to include the statement for surgeons to provide to patients before having the mesh implanted and signed by patients as part of the informed consent process.

FDA should act quickly – avoid putting patient safety on hold.

In our strong support for this reclassification proposal, we urge the FDA to issue a final order in a timely manner. Our concern is that the proposed order issued in January 2013 to reclassify metal on metal hips to require PMA approval has yet to be finalized (https://www.federalregister.gov/articles/2013/01/18/2013-01006/effective-date-of-requirement-for-premarket-approval-for-two-class-iii-preamendments-devices). We urge the FDA to speed up finalizing reclassification orders and to provide regular status reports with explanations as to why the orders are not finalized. Without final adoption, proposed orders such as these fail to protect the public.

FDA should facilitate tracking mesh implants and training surgeons.

Both the Panel and the agency noted the lack of rigorous, long-term data for surgical mesh products, which is unacceptable for a product that has been on the market for more than a decade. The American public deserves better than this. The agency should follow another of the panel's recommendations as summarized in the published proposed order:

> *"Panel members also recommended mandatory registration of implanted devices, as well as surgeon training and credentialing. They encouraged FDA to work with other stakeholders, such as clinical professional organizations and industry, to use existing databases and new data collection tools (e.g., registries) to develop a meaningful database on postmarket clinical outcomes."*

Consumers Union, and the advocates in CU's patient safety network listed below, strongly supports this FDA proposal. It is without a doubt important to reclassify surgical mesh for POP repair to Class III in order for the proper examination of its effects as compared to other procedures currently available to surgeons and their patients. We also urge the FDA to use this experience as an example and motivation to move more swiftly in the future when devices are clearly causing patient harm.

Sincerely,

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