December 9, 2018

To: Attorney General of Washington
Consumer Protection Division
800 Fifth Avenue, Suite 2000
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From: Jeffrey L. Clemons, MD
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Re: King County Superior Court Complaint No. 16-2-12186-1 SEA

Dear Attorney General Robert Ferguson:

We are a group of 63 surgeons (currently or recently practicing) in Washington that treat stress urinary incontinence (SUI) and pelvic organ prolapse (POP). Our group of surgeons includes Urogynecologists and Female Urologists (both are subspecialists in Female Pelvic Medicine & Reconstructive Surgery), as well as Gynecologists and Urologists (specialists). All 63 physicians are listed at the end of this letter.

We want to disclose that 3 surgeons in our group, Suzette Sutherland, Jim Rice, and I have been retained by counsel for Ethicon in connection with this case, to point out the obvious conflict of interest. However, this letter was physician generated, and was written without any assistance or payment from Ethicon. Furthermore, our concerns below apply to any other manufacturer of mesh, not just Ethicon.

Our primary concern is that this lawsuit will eliminate the mid urethral mesh sling as a treatment option for women in Washington. This would cause a major negative impact on women's health in Washington, because the mid urethral sling is the standard for surgical treatment of SUI. We agree with the American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU) Position Statement that the mid urethral mesh sling is the best minimally invasive surgical treatment for SUI.[1,2]

Here is the issue: the Washington Office of the Attorney General (AG) has filed a lawsuit against Ethicon related to all of their pelvic polypropylene mesh surgical devices, including (1) mid urethral slings for SUI, (2) transvaginal mesh products for POP (introduced in 2005, then removed from the market in 2012), (3) transabdominal mesh products for POP. (King County Superior Court Complaint No. 16-2-12186-1 SEA.)

Our interpretation of the AG complaint is as follows:

(1) The AG complaint claims that Ethicon violated the Consumer Protection Act in Washington. According to the AG Legal Complaint, Consumers are defined as all physicians and all patients. The AG claims that all physicians in Washington, including many of us in this group, were deceived or misled by Ethicon, when we made treatment decisions related to these devices.

(2) The AG complaint argues that the list of surgical risks in the Instructions for Use (IFU) pamphlets was incomplete (including non-mesh surgical risks such as infection, hematoma, death, etc.), and therefore, all physicians were deceived. Because of this, they claim that we were unable to counsel our patients about the surgical risks of mesh, and therefore, all patients were deceived.

This argument has no merit for the following reasons. We do not rely on the IFU to counsel our patients. Instead, we rely on our medical education in medical school, residency, fellowship, medical journals, textbooks, CME conferences, and local / regional / national meetings, as well as medical society guidelines, clinical experience, and discussion with colleagues. The IFU is not used to counsel patients. The IFU is a step-by-step instruction manual included with all surgical devices. The IFU is only available once the device is opened in the operating room, after the patient is already under anesthesia. Patients are counseled appropriately about the risks, benefits, and alternatives to surgery, prior to going to the operating room.

Also, the AG is not relying on the expert opinions of Washington surgeons, and their expert surgeons are not recognized leaders in our field. Washington is fortunate to have several well-known, nationally recognized physicians that specialize in the field of Female Pelvic Medicine & Reconstructive Surgery (FPMRS). Many of us have done research on SUI and POP, and we have published many peer-reviewed manuscripts on these topics. We have served on national and regional medical societies in women's health. It is astonishing to us that the AG is proceeding with this lawsuit without first availing themselves of the significant experience and expertise of this group.

Furthermore, the AG complaint has several other inaccurate and misleading statements:

(1) The AG complaint understates the scope of the problem with SUI and POP.

SUI and POP are not life threatening conditions. But SUI and POP both cause a major negative impact on the productivity and quality of life of women, affecting them physically, psychologically, socially, and sexually.[3,4] Women with SUI are unable to play with their children without leaking, participate in outdoor activities with family and friends such as hiking, biking, and swimming without leaking, or enjoy intercourse without the worry of leaking. They can suffer from embarrassment, loss of self-esteem, depression, and withdrawal from physical and social activities.

SUI is a highly prevalent condition affecting approximately 13% of women age 19–44 years and 22% of women age 45–64 years.[5,6] In addition, the economic costs are substantial, mostly due to incontinence pads, diapers, laundry, dry cleaning, bed pads, and skin care products.[3,4] Furthermore, surgery for SUI and POP is a common occurrence, as the lifetime risk for surgery for SUI or POP is 20% (separately, 13% for SUI and 12% for POP).[7]

Surgery for SUI and POP typically leads to a major improvement in the productivity and quality of life in these women.[1,8,9] These women are typically happy and grateful after surgery, and many of our patients have described their surgery as life changing, and wish they had done it sooner. This lawsuit is likely to deter women from seeking treatment for these conditions.

(2) The AG complaint repeatedly conflates the issues with mid urethral slings for SUI and transvaginal mesh for POP; these issues need to be viewed separately. We are concerned that this lawsuit will eliminate the mid urethral sling as a treatment option for women in Washington.

The mid urethral sling is one of the most significant and evidence-based advances in women's health over the last 20 years. Since its introduction to the US in 1998, it has essentially

replaced every other surgery used to treat SUI, because of high efficacy and low complication rates.[1,6] Interestingly, the success of the mid urethral mesh sling led to the development of transvaginal mesh implants for POP in 2004-05. The transvaginal mesh POP products had complication rates higher than the mid urethral sling, and most were removed from the market. The mid urethral sling continues to be the best option for the treatment of SUI for most women.[1,8,10]

In October 2008, the FDA issued a Public Health Notification to inform clinicians and patients of adverse events related to urogynecologic use of surgical mesh, and to provide recommendations on how to mitigate risks and how to counsel patients.[11] In July 2011, the FDA issued an update, noting that "serious complications associated with surgical mesh for transvaginal repair of POP are not rare", and that "it is not clear that transvaginal POP repair with mesh is more effective than traditional non-mesh repair in all patients with POP and it may expose patients to greater risk." The 2011 notification was specifically directed at transvaginal mesh for POP, not mid urethral slings for SUI or transabdominal mesh for POP.[12,13]

On November 20, 2018, the FDA issued an update on actions to strengthen requirements for transvaginal mesh for POP.[14] The FDA clearly differentiates between transvaginal mesh for POP, transabdominal mesh for POP, and mid urethral slings for SUI, and they state that "each of these procedures has unique risks and benefits and it is important not to confuse the procedures and the risks and benefits." [14] However, this lawsuit conflates the risks and benefits with these different surgeries.

(3) The AG complaint suggests that severe complications from polypropylene mesh are common. This is not true for the mid urethral sling, and the complication rates are very different for mid urethral slings for SUI compared with transvaginal mesh for POP. Again, the AG complaint inaccurately conflates the mid urethral sling for SUI with transvaginal mesh for POP.

The most common complications from the mid urethral sling are mesh exposure in the vagina (which is often caused by wound separation) and urinary retention. These complications are easily managed. For mid urethral slings, mesh exposures occur in approximately 2% of patients, and urinary retention requiring release of the sling occur in approximately 1% of patients.[8,10,12] These complications require a minor surgical revision. Fortunately, the more severe complications of mesh erosion (into the bladder or urethra) and chronic pain are uncommon. With transvaginal mesh for POP, the mesh exposure rate is higher, and varies with surgeon experience and technique; similarly, mesh erosion and chronic pain rates are higher for transvaginal mesh than for slings.

Recently, a very large study of the English National Health Service database provided reassuring long-term safety data for the mid urethral mesh sling. They reported a mesh sling removal rate (for all indications, including mesh exposure / erosion, chronic pain, retention), of only 1.4% at 1 year in over 90,000 women, 2.7% at 5 years in over 52,000 women, and 3.3% at 9 years in almost 7,000 women.[15]

Severe complications from the mid urethral sling are not common. The primary reason that the mid urethral sling is the most common surgery for SUI, is because the morbidity is *lower* than all of the other similarly effective surgeries (such as the Burch or the pubo-vaginal sling.)[8,16] The mid urethral sling has lower rates of several adverse events, to include: blood loss, operating time, bowel injury, hematoma, wound infection, length of hospital stay, prolonged urinary retention over 6 weeks, and return to the operating room for retention.[8]

(4) The AG complaint also suggests that polypropylene mesh should not be implanted in the human body, and even suggests that it causes cancer. These statements are not true, and they cause unwarranted fear and concern in our patients.[17,18]

In a landmark and definitive study from Sweden published earlier this year, the Swedish health care register identified all women over age 18 years (5,385,186 women), including all 20,905 women that had a mid urethral sling from 1997, and all 238,476 woman that had cancer (from 24 different organ systems). They found that the mid urethral polypropylene mesh sling is not associated with cancer. [17]

We all have had asymptomatic patients ask us to remove mesh due to fears generated by irresponsible advertising. The American Urology Association (AUA) recommends against removing vaginal mesh in asymptomatic women, because "there is no clear benefit to mesh removal in the absence of symptoms, and mesh removal in this circumstance exposes the patient to potential complications such as bladder injury, rectal injury and fistula formation." [19] The American College of Obstetricians and Gynecologists (ACOG) and AUGS make the same recommendation.[20,21] These fears affect patients who are vulnerable to exploitation, and have led many women to undergo unnecessary surgery to remove mesh, as described in The New York Times article earlier this year, "*How Profiteers Lure Women Into Often-Unneeded Surgery.*" [22]

The eight points listed below highlight our position:

1. We agree completely with the AUGS / SUFU Position Statement (attached) on polypropylene mesh mid urethral slings for SUI in women.[1,2] The mid urethral sling is the most well-studied anti-incontinence procedure in history, and has become the worldwide standard for surgery for women with SUI.[1,2,6]

(This document was drafted jointly by the American Urogynecologic Society (AUGS) and the Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction (SUFU), and endorsed by the American Association of Gynecological Laparoscopists (AAGL), the American College of Obstetricians and Gynecologists (ACOG), the International Urogynecological Association (IUGA), the Society of Gynecologic Surgeons (SGS), and the National Association for Continence (NAFC). Published January 2014; Updated June 2016; Updated February 2018.)

2. The polypropylene mesh mid urethral sling represents the best option for the surgical treatment of SUI for most women, especially when one considers the higher morbidity of other surgeries.[8,10,16] This lawsuit could lead to the loss of mid urethral slings for women in Washington state. This would be a setback of 20 years of surgical progress for women's health.

3. The AG claim that the polypropylene mesh sling is not appropriate for implantation in the human body is false. Polypropylene suture has been used for decades in cardiac, general, gynecologic, orthopedic, thoracic, and urologic surgery. Polypropylene mesh was first used in surgery to repair abdominal wall hernia in 1958 and has been used extensively in humans for this purpose for the past 30 years.[23,24] Various materials have been used over many decades for urethral slings, and polypropylene monofilament large pore mesh is commonly accepted around the world as the best material available for urethral slings.[1,2,8,10]

4. We were not misled or deceived by the IFU pamphlets. We do not rely on these for medical decision making or counseling. We rely on our medical education in medical school, residency, fellowship, medical journals, textbooks, CME conferences, and local / regional / national meetings, as well as medical society guidelines, clinical experience, and discussion with colleagues.

5. For polypropylene mid urethral mesh slings, our patients are appropriately counseled.

6. Polypropylene mesh does not cause cancer;[17,18] nor does it cause autoimmune disease.[25,26]

7. An important study from the University of Washington in 2018 showed that, "Following introduction of polypropylene mesh mid urethral sling in Washington state, women who underwent SUI surgery were slightly older with more medical comorbidities, yet did not appear to experience increased surgical complications. Fewer women underwent reoperation for recurrent SUI, and hospital stays were shorter, suggesting an improvement in care." This manuscript reflects our treatment of women in Washington.[27]

8. To be clear, we agree with a recent statement by AUGS: We are neither pro-mesh nor anti-mesh. We are pro-science, and science and evidence must lead the way.[21]

We acknowledge that some women have been harmed by complications associated with surgeries that involve (1) mid urethral mesh slings for SUI, (2) transvaginal mesh for POP, and (3) transabdominal mesh for POP. We take all surgical complications seriously, and our efforts to manage any patient with a surgical complication are unyielding.

Upon entering the profession of medicine, we are all held by the precepts of bioethics within the Hippocratic Oath, with perhaps the most important of these being non-maleficence: "primum nil nocere" when translated means, "first, do no harm." And yet, as with all surgeries, there are always risks, always the potential for harm. As surgeons, it is our responsibility to understand the potential risks and ensure that they are far outweighed by the intended benefits of any intervention.

We understand that there are additional risks associated with the use of mesh. Mesh exposure, mesh erosion, or mesh-related pain can occur. In most cases the mesh can be partially removed; occasionally, it needs to be completely removed. All of us have taken care of women with mesh complications. However, the majority of the cases in Washington that developed significant complications were done by less experienced surgeons, most of whom no longer perform these surgeries. Many of us who work in referral centers are now seeing fewer such patients, since most of the significant complications were in patients with transvaginal mesh for POP, and not with mid urethral slings for SUI. Most transvaginal mesh POP products are now off the market, and their use has become uncommon since the FDA warning in 2011,[28] and are now essentially limited to a small group of experienced surgeons. Currently, high-volume experienced surgeons place the majority of mid urethral mesh slings in Washington, with low complication rates. There are no procedures in medicine without complications, and for mid urethral mesh slings, the complication rates, and the severity of those complications, are well within accepted norms.

Regarding transvaginal mesh for POP, there may be a subset of women with POP that will benefit from its use. Therefore, in 2012, the FDA mandated that mesh manufacturers conduct research through the 522 Postmarket Surveillance Studies Program to determine if transvaginal mesh is beneficial.[29] Some manufacturers removed their transvaginal mesh products from the market, and other manufacturers are pursuing the research. These studies are ongoing.[30] In January, 2016, the FDA reclassified transvaginal mesh for POP from class II to class III, which requires premarket approval applications.[31] On February 12, 2019, the FDA will convene an advisory committee meeting to share the available evidence and seek expert opinion about the safety and effectiveness of transvaginal mesh for POP repair.[14] Transvaginal mesh for POP should be used judiciously by experienced surgeons with extensive training in pelvic surgery. The best approach to reduce complications from the use of mesh is to follow credentialing guidelines, as recommended by the American Urogynecologic Society.[32,33] Requiring hospital systems in Washington to follow these

guidelines through the Washington legislative system is a better approach than using lawsuits through the Washington judicial system.

As physicians it is our duty to advocate for our patients. We advocate for those patients that have been harmed by an unfortunate complication, to help undo what has caused them harm and provide them with the medical or surgical care they need. Some of us have done research that raised awareness of the complications from transvaginal mesh for POP that led to the FDA notification in 2011. We also advocate for women suffering from SUI whose quality of life is improved by the mid urethral sling. With its high efficacy rates, low complication rates, and minimally invasive approach, the mid urethral sling revolutionized treatment for SUI. Millions of women worldwide have been safely and successfully treated for SUI since the advent of the mid urethral sling.

This letter was written with the input, collaboration, and endorsement of the 63 physicians listed below.

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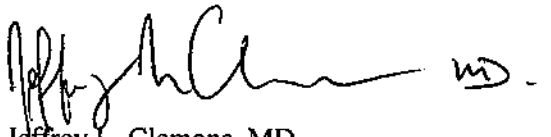
Sincerely,



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