

The crushing of innovation for treating female pelvic floor disorders: A story of “lead or be led”

📌 Litigation and negative public media attention threaten therapeutic innovations for pelvic floor disorders, reducing patients’ treatment options. This leader in female pelvic medicine galvanizes you to action, with a focus on scientific evidence and patient advocacy.

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With the decision by Astora Women’s Health to discontinue operations as of March 31, 2016, we have lost midurethral slings and pelvic organ prolapse repair mesh, technologies and kits that have been among the most widely used and studied (Steve Blum, Senior Vice President and General Manager, Astora Women’s Health, and Kathie J. Lenzen, Senior Vice President and General Manager, Endo Device Operations, e-mail communication to physician customers, February 29, 2016). US Food and Drug Administration (FDA)–mandated 522 postmarket surveillance studies on these products have stopped enrolling patients, and we will therefore never glean the full science from fully enrolled and

completed studies. This is a horrible precedent. How did this happen, and what do we need to do now to prevent further loss of helpful innovative technologies that benefit our patients with pelvic floor disorders?

Liability challenges precipitated shut down

Endo Pharmaceuticals, the parent company of Astora (previously American Medical Systems Women’s Health division), last year offered \$1.5 billion to settle a majority of its pending mesh litigation cases. I was told that the company wanted to put all of the negative noise from the relentless plaintiff attorney public media campaign behind it and refocus its attention on helping women with pelvic floor disorders.

Over the past year, 4 interested and capable buyers have been in discussions with the company to purchase and continue its product line. The company’s recent decision to not sell its product line and discontinue all operations was based on “the current legal environment and the ongoing challenges associated with vaginal mesh product liability” (Astora Women’s Health, e-mail

communication to physician customers, February 29, 2016). If it had chosen to sell its product line, the company always would have remained a potential deep-pocketed codefendant in any future litigation against the company that purchased its products, technologies, and intellectual properties.

This is a frightening scenario that threatens existing companies that want to remain in the prolapse and incontinence product space. This is a threat to all future innovation for pelvic floor disorder therapies, and it discourages anyone or any company to invest in innovative products that may help our patients. In addition, it is a threat to our mission as physicians and surgeons to provide the very best therapies to our patients who deserve and expect us to do so.

Let me be crystal clear: Currently available midurethral slings are also in the crosshairs of plaintiff attorneys, and we are at risk of losing them as well if we do not act quickly, decisively, and as a unified force. More than 60% of the mesh lawsuits have been against midurethral slings, not the prolapse mesh kits focused on in the FDA Public Health notice of July 2011.¹ In their class action



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lawsuits, plaintiff attorneys lumped together any procedure involving mesh in the pelvis to increase the number of their patient clients involved, which can drive up settlement awards, and they succeeded. In 2014, 128,030 sling procedures for incontinence were performed. Does anyone truly believe that the scientific literature supports that these patients would have been best served by 128,030 Burch procedures?

Some believe that Endo Pharmaceuticals' placement of \$1.5 billion in settlement funds was an error, "threw blood in the water," and led to what has happened. Some believe that companies should fight every lawsuit to win and not settle. By the companies winning cases, the plaintiff attorneys lose their incentives to advertise and file more cases, as they only receive money if they win (or get a settlement) and are out of pocket for their costs and time if they lose.

Plaintiff attorneys have a responsibility to zealously advocate for their patient clients. Defense attorneys have a responsibility to zealously defend their corporate clients. We surgeons must realize that we have a responsibility to zealously advocate for our patients and do

whatever is needed to best serve them and to protect the use (and development) of innovative products and therapies that give them value and a better quality of life.

Proactive steps surgeons can take

How do we do this? I suggest the following:

Implement expert oversight for litigation. Some of the large plaintiff awards were assisted by expert testimony based on a highly questionable scientific foundation. Judges give expert witnesses great latitude in their testimony, relying on the jury to discern the truth. I recommend that professional societies, such as the American College of Obstetricians and Gynecologists (ACOG), American Urological Association (AUA), American Urogynecologic Society (AUGS), Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU), and Society of Gynecologic Surgeons (SGS), establish a panel to review and carefully evaluate plaintiff expert testimony that has a questionable scientific foundation. If such a panel finds the scientific basis of testimony to be

biased, untruthful, or unethical, the societies must publicly reprimand and sanction these experts. Only then would these experts no longer be used by the plaintiff attorneys.

Such an expert panel also could serve to educate the judges in federal and state courts on real science and not manufactured opinions.

We need juries that can understand the science so they truly can decide on cases involving complex technologies.

Support professional leadership efforts. I am encouraged that AUGS is working to establish guidelines for the management of mesh complications. I have seen cases in which a small amount of mesh exposure, best treated by limited local excision of the exposed mesh, instead has been treated by complete excision of every polypropylene fiber placed, resulting in an unnecessarily morbid surgery that leaves a scarred and small vagina. Notably, some of the surgeons who excise every polypropylene fiber are also working as plaintiff experts, who may then testify that the scarred, small vagina was caused by the mesh and the implanting surgeon.

Our professional society leadership and volunteer committees, especially from AUGS, have done a tremendous amount of work in assisting with the FDA-required 522 postmarket surveillance study research design; establishing a Pelvic Floor Disorders Registry (<http://www.pfdr.org/>) and a sling registry; and developing credentialing guidelines for sacrocolpopexy, transvaginal mesh, and slings. They deserve our gratitude and our participation in the registries. It would be a tragedy if all of this work does not lead to fully enrolled and completed 522 studies so that we can scientifically make decisions on

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products before any more treatment options are removed from the market.

Use video to scrutinize surgical outcomes data. The surgical literature shows extreme variance in outcomes and complications for vaginal mesh surgery, including exposure rates from 1% to 20% with the same mesh products. This only can be explained by depth of surgical dissection and implanting technique. Surgical outcomes have been shown to be related directly to surgical volumes and experience.² I propose that going forward, any authors who publish their study outcomes and complication data on a surgical procedure must submit a surgical video that demonstrates exactly how the surgery was done.

Best serve the patient. We all need to rigorously follow our own surgery results, improve our techniques, and keep within our surgical skill sets. We need to share our outcome and complication data with our patients during the informed consent process, since we, and not the surgical literature, are performing their surgeries.

We need to be transparent and respectful of our colleagues with different skill sets, putting what is best for patients ahead of everything else. We must be mindful of our inherent biases toward surgeries we are personally very good at and comfortable with. We must respect that other surgeons may achieve better clinical outcomes than us with the same surgery. We need to teach each other the best reproducible surgical techniques to maximize outcomes and minimize complications.

We must humbly accept that not every surgeon can do every surgery (and should not try). If a patient would be best served with a surgery we are not skilled in, we must refer that patient to a colleague who is.

Encourage industry's part in

training. As new technologies are developed, we must be brutally honest with ourselves about whether or not we have the skill sets to use them. Industry must gauge the complexity of the surgical skill set necessary to use their products and limit attendance at their teaching labs to surgeons who have the skills required to obtain good outcomes and minimize complications.

We have reached the tipping point

We have seen the enemy, and it is us. We now need to advocate zealously for our patients. We will succeed only if we keep what is best for our patients at the forefront of everything we do. We must today decide to lead or be led. If we do not lead, we will be led by others—to places that may not best serve our patients. Make no mistake, this is a tipping point. The future of midurethral slings and potential future innovations lie in our hands right now.

Notably, just days prior to Astora's letter to its physician customers announcing the decision to discontinue all of its operations, the transobturator postanal sling system (TOPAS) for fecal incontinence, a product in the pipeline at Astora, received 3 unanimous 8-0 votes from an FDA device advisory panel on safety, efficacy, and benefit outweighing risk.³ The future of this technology is now uncertain as well.

I ask Endo Pharmaceuticals to reconsider abandoning all of its products and intellectual properties. I ask it to entertain discussions with large companies that want its technologies and intellectual properties and can indemnify it from future litigation. While there never is a guarantee of complete indemnification and the company does have a fiduciary responsibility to its shareholders,

industry also has a responsibility to patients and surgeons to allow helpful technologies to persist.

According to Astora's letter to its physician customers, "Patient health has always been our number one priority. As such, the business closure has been expedited so that you and your patients have the opportunity to assess alternative treatment options as soon as possible."

That letter was dated February 29. I do not feel that 31 days' notice is enough time for surgeons to assess—let alone learn and master—new treatment options. It would have been helpful if Endo Pharmaceuticals had given more notice and would at least have allowed other interested companies the option to purchase useful technologies and intellectual property to mitigate its rapid departure from the space. The company remains in the health care arena with its pharmaceutical products, and how it behaves leaving the surgical space will be noted and impact its brand and reputation.

Lessons from the morcellation situation

How quickly the power morcellator disappeared is a lesson to note very carefully, and it has important parallels to what we now face. I highly recommend that you read and study Lisa Rosenbaum's article in *New England Journal of Medicine*, "N-of-1 policymaking—tragedy, trade-offs, and the demise of morcellation."⁴ She eloquently discusses how decisions to terminate technologies based on passionate anecdotal stories and media campaigns, and not scientific study, does not serve the greater good. She explores lessons learned from the silicone breast implant saga as well, stating "the tendency to focus on eliminating

an immediate harm while failing to consider potentially greater harms caused by that reaction is heightened by the power of tragic stories.”⁴

We need a calmer, less emotional, and balanced scientific approach to evaluate technologies. We need to consider what harm is done by not allowing new technologies to be adequately studied, improved, and implemented. Dr. Rosenbaum discusses what Cass Sunstein and Timur Kuran call the “availability cascade,” “a phenomenon whereby stories inform public perceptions and anyone challenging those perceptions is vilified.”^{4,5}

No technology will ever be risk free, and there always will be some risks and complications that could be significant and chilling. However, patient autonomy requires a full discussion of a risk/benefit ratio that is based on science, and these scientific data must be allowed to be collected and learned. There even can be more significant and chilling complications from not using a technology as well.

It is challenging to speak science to emotion that is driven by tragic outcomes, but we can remain compassionate as we seek the science that will serve the greater good. Condemning proponents of carefully studied and properly implemented technologies as immoral is neither helpful nor constructive.

Crushing the ability to thoroughly and scientifically study new technologies is not in the best interest of our patients with pelvic floor disorders.

It is time to reawaken the better angels of our nature

Will we do the necessary work now no matter how uncomfortable it may make us feel? Or will we be intimidated and remain silent and disjointed? Will we participate in the registries and follow best clinical practice and credentialing guidelines? Will we hold ourselves and our colleagues accountable? It is time to remember why we became surgeons, and to start acting on our convictions.

To that end, we must ask ourselves, will we:

- honor the Hippocratic Oath that we took in medical school and “respect the hard-won scientific gains of those physicians in whose steps I walk, and gladly share such knowledge as is mine with those who are to follow”⁶
- “not be ashamed to say ‘I know not,’ nor will I fail to call in my colleagues when the skills of another are needed for a patient’s recovery”⁶
- zealously advocate for our patients to ensure we can offer them the very best therapies
- honor and respect the sacred trust patients place in us when we take

them to the operating room
• lead or be led?

This is personal for me. My mother struggled with pelvic floor disorders. I always felt it grossly unfair that women who chose to give us life could suffer for the rest of theirs for that decision. These women deserve our very best. The 40 million women with pelvic floor disorders deserve—and expect—that we lead. Will we?

I am hopeful that we will. I believe we will rise to today’s challenges and protect and fight for our patients. I believe that years from now we will look back and be proud that we did the right thing, and in so doing protected and encouraged innovations that significantly enhanced the quality of our patients’ lives. I believe patients will recognize our genuine efforts and in so doing give our profession the respect and trust that I feel has been diminished.

I believe we will draw the needed courage and resolve from the oath we recited in medical school and remember that, “If I do not violate this oath, may I enjoy life and art, respected while I live and remembered with affection thereafter. May I always act so as to preserve the finest traditions of my calling and may I long experience the joy of healing those who seek my help.”⁶

I do believe we will. 🚫

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