

March 31, 2010

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U. S. Food and Drug Administration
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Silver Spring, MD 20993

Dear Dr. Shuren,

Thank you for receiving my remarks last Wednesday during the formal appeal by Uromedica, Inc. of the FDA's non-approvable letter for its adjustable continence therapy (ACT) device. I clearly sensed your attentiveness and appreciated your genuine effort during our meeting to process and absorb my humble attempts to share the circumstances faced by women with stress urinary incontinence (SUI). I am particularly concerned about the women with moderate to severe symptoms whose surgery has failed or whose "cure" has been lost to encroaching pelvic floor weakness over time or intrinsic sphincter deficiency or both. Since I did not accompany my remarks with slides as did the other presenters and prepared no handout in advance, permit me to follow up now with a summary of the points I offered before the assembled group on your premises. This gives you a document that may be shared with those who were present for the meeting or with others, as you so choose.

By way of introduction, while I do not frequently meet with the FDA on such matters, I do routinely seek to represent the interests of patients and that of the general public as the Executive Director of the National Association For Continence. It is my role to do so because patient advocacy is a central part of our mission. Specifically, we support in our advocacy efforts access to safe, proven, and advanced technology, equality for the underserved, public health education so people are better equipped to be their own health advocates, and cost effective standards of care that safeguard quality of life for everyone confronted with bladder and bowel control problems, voiding dysfunction, and related pelvic floor disorders. NAFC has been in existence for over 27 years and is considered among the largest, the most prolific, and the oldest patient advocacy organization in the world in this field. Our call for access, equality, education, and standards has not wavered. Currently, we have about 22,000 visitors monthly to our web site.

As a medical doctor, you know there are different types of urinary incontinence. Stress urinary incontinence is the most common type of incontinence in women younger than 60 years and accounts for at least half of incontinence in all women.¹ At least 15 million women routinely experience symptoms of such unwanted urine leakage;² many are also in the prime of their lives, usually late 40's or early 50's when first seeking a solution. A third of them believe it's just a part of having babies and something to accept. Symptoms only worsen with age, causing incontinence to be a leading reason that family members place a loved one in a nursing home near the end of life. This helps to explain why a third of the general adult population believes incontinence is a natural, inevitable part of aging, a myth we fight with the media to debunk at NAFC.

Despite many technological advances in healthcare, few choices exist for women with SUI. Clinicians are trained to exhaust more conservative measures before sending patients into surgery. But many women are unable or unwilling to perform pelvic floor exercises consistently and correctly for the rest of their lives. Access to biofeedback therapy is not always available. Pessaries may be ill fitted or troublesome. No prescription drug is available for its symptoms in the U.S.

The newer, non-surgical therapies, such as bulking agents and collagen remodeling, are limited in what they achieve. Moreover, some women are not ideal candidates for surgery due to co-morbidities, even if severity of their symptoms warrants it. As Americans live longer, this is likely to be an increasingly important consideration. And the best of surgeons will confirm that every successive pelvic surgery produces successively poorer outcomes because the non-virgin tissue is undergoing still another procedure in a zone with established weakness and post-operative scarring. This explains why surgical outcomes do not always meet patient expectations or hopes³.

Researchers have documented that over a woman's lifetime 27% face repeat surgery for incontinence and/or prolapse.⁴ Women have anecdotally heard disappointing stories from their friends and relatives who still leak after surgery, whether a fascial sling, the Burch colposuspension, or the TVT. Recent, negative publicity about complications from synthetic mesh used in surgical pelvic procedures has dissuaded some women from even considering surgery for their symptoms, despite the fact that at least one-third of the 15 million affected have severe enough symptoms to be considered candidates for surgery.^{5,6} Clearly, more choices with promising outcomes are sorely needed for all women, but especially those who have witnessed failures and disappointment. We simply must offer these sufferers an acceptable alternative between irreversible, problematic surgery and "Kegels".

While requiring a minimally invasive surgical pathway for the placement of the balloons, the ACT procedure can be done under local anesthesia, making it an option for patients who have co-morbidities that might make surgery under general anesthesia a risk. Complications, hardly equivalent to those encountered with mesh implants, such as infection, bleeding, persistent groin pain and mesh erosion, are manageable, based on the literature I've read.

In closing, approval by the FDA of the ACT will help put a safe, simple, and minimally invasive treatment for recurrent female SUI in reach to women who would otherwise simply give up, and let me tell you, that is a devastating, depressing dead end. I urge you to reconsider your decision and allow an option that promises technological progress to unfold.

Should you or your team have questions that I might be helpful in answering, please contact me at any time. Thank you once again for attention and careful decision-making in this matter.

Yours truly,

Nancy Muller, Executive Director
National Association For Continence

cc: Marsha Henderson, Acting Director, FDA Office of Women's Health

References

¹ Hannestad YS, Rortveit, Sándwich S, & Hunskaar S (2000)

² Derived from Diokno AC, Sampelle CM, Herzog AR, Raghunathan TE, Hines S, Messer KL et al. (2004) and Hampel C, Wienhold D, Benken N, Eggersmann C & Thuroff JW (1997) and based on United States Census Data 2000

³ Albo ME, Richter HE, Brubaker L, Norton PA, Kraus SR, Zimmern PE et al. (2007). (The NEJM article recently revealed low success rates for the fascial sling compared to the Burch colposuspension of 66% vs. 49%, respectively, as compared with those in previous studies. Other studies have involved the increasingly popular TVT and shown to offer comparable results.)

⁴ Olsen AL, Smith, Bergstrom, et al (1997). Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstetrics and Gynecology*, 89:501-506.

⁵ Harding CK & Thorpe AC (2008)

⁶ Bump RC & Norton PA (1998)