

**Remarks to the FDA Appeals Panel
on behalf of the Adjustable Contenance Therapy (ACT) device by Uromedica
March 24, 2010**

Thank you for the opportunity to speak with you today. As Executive Director of the National Association For Continence, or NAFC, I represent consumers across our nation. NAFC is not receiving any compensation for my time or reimbursement of expenses incurred by my appearance here. It's my job to be here. And I'll be monitoring proceedings and decisions, as I routinely do that for all announcements.

To place my remarks in some context, allow me to share background information about NAFC. We are a 501(c) 3 corporation whose mission is to educate the public about bladder and bowel control problems and to advocate for patients. NAFC is broadly supported by consumers, healthcare professionals, private foundations, and industry. In existence for 27 years, NAFC is considered among the largest, the most prolific, and the oldest patient advocacy organizations in the world in this field. We currently have about 22,000 visitors monthly to our web site. All are looking for solutions.

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 I'm sure you know some of them because I'm talking possibly about your mother, your sister, a favorite aunt, or your college roommate or roommate's wife. From the phone calls, letters, and emails we receive daily at our national headquarters, I can attest to the fact that women limit their activities as a result of symptoms, placing them at risk of isolation, depression, and an unhealthy, sedentary lifestyle. That's after having been told by their OBGYN that when the symptoms get "bad enough," there's "always surgery." They 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. How tragic! And symptoms only worsen with age, causing incontinence to be a leading reason a family member places a loved one in a nursing home near the end of life. This is important to remember.

Just picture a day in one woman's life: skipping a workout class for fear of having a large, wet spot after aerobics, reaching in the closet to wear the same dark color clothing, hiding the smelly, soaked pad at a public restroom at WalMart, apologizing for wetting her best friend's white sofa during a brief afternoon visit, fearing the worst – that the teller at the bank is smelling urine while the transaction is being processed, dropping out of the church choir and the garden club, and skipping intimacy still one more night with her husband for fear of leaking on the sheets.

Despite many technological advances in healthcare, few choices exist for women with SUI. Naturally, more conservative measures should be exhausted before undergoing 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. Some women are not ideal candidates for surgery due to other co-morbidities even if severity of their symptoms warrants it. As Americans live longer, this is likely to be an increasingly important consideration.

And 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.⁵ Women have anecdotally heard disappointing stories from their friends and relatives who still leak after surgery, whether a fascial sling, the Burch colposuspension, or TVT. Recent, negative publicity about complications from mesh used in surgical 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.^{6,7} Clearly, more choices with promising outcomes are sorely needed for women.

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. Approval by the FDA 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 devastating, depressing dead end.

I urge you to reconsider your decision.

Footnote:

³For example, the fascial sling compared to the Burch colposuspension reveals low success rates of 66% vs. 49%, respectively, as compared with those in previous studies. Other studies have involved the increasingly popular tension-free vaginal tape (TVT) to surgically treat SUI.

References

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

² Derived from Diokno C et al. (2004) and Hampel C, Weinhold D, Benken N, Eggersmann C, & Thuroff JW and based on United States Census Data (2000)

³ Albo ME, Richter HE, Brubaker L, Norton PA, Kraus SR, Zimmern PE et al. (2007)

⁴ Harding CK & Thorpe AC (2008)

⁵ Olsen AL, Smith, Bergstrom, et al (1997). Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstetrics and Gynecology*, 89:501-506.

⁶ 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

⁷ Bump RC & Norton PA (1998)

⁸ Subak LL, Whitecomb E, Shen H, Saxton J, Vittinghoff E, & Brown JS (2005)