

FDA approves Botox for Vaginismus Study

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Manchester, NH ([PRWEB](#)) October 7, 2010 -- On August 11, 2010, plastic surgeon Peter T. Pacik, MD, FACS, received notification that the FDA approved his proposed study of a comprehensive program of intravaginal Botox injections and progressive dilation under anesthesia to treat primary vaginismus (IND 109343).

Vaginismus is a condition marked by involuntary spasms of the vaginal muscles, brought on by the fear of penetration. As a result, any attempt at intercourse, tampon use, or even a routine gynecological exam is not just painful, but virtually impossible. Vaginismus affects one-to-seven percent of women worldwide (about the same percentage as men with erectile dysfunction), and is the most common cause of unconsummated marriages. Vaginismus is often overlooked or misdiagnosed because the majority of health care providers are unfamiliar with this condition.

Botox, a drug derived from a botulinum toxin, interferes with the transmission of a chemical (acetylcholine) that is responsible for muscle activation. When administered correctly, Botox is as safe as aspirin. Botox has been used for decades to weaken over-active muscles and glands in patients with conditions such as cerebral palsy, stroke, excessive sweating, and migraines, as well as for cosmetic purposes. First used in 1997 for the treatment of vaginismus, Botox prevents the involuntary spasms that define this condition, allowing women to progressively dilate more comfortably and overcome their fear of penetration. Botox shows few side effects (vaginal dryness being the most common).

The FDA-approved treatment study includes Botox injections delivered to the spastic muscles inside the vagina, combined with progressive dilation under anesthesia and supervised dilation post procedure. The program also includes post treatment support, as patients transition from dilators to intercourse. Significant follow-up data will be included. The study is registered with www.clinicaltrials.gov (BTX-PV-01).

During the past five years, Dr. Pacik has treated over seventy vaginismus sufferers with this comprehensive program. There have been no complications or recurrences of vaginismus once the effects of Botox have worn off after approximately four months. A number of patients have gone on to enjoy healthy pregnancies.

Dr. Pacik's cure rate for treating severe vaginismus is over 90 percent, meaning these patients achieved intercourse within one week to four months post procedure. Many of these patients suffered for years with vaginismus, and had previously tried other forms of treatment (hymenectomies, talk therapy, physical therapy, hypnosis, alcohol, etc.) for an average of four-to-seven years. Dr. Pacik published an article on the treatment of his first twenty vaginismus patients in the 2009 issue of Plastic and Reconstructive Surgery¹

The FDA approval of Dr. Pacik's Botox for Vaginismus study represents a major breakthrough for women suffering from this condition, and will help bring much needed awareness to this condition among health care professionals and the general public. With this approval comes permission to recruit thirty patients for this study. Patients must be between the ages of twenty and forty, diagnosed with primary vaginismus, non



pregnant, and in good health.

Dr. Pacik has practiced plastic surgery for over thirty years in Manchester, New Hampshire, and belongs to a small group of prestigious surgeons who are double board certified by both the American Board of Surgery and the American Board of Plastic Surgery. As a recognized pioneer in treating patients with Botox for vaginismus, he is the author of *When Sex Seems Impossible: Stories of Vaginismus and How You Can Achieve Intimacy* (Odyne Publishing, 2010).

About The Plastic Surgery Center:

Founded in 1972 by Peter T. Pacik, MD, FACS, the Plastic Surgery Center has been providing state-of-the-art reconstructive and cosmetic procedures to patients in New Hampshire and New England. Working with Dr. Daniel A. Sterling, who is also double board certified in surgery and in plastic and reconstructive surgery, we are able to provide a wide range of cosmetic procedures including breast augmentation, breast lifts, breast reductions, body contouring after massive weight loss, face lifts, fat grafting, liposuction, rhinoplasty and tummy tucks as well as facial rejuvenation procedures including advanced skincare, chemical peels, dermabrasion and facial fillers.

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Reference:

(1) Pacik, PT. "Botox Treatment for Vaginismus" *Plastic & Reconstructive Surgery*, Vol. 124, Pages 455e-456e, December 2009.

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