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January 11, 2012

Mr. Thomas Feyer, Letters Editor  
Letters to the Editor  
*The New York Times*  
820 Eighth Avenue  
New York, NY 10018

Dear Mr. Feyer,

Your January 4, 2012 article "F.D.A. Orders Surgical Mesh Makers to Study Risks," by Barry Meier, does a great injustice to millions of women by misrepresenting the facts surrounding the recent FDA announcements regarding post-market surveillance studies on certain devices. The article falls far short of the quality of journalism and integrity we have come to expect of *The New York Times*. Allow me to elaborate my reasoning for such criticism.

- The tone of the article makes one think the manufacturers are either ignorant of risks for complications or hiding facts they wish not to disclose to authorities. This fuels fear and suspicion on the part of women suffering from symptoms of uncontrolled bladder leakage or the uncomfortable descent of pelvic organs, pushing them to the sidelines in silence instead of seeking diagnosis and treatment. The author's irresponsible alarmist tone is intensified by the lack of mentioning two important facts: 1) none of these devices was recalled by the FDA nor reclassified, and all remain available for usage in surgical procedures in women; and 2) the studies are expected to span approximately three years and must conform to study plans pre-approved by the FDA. Data from the studies will enable the agency to better understand the safety and effectiveness profiles of these devices.
- The author ill-defines stress urinary incontinence (SUI) and thereby contributes to public confusion. Female incontinence is not caused by prolapse. Often, urinary incontinence is not present as a symptom of pelvic organ prolapse (POP), and POP can even mask symptoms of SUI which may suddenly appear following successful surgery to repair POP. While actual causes of prolapse are indeed the result of damaged supportive muscles, ligaments, and their attachments to the bony pelvis, risk factors for prolapse include difficult vaginal deliveries, family history, obesity, advancing age, prior hysterectomy, chronic constipation and habitual coughing. In fact, some mesh kits used for POP repair may be superior in durability for some types of repairs over traditional, tissue-to-tissue procedures, despite the higher rate of post-operative complications, many

less serious than others. However, the less decisive clinical data to date do not permit one to reach definitive conclusions regarding mesh for POP and hence, post-market surveillance studies are needed.

- By quoting Dr. Maisel of the FDA as the author did, Mr. Meier leaves the reader with the impression only mesh surgically implanted through the abdomen is “well established.” This is not true. He also confuses statements about vaginal mesh for SUI with a complications rate in vaginal mesh repair for POP that he cites from a recent journal article. In fact, at the FDA’s hearing on the subject in September 2011, testimonies from leading clinical authorities clearly established that standard, vaginal mesh slings for SUI in women are considered the gold standard by which all future procedures and devices should be measured. The clinical data available on the newer, single incision mini-slings for SUI were considered by the FDA’s Obstetrics and Gynecology Panel to be insufficient to extend such an opinion to them as well and hence, post-market surveillance studies are needed.
- Mr. Meier sloppily dumps all “complications” in a single bucket, failing to clarify that “infections” he cites among the “serious injuries” are actually ordinary urinary tract infections easily treated in ten days or less with a broad spectrum antibiotic. The importance of distinguishing complications by their severity and ease of remedy was stressed by the Panel in September. In addition, risk factors for more severe complications and the importance of careful patient selection by doctors were two points the author completely failed to mention, both valuable to the readers to help place complications in a more meaningful context.

At the National Association For Continence (NAFC), we work hard to communicate objective, unbiased, helpful information to restore quality of life to people with bladder and bowel control problems and related pelvic floor disorders such as POP. We seek to engage consumers so they are equipped to be their own health care advocates. This kind of journalism undoes much of what we aspire to achieve through our web site, conversations with consumers who contact us, and printed educational literature we supply to the public. I am happy to help Mr. Meier and any members of your staff with their homework on any occasion, if I can be of assistance.

Sincerely,

A handwritten signature in cursive script that reads "Nancy Muller".

Nancy Muller, MBA, PhD  
Executive Director  
National Association For Continence  
cc: Barry Meier