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To Whom It May Concern:

As a co-petitioner, I strongly support Public Citizen's petition to the Food and Drug Administration to ban the marketing of all currently available non-absorbable surgical mesh products designed and labeled for transvaginal repair of pelvic organ prolapse (POP) and to order all manufacturers to recall such products.

As a urologic surgeon specializing in female urology and pelvic organ prolapse at the Mayo Clinic, I have refused to use any transvaginal mesh kits for POP. But I am in direct daily contact with referral patients who have been previously treated with them. As a result, I am fully aware of the complications, the management of complications, and their potentially lifelong ramifications. I have come to the conclusion that using mesh for transvaginal POP repair carries far more risk without any added benefit when compared with the standard surgical approaches without using mesh. I do not hold this view lightly. First, a systematic review of the published scientific literature from 1996–2011 has shown that transvaginal POP repair with mesh does not improve symptomatic results or quality of life over traditional non-mesh repair. Secondly, non-absorbable mesh used in transvaginal POP repair introduces needless increased risks not present in traditional non-mesh surgery for POP repair, and because of this, serious complications associated with surgical mesh for transvaginal repair of POP are too common. On a weekly basis, either I or my colleagues evaluate and treat patients suffering from the consequences of the non-absorbable mesh kits. The diagnoses run the gamut of mild vaginal erosion (or extrusion) to devastating urethral and/or bladder erosions with severe, debilitating, life-altering chronic pelvic pain. The patients have suffered needlessly because the standard POP repair without mesh, in properly trained hands, is easy, fast, and effective, avoiding the unique complications associated with non-absorbable mesh kits.

No small confounding factor in the widespread acceptance and use of the mesh kits comes from the immense industry pressure on physicians to adopt "the latest technology" without proper prior surgical training and independent scientific evaluation. And, all too frequently, industry knowingly targets less experienced surgeons, knowing these mesh kits have not, and never will be accepted by more experienced surgeons who are fully aware of their inherent risk without benefit. The end result is oftentimes physically and psychologically devastating for the unsuspecting patient. Additionally, vast amounts of medical dollars are wasted on these trocar-mesh kits, through repeat physician office visits for complications, and through repeat surgical repairs.

Therefore, it is my conclusion, based upon my surgical experience at Mayo in direct patient care, a careful review of the available literature, and the outstanding waste of medical insurance/Medicare dollars, that the use of non-absorbable mesh kits for transvaginal POP repair should be, at a minimum, banned until further data is derived from multiple independent, non-industry-supported research groups which prove a clear benefit without unwarranted risk. Anything less would be surgically irresponsible and ethically unacceptable. I do feel this position is extreme. However, extremism in the pursuit of surgical responsibility, patient care, financial responsibility, and medical ethics is the only honorable endpoint. To quote Dr. William Mayo, founder of the Mayo Clinic, "The best interest of the patient is the only interest to be considered."

Respectfully submitted,

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