United States Senate

WASHINGTON, DC 20510

August 19, 2014

The Honorable Margaret A. Hamburg
Commissioner Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Commissioner Hamburg,

We write to express my concern, and those of my constituents, regarding the use of power morcellation devices for the minimally-invasive surgical removal of uterine tissue or fibroids. The use of these devices in laparoscopic procedures was intended to reduce surgical trauma and improve recovery times. However, it has become increasingly clear that the use of power morcellation involves risks that are greater than originally determined. Recent studies conducted at Brigham & Women's Hospital in Boston have demonstrated a risk of malignant tumor dissemination nine times greater than is currently communicated to patients considering this surgical option.

On April 17th the Food and Drug Administration issued a safety communication discouraging the use of power morcellation for the removal of uterine tissue or uterine fibroids and recommending convening a panel to review communication of risk through product labeling. Shortly after that communication, researchers at Columbia University College of Physicians and Surgeons in New York determined that that the rate of uterine malignancy in women undergoing power morcellation procedures was much greater than previously reported. Johnson & Johnson's Ethicon division, the leading manufacture of morcellation equipment, promptly withdrew their products from the market.

In light of this new evidence, we urge the FDA to request that other manufacturers of laparoscopic morcellation devices withdraw their equipment from the market until additional risk assessments and patient and clinician education can be performed. Furthermore, as the FDA prepares to make a final determination on the use of these devices, we urge you to seriously consider and not discount the testimony presented during the FDA's July hearings by our constituents who devastatingly lost family members to cancer after a power morcellation procedure. We thank you and the staff of the FDA for their sound judgment and commitment to protecting the safety of the public health.

Sincerely,

Kirsten Gillibrand

Kirsten Gillibrand
United States Senator

Charles E. Schumer
United States Senator