ROBERT P. CASEY, JR.
PENNSYLVANIA

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United States Senate

WASHINGTON, DC 20510

October 6, 2014

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

Dear Commissioner Hamburg:

I write today to request that the Food and Drug Administration (FDA) closely evaluate the safety concerns that have been raised regarding the use of medical devices known as "power morcellators" during surgeries to remove the uterus or uterine fibroids.

In recent months I have heard from a number of constituents regarding these devices, raising concerns that the use of power morcellators in uterine morcellation can scatter cancerous tissue throughout the abdomen, and that this can, in turn, significantly worsen the prognosis of women who undergo this procedure.

In response to these safety concerns, Johnson & Johnson, the leading manufacturer of power morcellators, has pulled their devices from the market. One Pennsylvania insurer, Highmark, will no longer cover this procedure in its health insurance plans, and several health care providers, including UPMC in western Pennsylvania, will no longer perform this procedure.

I understand that FDA has recently issued a safety communication discouraging the use of laparoscopic power morcellation, and intends to consider the safety of these devices further. Given the widespread use of these devices and the seriousness of the claims made against these products, I urge the FDA to swiftly and closely evaluate the concerns that have been raised, and take any additional action necessary that is appropriate to safeguard the health of the public.

Sincerely,

Bob Casey, Jr.

Robert P. Casey, Jr.
United States Senator

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