

Congress of the United States
Washington, DC 20515

The Honorable Gene Dodaro
Comptroller General of the United States
441 G Street, NW
Washington, DC 20548

August 7, 2015

Dear Comptroller General Dodaro:

Hundreds, if not thousands, of women in America are dead because of a medical device known as a laparoscopic power morcellator.

These devices are gynecological tools used to remove uterine fibroids. The blades of this device shred the uterine fibroids, which are then removed through a laparoscopic incision. For 2 decades it was branded as a safe, routine procedure. However, if a uterine fibroid is harboring an undetectable cancer, the morcellation of that cancerous tissue and its removal through the abdominal cavity can spread that cancer throughout a woman's body. This device can take a Stage 1 treatable cancer immediately to a Stage 4 terminal cancer. For too many women, this routine procedure ended with a death sentence.

Despite the long history of this device, only recently has the Food and Drug Administration (FDA) put out guidance that the use of laparoscopic power morcellators increases the risk of spreading unsuspected cancers in women to as high as 1 in 352 cases. In November 2014, the FDA put a black box warning on the device. The warning states that "[u]terine tissue may contain unsuspected cancer" and that "[t]he use of a laparoscopic power morcellator during fibroid surgery may spread the cancer, and decrease the long-term survival of patients." As of the date of this letter, the morcellator remains on the market.

It is unclear exactly how many women may be dead as a result of an unsuspected cancer having been spread by this device. FDA's warning came decades after some studies were already pointing to a serious problem. For example, a 1990 study found about one-in-200 women had a hidden uterine sarcoma, a rare type of cancer. A 1994 study found a one-in-444 risk. Other studies from 1999 and 2008 found the risk to be one-in-462 to one-in-253 women. Despite these studies, as late as last year, the FDA, the medical device industry, and many gynecologists pointed to the risk of a hidden cancer as being low, only one-in-10,000. How did they get it so wrong for so long?

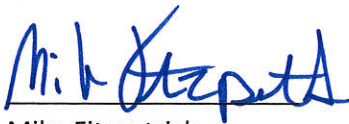
In light of these concerns, we respectfully request you investigate the root cause failure that ultimately led to the FDA's black box warning on the use of laparoscopic power morcellators in November 2014—

over 2 decades after it was first approved. As part of this investigation, please consider the following questions:

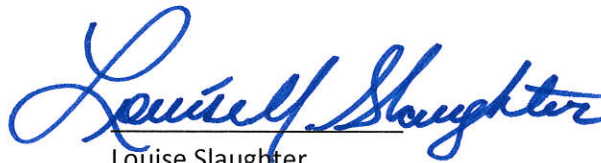
1. Did the FDA's reliance on the 510(k) approval policies and procedures sufficiently identify risks of adverse events before the laparoscopic power morcellator was allowed to enter the market?
2. Were the medical device reporting regulations (21 CFR 803) appropriately followed to protect patient safety in the case of the laparoscopic power morcellator by manufacturers, importers, user facilities, and the FDA?
3. What activities or training did manufacturers provide to clinicians and what professional society standards, if any, apply to training on the use of these devices?
4. What steps is the FDA taking after issuing the black box warning to further determine whether the laparoscopic power morcellator is safe to remain on the market?

Thank you for your timely attention to this request. If you have any additional questions, please contact Justin Rusk in Congressman Fitzpatrick's office at 202-225-4276, or Cheri Hoffman in Congresswoman Slaughter's office at 202-225-3615.

Sincerely,



Mike Fitzpatrick
Member of Congress



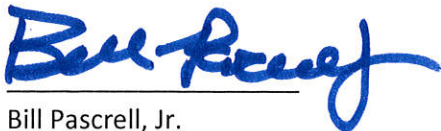
Louise Slaughter
Ranking Member, Committee on Rules



Ralph Abraham, M.D.
Member of Congress



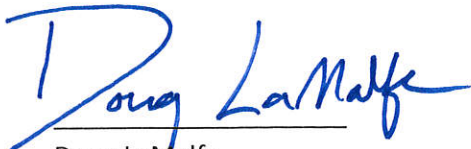
Rosa L. DeLauro
Appropriations Committee
Ranking Member, Subcommittee on Labor,
Health and Human Services, Education, and
Related Agencies



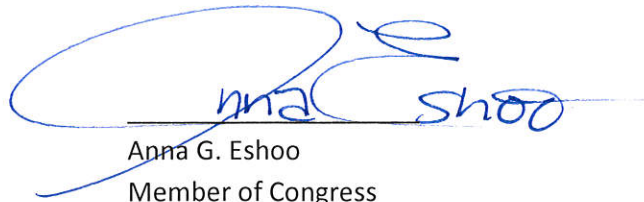
Bill Pascrell, Jr.
Member of Congress



Lou Barletta
Member of Congress



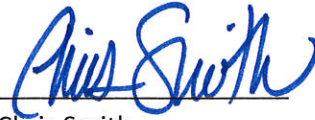
Doug LaMalfa
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Chris Smith
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Stephen Lynch
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Rick Larsen
Member of Congress