Congress of the United States
Washington, DC 20515

Fred Upton
Chairman
Committee on Energy and Commerce
2125 Rayburn House Office Building
Washington, DC 20515

Frank Pallone
Ranking Member
Committee on Energy and Commerce
2322A Rayburn House Office Building
Washington, DC 20515

September 22, 2016

Dear Chairman Upton and Ranking Member Pallone,

As you know, the Food and Drug Administration (FDA) plays a critical role in reviewing and approving medical devices. But we have concerns that the FDA's Center for Devices and Radiological Health (CDRH) is struggling to accomplish its fundamental mission to protect patient health and safety.

While many medical devices prove lifesaving, we know that some can cause harm and have devastating consequences on patient health. In fact, each and every one of us has constituents who were harmed by a device. Whether it is a device such as the laparoscopic power morcellator or the permanent contraceptive device Essure, we are constantly presented with tragic stories of patients who, seeking a cure or a treatment, instead have had their world turned upside down, or worse, lost their life.

The stories of those harmed by medical devices continue to grow. Many have now courageously taken their fight to Congress in an effort to save others from a fate similar to their own. For example, over thirty thousand victims of the Essure device have joined together online sharing stories of how this device caused them serious injury. These women continue to fight the FDA to protect the health of future women.

Moreover, hundreds, if not thousands, of women have been killed or seriously injured by the laparoscopic power morcellator device. It took victims of morcellation, the ones in the worst position to act, to get the FDA to finally take notice. In the 21st century, it should not take a victim to raise the issue of the unsafe consequences of these devices to the attention of regulators.

Many other medical devices have caused severe harm to those who they were supposed to benefit. In fact, according to a study by Johns Hopkins Medicine, medical errors are the third leading cause of death in the United States. That amounts to nearly 10% of all annual deaths in the United States. While not all medical error deaths are attributable to unsafe devices, there is no doubt that an improved ability by regulators and the medical community to identify and remove unsafe devices from the market would save potentially thousands of lives each year.

Last summer, the House of Representatives debated and passed the 21st Century Cures Act. This bill included important medical innovation reforms and increased funding that will undoubtedly save lives. But absent from that debate were the voices of those whose lives could have been saved by improvements in the FDA's ability to identify unsafe medical devices.

Congress cannot ignore the voices of those harmed by unsafe medical devices. We must allow them to tell their stories, present their innovative policy solutions, and help us bring our medical device safety laws into the 21st Century. We must, and we can, maximize innovation and maximize safety.

With the 21st Century Cures Act still pending in Congress, and the Senate continuing its work on a medical innovation package, the time is now for Congress to take action. Therefore, we respectfully request that the Committee on Energy and Commerce hold hearings on the impact unsafe medical devices have had on patient outcomes, as well investigate ways to improve the FDA's ability to monitor and rapidly act when presented with evidence of potentially deadly medical devices.

Sincerely,

Mike Fitzpatrick
Member of Congress

Louise Slaughter
Member of Congress

Christopher H. Smith
Member of Congress

Gwen Moore
Member of Congress

Stephen F. Lynch
Member of Congress

Ryan Zinke
Member of Congress

Brenda L. Lawrence
Member of Congress

cc:
Senator Lamar Alexander, Chairman, Senate Committee on Health, Education, Labor, and Pensions
Senator Patty Murray, Ranking Member, Senate Committee on Health, Education, Labor, and Pensions
Dr. Robert Califf, Commissioner, Food and Drug Administration
Dr. Jeffrey Shuren, Director, Center for Devices and Radiological Health, Food and Drug Administration