Congress of the United States
House of Representatives
Washington, DC 20515

October 30, 2017

The Honorable Dr. Scott Gottlieb, M.D.
Commissioner
The Food and Drug Administration
10903 New Hampshire Avenue
White Oak, RM 322346
Silver Spring, MD 20993

Dear Commissioner Gottlieb,

We are deeply concerned about the Food and Drug Administration's inaction on the dangerous medical device Essure and we request a meeting with you to address these matters. Despite widespread safety concerns, the FDA has allowed Essure to remain on the market even while mandating that the manufacturer, Bayer, conduct an additional post-market safety study. However, a year and a half after the study was initiated, it is unclear whether Bayer has acted with urgency to enroll patients, or if the study results will be delayed. The FDA cannot continue to allow Bayer to drag its feet on this post-market study while women are continuing to suffer.

This device is a prime example of systemic medical device oversight shortfalls and insufficient enforcement to ensure the safety and efficacy of medical devices. We are writing to request a meeting to address our concerns regarding Essure in particular and post-market surveillance on Class-III devices more broadly. These concerns include the ongoing issues with device labeling and the other methods FDA uses to communicate potential health risks to doctors and patients, as well the FDA's role in regulating pre and post-market safety studies.

Doctors and patients have filed over 18,000 adverse events reports related to Essure to the FDA describing numerous negative side effects. In over half of the incident reports, women were required to have invasive surgery to remove the Essure sterilization coils because of severe problems such as pregnancy, auto-immune disease, and device migration leading to organ and tissue perforation. Many women had to undergo full hysterectomies based on the damage done by Essure. However, many of these adverse effects occurred beyond the original 3-year post-market study required by the FDA.

In 2015, the GAO released its findings on a study requested by Congresswoman DeLauro which revealed that following a FDA post-market safety study request, companies lack incentive to enroll participants and are slow to report findings. The Bayer post-market study on Essure has held true to those GAO findings. In the post-market study plan released by the FDA in March of 2016, Bayer planned to enroll 78 patients per month when all approved sites were activated. According to the FDA website, there are currently 60 approved sites but only one patient has been enrolled in the study.

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In order to address our concerns over the progress of the post-market study we hope to address the following questions at our meeting:

1. What is the FDA doing to ensure Bayer complies with the timeline for recruiting patients outlined in the study plan?
2. Bayer has announced publically that 100 patients have been enrolled in the Essure post-market safety study. When will the official number of patients enrolled be released?
3. How many of the 60 approved sites are actively recruiting patients?
4. How is Bayer ensuring that potential participants are informed about the black box warning? How is this being documented?
5. Will participants be tested for a nickel allergy before enrolling in the study? If they decline to implant women with suspect nickel sensitivity, does this skew the data for the percentage of women who suffer an adverse reaction to the device? Will the nickel contraindication be placed back onto the current labeling for Essure?

The FDA is the leading regulatory authority on medical device safety, and as such, should uphold its responsibility by requiring Bayer to complete the post-market study in a timely fashion. We ask that you enforce accountability measures to ensure that participants are enrolled in the post-market study in a reasonable timeframe in order to complete the post-market study as scheduled so the risks associated with the Essure device will be documented and made public. We look forward to discussing our concerns about Essure post-market surveillance and the other issues surrounding Class-III devices with you at a meeting within the next month. Please contact Ryann Kinney, scheduler in the office of Congresswoman DeLauro, at rosadc.schedule@mail.house.gov, to schedule a meeting. We look forward to hearing from you soon.

Sincerely,

Rosa L. DeLauro
Member of Congress

Jan Schakowsky
Member of Congress

Louise M. Slaughter
Member of Congress