MICHAEL G. FITZPATRICK
8TH DISTRICT, PENNSYLVANIA

COMMITTEE:
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OVERSIGHT AND INVESTIGATIONS
VICE CHAIRMAN

FINANCIAL INSTITUTIONS
AND CONSUMER CREDIT

Congress of the United States
House of Representatives
Washington, DC 20515–3808

WASHINGTON OFFICE:
2400 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515
(202) 225-4276
FAX: (202) 225-9511

DISTRICT OFFICE:
1717 LANGHORNE NEWTOWN ROAD, SUITE 400
LANGHORNE, PA 19047
(215) 579-8102
FAX: (215) 579-8109

Jeffrey Shuren, M.D., J.D.
Director, Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

February 17, 2016

Dear Dr. Shuren,

As you are aware, thousands of women have filed formal complaints to the Food and Drug Administration regarding the permanent contraceptive device Essure. These injured women have reported numerous symptoms related to this FDA-approved device, such as extreme pelvic pain, allergic and immunological reactions, heavy bleeding, unexplained weight gain, loss of teeth and hair, and broken coils migrating throughout their body and puncturing internal organs.

Tragically, this device has also killed innocent women and unborn children. The FDA's public materials related to Essure have cited five reports of fetal deaths.

However, my office is in receipt of a review of adverse event reports related to Essure, conducted by women harmed by this device and an adverse event data expert. This independent report counts 303 fetal deaths. A copy of this report is enclosed.

In light of this immense discrepancy, I request that the FDA conduct a thorough review of this document and all of the adverse event reports received by those harmed by Essure as part of FDA's on-going review of this medical device.

Additionally, my office is in receipt of an unsealed complaint filed in the U.S. District Court for the Northern District of California which named the United States of America, 27 States, and the District of Columbia as plaintiffs against Conceptus, Inc., Bayer AG, Inc. and Bayer Healthcare, LLC. A copy of the complaint is enclosed.

The complaint alleges that the manufacturer of Essure gave substantial and illegal financial inducements to providers to encourage them to use Essure, a procedure that costs the government almost $3,500 per patient.

According to the complaint, the manufacturer of Essure provided illegal kickbacks in the form of free medical equipment valued at $20,000. Additionally, the complaint alleges that the manufacturer of Essure would set up "referral lunches" to generate business by connecting primary care physicians and Ob/Gyns to create what the manufacturer called "coin-operated doctors," designed to lead to the

increased use of Essure. Furthermore, the manufacturer provided free marketing and advertising services to Ob/Gyns to encourage them to use Essure on their patients.

These alleged illegal kickbacks cost the taxpayers millions of dollars due to false claims against government healthcare programs such as Medicare, Medicaid and Tricare.

In addition to the review of 303 fetal death reports, I request that the allegations of illegal kickbacks filed against the Essure manufacturer also be included as part of the review being conducted by the FDA.

Should you have questions regarding either of these documents, please do not hesitate to reach out to Justin Rusk in my office at 202-225-4276.

Sincerely,

Mike Fitzpatrick
Member of Congress

Enclosures: Fetal Deaths Report
Complaint Pursuant to the Federal False Claims Act