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To: **ALL Medical Specialties**

Emphasis Specialties:
Obstetricians /Gynecologists General Surgeons
Asthma and Allergy Specialists Internal Medicine Physicians Emergency Medicine Physicians
Pain Management Specialists Family Practice Physicians Primary Care Physicians
Psychologists/Psychiatrists Rheumatologists Gastroenterologists

Subject: **Notification of FDA MANDATE, ESSURE BLACK BOX WARNING (BBW)**

05/09/18

Dear Colleague,

My name is Dr. Julio Cesar Novoa, M.D. I am a practicing OB/GYN and a medical consultant working pro-bono with a number of social media forums, including the **UNITED STATES ESSURE PROBLEMS** Facebook forum, as well as, a number of international Facebook forums associated with medical complications of the ESSURE Permanent Birth Control device. The number of members in these social media forums now exceeds 40,000.

The forums have been notified that you are offering the placement of the ESSURE Permanent Sterilization device.

There have been concerns and complaints that doctors placing the device are not notifying their patients about the Bayer and FDA Mandate regarding the ESSURE Black Box Warning (BBW) and Patient Checklist.

We have been advised that at least one of your patients has stated that you are providing information about the ESSURE without discussing the Black Box Warning (BBW) and Patient Checklist.

The rapid and proper dissemination of this information may have been an oversight on the part of the FDA and Bayer to properly notify you.

Currently, the ACOG is challenging the ESSURE Mandate. This lack of cooperation does not mitigate the responsibility of each physician managing and placing ESSURE to properly inform their patients regarding the potential risks, side-effects and complications of the device. In order to avoid medicolegal issues, we are notifying you of this mandate and request that you modify your Informed Consent protocols, management and advertisement of the ESSURE device accordingly.

Below are the current online links to FDA regarding the Black Box Warning (BBW) and Mandate.

US FDA/Bayer Black Box Warning (BBW)
WARNING: Some patients implanted with the ESSURE System for Permanent Birth Control have experienced and/or reported adverse events, including perforation of the uterus and/or fallopian tubes, identification of inserts in the abdominal or pelvic cavity, persistent pain, and suspected allergic or hypersensitivity reactions. If the device needs to be removed to address

such an adverse event, a surgical procedure will be required. This information should be shared with patients considering sterilization with the ESSURE System of Permanent Birth Control during discussion of the benefits and risks of the device. (http://labeling.bayerhealthcare.com/html/products/pi/ESSURE_pib_en.pdf)

"On April 9, 2018, the FDA restricted sales of the Essure device to only doctors and healthcare facilities who use the FDA-approved "Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement". Sale and distribution of Essure is limited to healthcare providers who agree to review this checklist with patients, and give them the opportunity to sign it, before Essure implantation. The FDA has approved this new safety measure to ensure that the device meets our standards for a reasonable assurance of safety and effectiveness.

The FDA also approved Bayer's new labeling that includes:

- The following statement: "The sale and distribution of this device are restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Bayer."

- Bayer's Patient-Doctor Discussion Checklist – Acceptance of Risk and Informed Decision Acknowledgement, which is part of the patient information booklet, and has key items about the device, its use, and safety and effectiveness outcomes, which the patient should be aware of as they consider permanent birth control options."

(https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm)

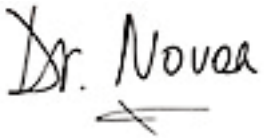
It is clear that current international data and the FDA/Bayer BBW mandate raises concerns about ESSURE and its significant risk factors that must be considered, discussed and properly managed. These complaints should not be dismissed as normal gynecological problems, especially symptoms associated with abnormal bleeding, pelvic pain or allergic/autoimmune symptoms.

Due to the complexity of the foreign body reaction and potential life-threatening risks of removal, the management of ESSURE complications warrants a multidisciplinary approach to patient care.

We, within the forums and your patients, would like you to be aware of the current situation regarding the ESSURE and the proactive notification by patients of doctors not complying with the mandate to the FDA and the medical boards of their physicians.

Disclosure: No conflicts of interest to report regarding this written opinion

Sincerely,



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ESSURE PROBLEMS Facebook forum