Julio Novoa, M.D.
10871 Pebble Hills Blvd.
El Paso, TX 79935

Bayer HealthCare
Pharmaceuticals Inc.
100 Bayer Boulevard
Whippany, NJ 07981

Dear Julio:

You and I share a commitment to women's health and, for that reason, feel it is necessary to follow up with you about our permanent birth control device, Essure. We at Bayer care deeply about women's health, which is why we strive to provide women safe and effective options to make decisions about their families and reproductive futures. We have seen some of your statements on the internet, your YouTube video, and your letter directed to human resource departments at unidentified companies. We feel it is necessary to correct a number of misstatements you have made about Essure. We are sure you agree that women's health decisions should be made on the basis of accurate facts.

First, as you know, the Food and Drug Administration (FDA) held a public meeting of the Obstetrics and Gynecology Devices Panel Advisory Committee on September 24, 2015 ("Ad Comm"). In a letter dated October 25, 2015, posted on your public Facebook account, you repeat allegations of "improper or fraudulent data collection during the original trials which was used to obtain Class III premarket approval from the FDA." These allegations are untrue. Bayer takes claims of clinical trial misconduct seriously, but the FDA also has disputed the allegations:

> The FDA is aware of allegations from women who participated in the original Essure clinical trials that the feedback they provided about the comfort wearing the device was not recorded accurately by clinical staff. As part of the original PMA approval, **FDA performed inspections at Conceptus and one clinical site**. **These inspections audited data** provided in support of the PMA, as well as sponsor activities during the studies, **and did not report findings concerning the case report forms or patient comfort/satisfaction data submitted in support of the PMA.**

FDA Review Document at 19 (emphasis added).[1] In addition, Bayer has investigated the records in question. We found no evidence of improper or fraudulent data collection. The trial site itself has been asked about these allegations in the press. They responded that ". . . . The information recorded was provided by the patient." FDA also has begun auditing Essure clinical trial data, beginning with the transvaginal ultrasound study, and FDA's own investigation, to date, has led it to reject these allegations. As Dr. Julia Corrado, FDA Division of Reproductive, Gastro-Renal, and Urological Devices, explained at the Ad Comm, the FDA "concluded that **there was not a pattern of discordant reporting**." Transcript at 226-27 (emphasis added).[2] In sum, the Essure clinical trials followed standards of Good Clinical Practice.

Second, we are concerned about erroneous statements in a YouTube video you made about supposed deaths from Essure placements. In the YouTube video you allege that there have been multiple deaths from Essure and Essure placement. Bayer reports

[1] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM463486.pdf
[2] http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/ObstetricsandGynecologyDevices/UCM467456.pdf

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adverse events to FDA consistent with FDA regulations. Bayer is not aware of any deaths directly related to the Essure device. Similarly, we are not aware of reports in the medical literature of any deaths directly related to the Essure device. As you would agree, all procedures in medicine carry risks. It is not good clinical practice to make unfounded claims without putting the evidence in context and how it may compare to other procedures or options. That would undoubtedly put patients at risk.

Third, we have seen multiple statements from you using the terms "ESSURE Induced Abortion" and "E-babies," but we have not seen you cite any references and we want to be sure your audience is not misled by inflammatory terminology. It simply is not accurate to say, as you do, that ESSURE has "exceptional high rates of failure leading to ESSURE Induced Abortion…ectopic pregnancy and premature delivery of ESSURE babies (E-babies)." Clinical trial data shows that Essure is highly effective once a confirmation test shows appropriate placement and tubal occlusion. Several published papers also demonstrate Essure's high efficacy rates, with five studies based in the U.S. overall showing an efficacy rate of 99.2%: Anderson (2013), Howard (2013), Deraleu (2012), Savage (2009), Shavell (2009), and Levie (2006). Further, as of the FDA Ad Comm, postmarket monitoring reported an overall pregnancy rate of 0.21%. The pregnancy rate with Essure compares favorably with that of surgical sterilization and is lower than the rate with several other forms of contraception.

The medical literature on pregnancy outcomes with Essure primarily comes from closely monitored conception after Assisted Reproductive Technology[3] and does not report high rates of premature membrane rupture, preterm labor or delivery, or serious complications. Moreover, postmarket reports indicate that other adverse events (e.g., miscarriage, stillbirth, preterm delivery, fetal anomalies) are within the background rate for pregnancies in similarly aged populations.

We are particularly concerned that you may be creating an atmosphere of unfounded fear, and that you may be encouraging women who are not experiencing adverse symptoms from Essure to seek removal of Essure. We know that you are referring women to your friends for removal, as well as advertising your own removal services. We would hope that you agree that urging women to have surgery based on fear, rather than evidence, may be dangerous to women's health. And without appropriate physician-patient relationships and full knowledge of their medical history, one certainly should not endeavor to do so through social or traditional media. I ask you, as a fellow physician, to carefully consider these concerns.

[3] Essure is not indicated or labeled for use in this manner. Essure is approved by the FDA for women who desire permanent birth control (female sterilization) by bilateral occlusion of the fallopian tubes. Bayer does not promote or endorse off-label use of any of our products. We encourage healthcare providers to refer to the FDA-approved Instructions for Use (IFU) available here to guide appropriate use of the product.

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In conclusion, Bayer takes patient safety very seriously. That is why we provide accurate and complete safety information about Essure and all of our products. The information is based on real data that is analyzed by our internal experts along with the FDA and agreed upon with the FDA and their review committees. We were open and transparent at the FDA Advisory Panel meeting in September and presented a thorough review of the available data. More importantly, the data we presented was consistent with the data the FDA presented from their thorough review. We request that you stop perpetuating misunderstandings and misinformation about Essure and its safety. Overall, data from the extensive clinical program, peer-reviewed literature, and continuous postmarket monitoring support the safety and efficacy of Essure. Bayer stands by Essure as an important option in permanent contraception for women who have completed their families.

You and I have communicated numerous times over the past two years and even had a very detailed face to face discussion at ACOG's 2015 Annual Meeting. I have always been honest and transparent with you and have been willing to provide you with any information you request. I once again invite you to reach out to me if you have further questions about the facts and studies referenced in this letter or still have any concerns or questions you would like addressed. We anticipate that as a physician, you will support an evidence-based approach to important decisions of women's health.

Sincerely,

Edio Zampaglione, MD
Vice President, US Medical Affairs – Women's HealthCare
Bayer HealthCare Pharmaceuticals