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Dear Edio,

I am writing this letter in response to your letter of concern which I received by email on December 16, 2015.

I appreciate you notifying me of your concerns regarding the allegations of improper or fraudulent documentation of patient responses on their surveys during the ESSURE PMA clinical trials. However, I am deeply concerned and disappointed with the position of both Bayer and the FDA as to the validity of their most recent audit, as well as, the acceptance of the fact that discordance in documentation is acceptable because it appears to represent a low number of cases.

I would beg to differ. **ANY** discordance in data collection is **NEVER** acceptable and when it is found to exist, the most prudent and logical response is to invalidate the entire study.

As you are aware, I attended the September 24th, 2015 Obstetrics and Gynecology Device Panel Advisory Committee (Ad Comm) meeting and was witness to the allegations presented by patients who stated that their responses were altered by the surveyors or trial center in order to give the impression that the ESSURE device is safer with fewer side-effects and complications than actually exists.

These allegations had previously been presented to the FDA by PMA trial patients which is one of the main reasons that the FDA attempted to review the merits of these allegations before the meeting and present their findings to the Ad Comm on the September 24th, 2015.

Unfortunately for both Bayer and the FDA, the Ad Comm investigation provided absolutely no credible evidence to negate the allegations presented by the patients from the PMA trials. Despite the fact that Bayer claims that the allegations are not true (paragraph 2 of your letter), Bayer has yet to provide any facts negating the allegations.

In paragraph 3 of your letter, you state that the FDA has disputed the allegations by stating that during the original PMA approval process, the ***"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."***

Firstly, the allegations of improper or fraudulent data collection did not surface during the PMA audit process; and, therefore, the FDA had no reason to do more than a superficial and limited evaluation of the data in terms of whether or not the data that was submitted to the FDA matched the data that was documented in the surveys presented by the trial centers. However, based on the allegations presented by patients who participated in the PMA trials, it is obvious to them, that the survey information that they stated to the surveyors was not truthful or accurate regarding the serious complications that these patients were having with the ESSURE device. These patients allege that there was an intentional falsification of patient information AT THE TIME OF DATA COLLECTION AND/OR DOCUMENTATION. If this is the case, the only manner for Bayer or the FDA to have detected a discordance was to have directly contacted each patient named in the audit and confirmed that each of their responses matched what the surveyors entered into the data pool. Unless the FDA specifically did this during its audit, there is no way to confirm that alteration or falsification of data did not occur.

Further, it is important to understand why there was a time delay in the surfacing of these allegations. Based on the testimony of these trial participants, they were not aware that their responses did not match what was documented by the surveyors until the patients reviewed their medical records or the patient comfort/satisfaction data response sheets provided to them under Freedom of Information and Release of Medical Records laws, years after the study(studies) was(were) completed.

In regards to the allegations of alteration/false documentation submitted at the **patient comfort/satisfaction data level**, how did either Bayer or the FDA determine the accuracy of the data documented and submitted by the clinical staff on behalf of patients compared to what the patients actually stated as opinions or points of fact? If we are to determine the validity or truthfulness of such allegations, how would the audits done by either Bayer or the FDA disprove these allegations as you state in paragraph 2 of your letter?

Did Bayer or the FDA contact the patients listed in the audit to confirm that their survey opinions/comments matched the information submitted by the trial surveyors and/or trial centers?

Based on the minutes presented at the Ad Comm meeting, not only was this not done, it simply could not have been done. I am very surprised that you have used the testimony of Dr. Julia Corrado to defend Bayer's position on this matter. Not only is the quoted testimony of Dr. Julia Corrado in paragraph 4 of your letter not relevant regarding the allegations of improper or fraudulent data collection during the PMA trials, it is taken completely out of context in regards to the determination of discordance during the PMA trials and only serves to catastrophically cripple both Bayer's and the FDA's defense on the subject.

Specifically, on page 225 of the minutes, Dr. Corrado states that during the FDA's investigation of the allegations of fraudulent data collection, the FDA attempted to audit the case report forms from the Phase II and pivotal studies and the FDA was not able to.

"So when FDA became aware of this issue at the time of the meeting we had with some patients who had bad experiences with the product, we took it very seriously, and we looked into whether it was possible to audit all of the case reports from the Phase II and pivotal studies, and we were told that these forms are not required to be maintained beyond a few years. So that was not possible for us to do. What we did do is we were in the process of reviewing the--a later IDE study for the transvaginal ultrasound protocol, and that study enrolled approximately 600 women."

Therefore, despite the fact that Bayer states that the allegations are untrue, it apparently has NO CASE REPORTS that can be audited from the PMA trials, or, if they do exist, it has not provided them to the FDA for review.

So what is Bayer's position on this? Since it claims that, ***".....Bayer has investigated the records in question (FDA, Conceptus site inspection audit). We found no evidence of improper or fraudulent data collection…..,"*** I find Bayer’s position to be without merit.

How did Bayer evaluate site inspection records without a review of PATIENT CASE REPORTS, which apparently no longer exist, and, due to the absence of these records, was the reason the FDA had to review a more recent IDE study rather than the original PMA data?

If the PATIENT CASE REPORTS were available for review, why were these not turned over to the FDA, Dr. Corrado and the Ad Comm for review?

Further, how can either Bayer or the FDA defend its position of the validity and accuracy of the PMA data collection process by comparing it to a completely different study which did not include the original PMA patients nor any information from the original PMA studies?

Is Bayer's and the FDA's position so weak as to require the proverbial "Grasping at Straws" defense by basically stating that "Since I don't have any information to defend my behavior on the date in question, let me present evidence on what I was doing 5 years later for you to consider." Really????

Is this the Bayer corporation's defense of Conceptus and explanation on not being able to provide any direct evidence to defend against the allegations of women who have claimed to have been permanently scarred by the ESSURE device?

Is Bayer actually using the results of a non-PMA IDE study review that showed the presence of discordance to rebut the sworn testimony of fraud by patients that actually participated in the PMA trials????? If so, such a position, is to say the least, embarrassing and only serves to support the opinions of thousands of women that the PMA clinical trials and subsequent inferences from data collected by Bayer fail to meet the minimum standards of acceptable data collection.

If it is true that patient medical records from the ESSURE PMA clinical trials were destroyed, this is, in my opinion, **a significant violation of the public trust, especially considering the fact that the ESSURE device was granted Class III premarket approval**. As a standard of professional practice, NO DOCUMENT for a Class III device should have **EVER** been destroyed and should have been kept indefinitely in the archival records of the Conceptus/Bayer corporation(s) and/or the FDA.

Standard protocol for patient survey documentation requires that the patient fill out the survey, sign and date the survey and that the surveyor give a copy of the survey back to the patient, as well as, keep a copy of the survey in the medical records of the patient, since a survey, regardless of the reasoning, is an evaluation of patient response to a procedure or treatment and is part of the medical records. In this manner, clinicians and doctors, avoid accusations/allegations of incorrect documentation, or intentional alterations of patient responses by having the patient sign the Review of Systems (ROS); or in this case, survey of patient comfort/satisfaction. Was this done regarding the audited information or the information for each patient in the trials? If not, any statement by a trial center that the responses were "those of the patient" fail to confirm this as a point of fact and fail to provide any evidence that what the patient actually stated was accurately documented in the survey data. The discordance could be extreme, which is the reason that such a disparity of position exists between the patients' opinions and those documenting those opinions, which is why allegations of fraud now exist.

In the Ad Comm minutes (p. 226), Dr. Corrado states that their investigation of the IDE study suggested at least 6 cases of discordance in patient record keeping. Not only does this merit a more thorough investigation of the IDE study, but demands the consideration that any published journal articles using this data should be immediately retracted until a forensic audit of the study can be done.

Even more troubling than the defense of Bayer regarding the allegations of fraud during the PMA trials by using an audit analysis of an IDE study in its stead, is the fact that Bayer seems to suggest the presence of discordance in patient record keeping is acceptable as long as, ***".....there was not a pattern of discordant reporting.***" This defense is simply incomprehensible to me. Is Bayer or the FDA suggesting that discordance (fraud?) is acceptable as long as the incidence is low or not based on a pattern??? If 6 out 600 reports were associated with discordance, which represents 1% of cases, would Bayer consider this to be an acceptable level of fraud? If so, does Bayer feel that if PMA trial records supported the same percentage of discordance, this would be an acceptable situation considering the potential life-threatening repercussions to women that such a discordance would cause? I think not, nor do I believe that the general public would agree with any person, group or corporation stating that discordance at any level or degree is acceptable.

Further, the fact that ANY discordance was found in the IDE study only bolsters the credibility of the allegations and general public opinion that discordance (fraud?) could have existed during the PMA trials, especially considering the significant conflict of interest that existed by those in a position to alter the patient data that was collected.

Of course, the damage could be mitigated if Bayer would provide the medical records and survey materials from the PMA trials in their entirety for independent and unbiased review to rule out any discordance as alleged by the patients in question. Where does Bayer stand on this request?

Additionally, based on the fact that Dr. Correa and the Ad Comm was not provided the original patient survey information from Bayer for review from the PMA trials, I have serious concerns and questions regarding what information was available from the PMA trials which was used by Chudnoff, Nichlos and Levie in their paper, published 13 years after the PMA trials. Does discordant data also exist in this publication unbeknown to the authors, and if so, should this journal publication be retracted until a forensic audit can be done? (Chudnoff SG, Nichols JE Jr, Levie M. Hysteroscopic Essure inserts for permanent contraception: extended follow-up results of a phase III multicenter international study. J Minim Invasive Gynecol 2015;22:951-960)

Moving on to your second comment regarding my YouTube.com videos. In your fifth paragraph, you misstate that I said that there have been supposed deaths from the placement of the ESSURE. I state in my videos that there has been at least one reported death which occurred during the **surgical procedure** of the ESSURE; as well as, numerous ESSURE device failures leading to pregnancy which, in turn, have been associated with miscarriage, ectopic pregnancy, and life-threatening complications to the conceptus (fertilization, embryo, fetus, or neonate), as well as, the patient. It is sadly ironic that Conceptus Inc, creator of the ESSURE device, named itself after the medical term **for a pregnancy**, which the ESSURE was designed **to prevent**. Or is the irony in the fact that the exceedingly high failure of the ESSURE may actually represent what it is actually doing, which is the opposite of what it is designed to do, which is prevent a conceptus?

You also state that, ***"....Bayer reports adverse events to FDA consistent with FDA regulations."*** I believe this comment to be disingenuous.

Is it not true that in the past 2 years Bayer has admitted that an Excel file containing 16,047 adverse reports from patients with the ESSURE device originally kept by Conceptus, Inc was not provided to the FDA consistent with FDA regulations?

On page 228 of the minutes of the Ad Comm meeting, Dr. Andrea Machlitt (Bayer HealthCare, Global Pharmacovigilance) stated that of 17,563 adverse reports listed in the Bayer global safety database, ***"....United States accounts for about 15,000 of these reports..."***

Do these reports, stated by Dr. Machlitt, include the Excel file containing 16,047 adverse reports? Or are we to assume that the total number of adverse reports held in the Bayer database exceeds 32,563?

If either is the case, how is it possible that Bayer has not insisted that these reports be included in the MAUDE data??? Currently, 5000+ adverse reports are listed in the MAUDE data. Why, if Bayer is reporting to the FDA, **"....consistent with FDA regulations…"** why does it appear that the MAUDE data does not include these adverse reports???? **Why are we again debating another example of discordance in data documentation regarding Bayer and/or the FDA??**?

Since Bayer purchased Conceptus in 2013, Bayer is legally responsible for correcting the corporate errors created by Conceptus regarding this subject. Bayer, as a multi-billion dollar corporation with practically

unlimited resources, and one that claims to have thoroughly investigated the allegations of fraud, should have had no difficulty in properly documenting these 16,047 adverse reports and have them included in the MAUDE data, rather than only the 5000+ adverse reports currently documented in the MAUDE data. In order to be ***"...consistent with FDA regulations…,"*** at a minimum, Bayer could and should have made sure that the adverse reports as stated by Dr. Machlitt, were documented in the MAUDE data. Why has there been a delay in this documentation considering the fact that Bayer has been aware of the Excel file for more than 2 years, if Bayer has been doing everything possible to make sure that the general public is fully aware of problems with the ESSURE device?

If we are to accept the premise that, ***"...Bayer is not aware of any deaths directly related to the Essure device...,"*** this does not negate the premise that the ESSURE has been **associated** with these outcomes.

As a practicing OB/GYN, I am keenly aware of the risks associated with any medical procedure and after 3 years of review of available data, my opinion regarding the ESSURE device has not changed. The ESSURE device poses too high a risk of potential and actual complications to recommend it for use as a permanent form of birth control.

Further, I take offense to your comment that, ***"It is not good clinical practice to make unfounded claims without putting evidence in context and how it may compare to other procedures or options. That would undoubtedly put patients at risk."***

Firstly, my comments are not unfounded claims. They are based on a review of the complaints from patients that I have advised or treated with problems with the ESSURE; and based on the allegations from hundreds of patients posting their personal experiences online; as well as, the thousands of patients that signed a petition to have the ESSURE device immediately removed from the US market whose concerns are delineated in the 32 page Citizen Petition filed with the FDA on February 20, 2015 by the Kock Parafinczuk & Wolf, P.A.

On the contrary, I opine that it is not good clinical practice for Conceptus to have based the PMA approval of the ESSURE on two non-randomness, non-blinded, prospective studies that lacked a comparator group and enrolled only 926 women in the Phase 2 and Pivotal study groups. Of those enrolled, only 745 underwent the procedure, a loss of 19.5% of the original study group participants.

It is not good clinical practice for Bayer to have promote the safety and reliability of the ESSURE on an **non-intention-to-treat analysis** and with a **consideration of only women who had successfully undergo the procedure and had 3-month hysterosalpingograms showing correct placement of the ESSURE and bilateral tubal occlusion.**

It is not good clinical practice for Bayer to promote the validity of a study that systematically eliminated patients from the study that produces a biased exclusion criteria which inevitably gives a safety and effectiveness profile which is far from accurate.

If a study were to intentionally filter out results that would give the false impression of a high rate of safety and efficacy, would this not be considered a false claim?

The fundamental weaknesses of the PMA trials and subsequent studies are the significant rates of attrition of participants. This is that the same pattern of attrition seen in the Survey On Use and Characteristics of Definitive Contraception with Essure (SUCCES II)?

In your presentation to the Ad Comm meeting in September 2015 (page 7), the original N value of participants was 2600, yet when reviewing the 3 month and 2 year interval regarding patient satisfaction, the number of participants had dropped to 2281 and 1219, respectively. This suggests and 12.3% and 53%

discrepancy in patient responses regarding critically important questions regarding complications to the ESSURE, such as, post-operative pain and bleeding associated with the ESSURE.

More recent journal publications regarding safety and efficacy of the ESSURE suggest unacceptably high rates of device failure leading to pregnancy, miscarriage, premature rupture of membranes; as well as, post-operative surgeries to correct side-effects to the ESSURE device to include major surgery requiring general anesthesia, such as salpingectomy, salpingotomy and hysterectomy.

- Gariepy (2014), Contraception: This study from Yale and UC Davis found that the risk of pregnancy among women using Essure is more than 10 times greater over a 10-year period than using the more commonly performed laparoscopic sterilization. Total pregnancy rate is estimated at 96 per 1,000 with ESSURE compared to 24-30 per 1,000 laparoscopic tubal ligation.
- Sedrakyan (2015), British Medical Journal (BMJ): This study by researchers from Cornell University in New York and funded by the National Institute of Health and the Food and Drug Administration (FDA) compared 8,048 of whom were treated with hysteroscopic sterilization and 44,278 with standard sterilization. The study found that women who had undergone the ESSURE procedure were 10 times more likely to need a repeat operation within a year – equalling around in 1 in 50 women.
- Dhruva (2015), New England Journal of Medicine: This journal article is highly critical of the PMA ESSURE approval. ***"...Given the limitations of the relevant studies, it's not surprising that so many years passed before safety issues with Essure were recognized. To identify adverse events occurring in day-to-day practice, the FDA examines reports voluntarily submitted to its MAUDE database. Although passive adverse-event reporting is known to underestimate adverse-event rates, as of June 2015, a total of 5093 adverse-event reports related to Essure had been made to MAUDE, most of which listed multiple safety concerns. These reports led the FDA to update the device label in 2013 to include information about risks of chronic pain and device migration and to reconvene its Obstetrics and Gynecology Devices Panel to reassess safety and effectiveness. Though Essure offers possible advantages to women seeking sterilization, the evidence suggests that it is neither as effective nor as safe as the premarketing-approval evaluation indicated. An intention-to-treat analysis using a Markov model and incorporating all relevant available data, including data from the manufacturer and elsewhere, suggests that there's a 5.7% annual risk of pregnancy after hysteroscopic sterilization,4 and in 2012 the instructions for use of Essure were updated to acknowledge the occurrence of hundreds of unintended pregnancies..."***

Although I agree that efficacy rates in some published studies show rates of sterilization as high as 99.2%, these efficacy rates are associated with ideal study parameters rather than real world scenarios. They generally do not include 3 major factors which, I opine, the authors and Bayer have put little emphasis on in a real world assessment of why the ESSURE has pregnancy rates 10 times higher than what is stated by Bayer and the authors you mentioned.

These factors include the fact that:

- the rate of efficacy is calculated without including the failure rates of proper insertion.The studies you mentioned listed insertion failure rates of between 1-3%. There was greater than 14% improper insertion rate in the PMA trials, as well as, an over 26% delivery catheter malfunction rate (Loffer, 2013)
- high failure rates are claimed to be due to the failure of the patient to keep follow-up appointments or complete the HSG confirmation test, which did not appear to be the case in the studies you noted, but are an unavoidable reality in the real world when doctors place the ESSURE device in patients, especially Medicaid patients, knowing that the patient will lose their insurance before the 3 month HSG confirmation test can be done.

- failure is due to the incompetency of the surgeon inserting the ESSURE. In the studies cited, competency does not appear to be a concern. Based on the number of insertions, these studies involve expert-level hysteroscopic surgeons. This is not the case in the real world, where a significant number of surgeons are improperly placing the ESSURE because of improper training.

These explanation do not negate the fact that the ESSURE is difficult to place even by expert- level hysteroscopic surgeons and no study that I am aware of is considering the high risk of delivery catheter malfunction which put patients at significant risk of intra-operative and post- operative complications.

Improper insertion and delivery catheter malfunction appear to account for over 20% of complications with the device and significantly offset any benefit promoted by a high efficacy rate. This represent a critical flaw in any promoting of efficacy of the ESSURE by either the authors of the studies you cited.

Bayer claims that, ***"...Clinical trial data shows that Essure is highly effective once a confirmation test shows appropriate placement and tubal occlusion…,"*** is equally flawed in its logic.

The risk vs benefits of a device must include potential and actual adverse side-effects from the moment the device is attempted to be inserted in the human body. Cherry-picking case reviews that do not include complications with the device to include malpositioning and device malfunction is unacceptable and unethical. **It is comparable to a company promoting the safety of a parachute by claiming a 99.2% safety rating once the chute properly opens but does not include in its calculations the fact that it fails to properly open over 20% of the time.**

Loffer made an excellent point regarding his review of the 2002-2012 ESSURE MAUDE data by stating, ***".....The MAUDE data are not intended to be used to establish rates of adverse events, but they are useful for clinicians because they cover infrequent complications that may not be published and/or those that may not come to light until substantial clinical experience with a device has accrued."*** The flaws with limiting your references to medical journal publications is the fact that complications with the ESSURE are far more common than are either listed in the MAUDE data or medical journals. The real world complications of the ESSURE are far worse than have been published or even imagined.

Although Loffer noted a significantly high rate of ESSURE device failure leading to ectopic pregnancy, he made no comment on the outcome of other types of pregnancy which should have included miscarriage, second and third trimester abortion, stillbirth, premature delivery, and premature rupture of membranes (PROM) leading to preterm delivery.

Loffer report reviewed only 457 adverse reports in his commentary spanning a period from 2002- 2012. Since 2012 and in a span of only 3 years, the number of adverse cases reported in the MAUDE data has increased 10-fold. Although the MAUDE data may include failure of ESSURE leading to abortion or eventual delivery, it does not include separate categories for each and, therefore, neither the PMA, MAUDE data or subsequent studies address these concerns. Despite the fact that the ESSURE is not 100% effective, **the potential risks of ESSURE failure to the conceptus and patient and the outcomes to the patient's baby have never studied.**

Taking into consideration the advertised and often quoted number of 750,000 kits sold, the number of expected failures can be estimated by the following:

- **750,000 kits sold x 0.21% = 1575 ESSURE failures leading to pregnancy**

However, real world number of failures leading to pregnancy is between 5-9% or 15x higher than traditional tubal ligation and can be estimated by the following:

- **750,000 kits sold x 5% = 37,500 or 750,000 kits sold x 9% = 67,500**

So in observing good clinical practice, what is Bayer and the FDA doing about the estimated 37,500-67,500 pregnancies are appear to be the real number of ESSURE failures and is Bayer studying the outcome of any ESSURE related births? If not, why not?

In fact, there appears to be no clinical study supporting your contention that ESSURE does not cause abortion, premature delivery and premature rupture of membranes comparable to tubal ligation or other forms of contraception. You cite Assisted Reproductive Technology (ART) and postmarket reports as evidence that miscarriage, stillbirth, preterm delivery, and fetal anomalies are within, ***".....background rate for pregnancies in similarly aged populations."*** Since no reference was given regarding the ART data, I assume that you are referring to studies regarding hydrosalpinx, in vitro fertilization (IVF), and the ESSURE. None of these studies are relevant to your comment regarding ESSURE failure pregnancies and certainly do not support your defense of the product.

My comments regarding Essure Induced Abortions and E-babies are based on the actual experiences of hundreds, if not thousands of women, who state that they have been injured by the failure of the ESSURE. Despite the fact that you or Bayer may consider these terms to be ***"inflammatory terminology,"*** they have become mainstream terminology of reference based on patient experiences. Whether or not some feel that the terms place the ESSURE in a negative light, it is a condition that the ESSURE and Bayer created for themselves based on the utter failure of the product and those that were in a position to protect the public.

Prior to the creation and use of the ESSURE, the terms, "spontaneous abortion and miscarriage" were used as terms to describe the **natural death of an embryo or fetus** before it is able to survive independently, most commonly up to a 20 week cutoff.

A miscarriage or abortion which a patient states was caused by the ESSURE device or when the ESSURE device is present is not a "natural death" and, therefore, neither of the aforementioned terms apply. Despite what Bayer feels, it can not ignore the fact that in the minds of many affected women with ESSURE failures which lead to the death of their babies, the term ESSURE induced abortions has now replaced spontaneous abortion as an accepted term of reference in these cases.

Further, in the over 600 cases of documented pregnancies, just within the ESSURE Problems forum representing approximately 25,000 members, the term ESSURE baby, or E-baby is a mainstream term which specifically describes the failure of the ESSURE device leading to pregnancy with an attempted continuation of the now high-risk pregnancy to term. The fact that the ESSURE has failed, regardless of the explanation from Bayer, is a point of fact. The fact that these ladies chose to describe their babies as E-babies is also a point of fact protected by the Freedom of Speech and the First Amendment to the US Constitution.

Is Congressman Mike Fitzpatrick's **"E-bill," revoking the PMA status and banning the sale of the ESSURE device, "inflammatory terminology?" Absolutely NOT**, since this is another example of a point of fact and accepted description of reference for the ESSURE.

Regardless of Bayer's opinion, it is remarkably hypocritical for Bayer to attempt to lecture me on the creation of fear and any financial gain on my part that Bayer appears to be implying I am getting from my comments and opinions regarding the ESSURE.

My opinions are founded in evidence supported by patient experiences, the MAUDE data, and a number of journal publications regarding the significant limitations of the ESSURE device compared to traditional tubal ligation. One of the duties of a physician is to properly inform the patient and public but even more important is for the doctor to be properly informed. My comments always include a recommendation for

the patient and her doctor to become more educated regarding her birth control options and the management of the complications of the ESSURE device. These include the surgical removal of the device **when there are clinically documented indications to remove the device.**

I do not recommend prophylactic removal of the ESSURE device and always recommend that patients manage their care with educated and experienced surgeons; not those that are simply Essure-certified (E-certified) and who chose to manage their patients without consideration for what is written in the procedural manual or based on the individual concerns of their patient.

The accusation of a conflict of interest for personal monetary gain is false and "inflammatory." My assistance on multiple national and international ESSURE problems forums takes up approximately 20% of time, yet generates less than 1% of the revenue associated with my practice.

My main concern is ALWAYS the patient. Management of patients ALWAYS includes a recommendation to manage their care starting with the doctor that inserted the ESSURE. Unfortunately, in many cases doctors are unwilling to help these patients that have legitimate problems. My recommendations for care to other doctors is based on their significant experience and compassion regarding the management of problems with the ESSURE and not because their are my "friends."

If Bayer were truly concerned about the current atmosphere regarding the ESSURE and its claims that it is doing everything it can for the benefit of women, why has Bayer still not changed its advertising of the ESSURE device as a **non-surgical** procedure despite the fact that it has always been a surgical procedure and the fact the Ad Comm agreed with me that the advertising should be changed?

As a fellow physician, what is Bayer really saying about itself when it continues to post advertisement claims that are clearly false and misleading?

What is Bayer saying about itself when it knows that inadequately trained doctors are providing improper care and management to women which make these women continue to suffer on a daily basis regarding the complications of the ESSURE to the point of destroying everything that they hold dear?

As a fellow physician, I have reviewed the evidence. I have considered the potential risks vs the benefits of the ESSURE compared every other form of birth control, and my opinion has not changed.

Conceptus failed to follow the regulation as required by law during the PMA process. Bayer has tried to correct the situation but has failed. The ESSURE device has failed to live up to its promotion. Every month, over 100 major surgeries are performed, just within the ESSURE Problems Facebook forum, due to ESSURE related complications.

In the wrong hands, even with your Board-certified, E-certified doctors, problems with the ESSURE can be life-threatening.

When it fails to do what is was promised to do, it is life changing and potentially life taking.

The risks to the general public warrant the immediate removal of the device from the US and international market. This is what is right. This is what is just. And, above all, this is what is honorable.

Sincerely,

Julio