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Reply to Fort Lauderdale Office

February 20, 2015

Dr. Margaret A. Hamburg
Food and Drug Administration
U.S. Department of Health and Human Services
5630 Fishers Lane, Room 1061
Rockville, MD 20852

CITIZEN PETITION

The undersigned submits this petition pursuant to 21 C.F.R. §§§§§ 10.30, 7.45, 814.46(a), 814.47, 814.82(c) and Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 352, 321 to request that the Commissioner of the U.S. Food and Drug Administration ("FDA"): (1) issue an order finding that Pre-Market Approval Order[1] ("PMA") for the medical device known as Essure has been violated; (2) issue an order requiring Bayer[2] to disclose the violations mentioned *infra* to the public; (3) issue an order finding that Essure is "adulterated" and/or "misbranded" and cannot be marketed, distributed, or advertised; (4) issue an order requiring Bayer to withdraw and issue a notice of retraction of the misleading representations outlined *infra*; (5) immediately revoke the PMA Order; (6) immediately place a temporary suspension on the PMA until an approval process free from fraud is completed; (7) amend the PMA Order to require Bayer to disclose the concealed violations mentioned *infra* or to include a black box warning that the PMA has been suspended and/or (8) initiate a recall due to gross consumer deception. These requests are being made for the safety of hundreds of thousands of women and so that the public and their doctors can make informed decisions and recommendations.

In short, the undersigned submits this petition for the following three reasons, which are fully explained *infra*:

First, the "expedited" PMA process for Essure was replete with **fraud on the FDA** including the **altering of medical records of trial participants**- medical records were altered to reflect (1) favorable data, including less pain then was experienced and (2) certain birth dates. Most egregiously, clinical trial participants' answers were **physically crossed out and changed by the applicant**[3] as it related to affirmative findings of pain, adverse events, unusual pain, and

[1] See Exhibit "A."
[2] "Bayer" includes Bayer HealthCare Pharmaceuticals, Inc., Bayer Essure, Inc., Bayer Corp., Bayer HealthCare, LLC and Bayer A.G.
[3] "Applicant" and "Holder" refers to Conceptus Inc. and Bayer due to the two company's subsequent merger.

unusual health related events. This is not a mere allegation of fraud but fraud supported by **sworn testimony** of several of **the actual clinical trial participants for Essure** which the PMA was based on. This type of fraud on you and the public cannot be ignored or tolerated. See Exhibit "B."

Second, the conditions of the PMA Order have been violated on several occasions. The relevant PMA specifically states, "**Failure to comply with conditions of approval invalidates this approval order.**" This is an order from the FDA which leaves no room for discretion. Citations and Form 483's memorializing the failures to comply with the conditions **issued from FDA** are attached as Exhibit "C."

Lastly, **several federal laws have been violated** as it relates to the manufacturing, control, and marketing of Essure. The specific federal laws are discussed *infra* and findings from the FDA memorializing the violations are attached as Exhibit "C."

A. ACTION REQUESTED

To prevent future complications and to promote the health, safety and awareness to women and their doctors across the United States, the undersigned respectfully requests that the FDA take the following action: (1) issue an order finding that PMA Order for the medical device known as Essure has been violated; (2) issue an order requiring Bayer to disclose the violations mentioned *infra* to the public; (3) issue an order finding that Essure is "adulterated" and/or "misbranded" and cannot be marketed, distributed, or advertised; (4) issue an order requiring Bayer to withdraw and issue a notice of retraction of the misleading representations outlined *infra*- including that Essure is a "drug"; (5) immediately revoke the PMA Order; (6) immediately place a temporary suspension on the PMA until an approval process free from fraud is completed; (7) amend the PMA Order to require Bayer to disclose the concealed violations mentioned *infra* or to include a black box warning that the PMA has been suspended and/or (8) initiate a recall due to gross consumer deception. The exact wording of the citation to the existing order is detailed *infra.*

The relevant PMA Order calls for strict compliance with federal law and the PMA Order. In fact, the relevant order **leaves no room for deviation <u>or for discretion in invalidating</u>** the same: "Failure to comply with conditions of approval **invalidates this approval order**.[4]"

In order to reap the benefits of such unfettered protection, the holder of the PMA must strictly comply with the order and federal law. Due to (1) the fraud used in obtaining the PMA that was committed **against you**, the FDA, and against women across America; (2) the documented violations of the conditions of the PMA; and (3) the violations of several federal laws and regulations, this PMA Order needs to be revoked immediately or temporarily suspended until a fair and "fraud-free" approval process has taken place, until Bayer is ordered to cease referring to Essure as a "drug," and until Bayer discloses all adverse events and violations to women across America.

[4] Note: The Order does not state "Failure to comply with conditions of approval *may* invalidate this approval order."

B. STATEMENT OF GROUNDS

I. Background and Interested Parties

This petitioner represents hundreds of women who were implanted with a female birth control device, known as "Essure." In short, the device is intended to cause bilateral occlusion (blockage) of the fallopian tubes by the insertion of micro-inserts into the fallopian tubes which then anchor and elicit tissue growth, theoretically causing the blockage. However, in many women, the devices **migrate from the tubes, perforate organs, break into pieces, and/or corrode wreaking havoc on the female body**.

II. PMA Process for Essure

By way of background, Premarket Approval ("PMA") is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. According to the FDA, Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury.

An approved PMA is, in effect, a private license granting the applicant (or owner) permission to market the device- assuming it complies with federal laws and is not "adulterated" or "misbranded."

FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is **normally longer**. Before approving or denying a PMA, the appropriate FDA advisory committee may review the PMA at a public meeting and provide FDA with the committee's recommendation on whether FDA should approve the submission.

However, the PMA process for Essure was **"expedited"** and several **trial candidates' medical records were altered to reflect favorable data.** According to the FDA, a class III device that **fails to meet PMA requirements** is considered to be **adulterated under section 501(f)** of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") **and <u>cannot be marketed, distributed, or advertised under 21 C.F.R. 814.80.</u>**

Further the PMA Order was subject to several conditions. In the PMA Order issued by the FDA, the FDA expressly stated, "Failure to comply with the conditions of approval **<u>invalidates this approval order</u>**." The following were conditions of approval:

- Within 10 days after the holder receives knowledge of any adverse reaction to report the matter to the FDA.

- Report to the FDA whenever it receives information **from any source** that **reasonably suggests** that the device **may have** caused or contributed to a serious injury.

- Effectiveness of Essure is established by annually reporting on the 745 women who took place in the clinical tests.

- Successful bilateral placement of Essure is documented for newly trained physicians.

- Warranties are truthful, accurate, and not misleading.

- Warranties are consistent with applicable Federal and State law.

Although failure to comply with just *one* of the conditions invalidates the PMA Order, The PMA holders failed to comply with *several* conditions; thereby invalidating the PMA pursuant to the very language of the PMA Order. Specifically:

- The PMA holder failed to timely provide the FDA with reports after twelve months, eighteen months and then a final report for one schedule. The holder also failed to timely submit post approval reports for its six month, one year, eighteen month **and** two year reports. All reports failed to meet the respective deadlines.

- The PMA holder failed to document successful placement of Essure concealing the failure rates.

- The PMA holder failed to notice the FDA of several adverse reactions and actively concealed the same. The holder **failed to report 8 perforations** which occurred as a result of Essure **and was cited for the same by the FDA** via Form 483.

- The PMA holder failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury. Again, the holder **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483.

- As outlined in "Gross Consumer Deception Warranting Recall" of this Petition, the PMA holder's warranties were not truthful, accurate, and not misleading.

- The PMA holder's warranties were not consistent with applicable Federal and State law.

- The PMA holder failed to notice the FDA of their internal excel file containing **16,047 entries of complaints since 2011.**

The holder was also found to be:

- erroneously **using non-conforming material** in the manufacturing of Essure and not tracking where it went;
- failing to use **pre-sterile and post-sterile cages;**
- manufacturing Essure **at an unlicensed facility**;
- manufacturing Essure for three years **without a license to do so**;
- Not reporting … complaints in which their product migrated;
- Not considering these complaints in their risk analysis for the design of Essure;
- Failing to document CAPA activities for a supplier corrective action;

Specifically,

- On January 6, 2011, the FDA issued a violation to the holder for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." **These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes.** The PMA holder were issued these violations for dates of incidents 9/1/10. 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.
- The holder had notice of 168 perforations but only disclosed 22 to the FDA.
- On January 6, 2011, the holder was cited for its risk analysis of Essure being incomplete. Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure **didn't include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity**.
- On January 6, 2011, the holder was cited for not documenting Corrective and Preventive Action Activities. Specifically, **the FDA found that there were failures in the holder's design. The FDA also found that the holder's CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures.** The FDA found that the holder's engineers learned of this and it was not documented.
- On July 7, 2003, the holder was cited for not analyzing to identify **existing and potential causes of non-conforming** product and **other quality problems.**

Specifically, two lot history records showed rejected raw material which was not documented on a quality assurance form, **which is used to track the data.** (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went)

- On July 7, 2003, the holder was cited for **not following procedures used to control products which did not confirm to specifications.**

All of the above violations are memorialized in the findings attached as Exhibit "C." In response, the holder admitted that "the device may have caused or contributed to a death or serious injury, and an MDR Report is required to be submitted to FDA." Essure's PMA was conditional. The FDA has memorialized that these conditions were violated on several occasions.

This PMA Order became "invalid" and the product "adulterated" and "misbranded," pursuant to (1) **the FDA-** due to the holder's failure to conform with the FDA requirements prescribed in the PMA Order and (2) violations of Federal Statutes and Regulations noted *infra.* Pursuant to the PMA (which reads: "**Failure to comply with conditions of approval invalidates this approval order**"), the C.F.R., and the FD&C Act:

- the PMA is invalid and should be withdrawn or temporary suspended; and

- the product is "adulterated" and "misbranded" and thus, **could not have been and should not be marketed or sold to the public** and should be recalled due to the gross consumer deception described *infra.*

In short, the PMA became invalid as the holder: (1) failed to meet regular reporting requirements; (2) failed to report known hazards to the FDA; and (3) failed to comply with Federal laws regarding marketing and distribution as specifically described *infra.* The fact that the holders failed to comply with these conditions is not a mere allegation. These failures to comply with both the PMA and Federal regulations are memorialized in **several FDA findings,** including Notices of Violations and Form 483's issued by the FDA.

III. Fraud in the PMA approval process

The FDA is responsible for protecting the public health by assuring the safety, effectiveness, quality, and security of medical devices. FDA regulations provide 180 days to review the PMA and make a determination. In reality, the review time is **normally longer**.

However, Essure went through an "expedited" approval process as it was touted as a major advancement in women's health as it could allegedly be done in office and with no incisions or "downtime." The petitioner recognizes that certain devices may obtain an "expedited track" status however; at no time should any PMA be based on fraud.

The PMA process for Essure was replete with **fraud on the FDA** including the **altering of medical records of trial participants**. Medical records of trial participants were altered to reflect (1) favorable data, including less pain then was experienced and (2) certain birth dates.

First, the medical records of Kimberly Hudak, a trial participant for the Essure device, were altered to reflect less pain then she was experiencing and **her answers were physically crossed out and fraudulently changed** by the applicant as it related to affirmative findings of pain, adverse events, unusual pain, and unusual health related events.

In fact, when Kimberly Hudak was reporting **severe pain** to the clinical trial doctor, Dr. Linda Bradley, the applicant was noting that Kimberly Hudak's level of comfort was "**excellent**."

Most egregiously, the **applicant physically crossed out Kimberly Hudak's actual responses in medical questionnaires and changed her responses** regarding whether she had experienced any adverse events, unusual pain, and unusual health related events. In one record, the applicant **crossed out Kim Hudak's unusual health related events to give the appearance as if there were none**. In other records, her responses were crossed out and changed by the applicant to reflect that she was not experiencing pain, adverse events, and unusual health related events. After altering the documents, **the applicant then initialed the alterations and submitted them to the FDA.**

In short, the applicant's trials were based on fraudulent findings. This is not a mere allegation but a statement supported by the sworn testimony of Kimberly Hudak. This cannot be ignored by the FDA. Kimberly Hudak has expressed a willingness to appear and testify in front of the FDA with the altered records in hand. See Exhibit "B." Unfortunately, this was not an isolated incident.

In June of 2000, during a determination/agreement meeting with the PMA applicant, the FDA agreed that it would "file the PMA **if the pivotal study…met specific age requirements**." See July 2002 Transcript of Device Panel Meeting attached as Exhibit "D."

With this in mind, the applicant again **altered medical records of its trial participants.** Specifically, the birth date of Patricia Reese was changed in her clinical trial records.

Patricia Reese's birth date was changed or somehow altered from 3/27/76 to 3/27/56, which raises the question as to why this was done? It is clear that the records were altered considering earlier records from the applicant's doctor conducting the trial studies contained her correct date of birth. See Exhibit "B."

How many other records were altered? This petitioner was only able to speak with two trial participants and 100% of them had altered medical records as it relates to this PMA approval process. This fraud alone committed on you and subsequently the public demands an investigation and hearing.

IV. Applicable Federal Laws

The holders of Essure PMA Order had a duty to **distribute, advertise, promote, and report adverse events** regarding Essure consistent with the following Federal law and regulations:

- 21 C.F.R. 814.80-A device **may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with a conditions of approval** specified in the PMA approval order for the device.

- 21 C.F.R. 820.65- establish and **maintain procedures for identifying with a control number each unit, lot, or batch of finished devices** and where appropriate components. The procedures shall facilitate corrective action.

- 21 C.F.R. 803.1(a)- This part establishes **the requirements for medical device reporting for device user facilities, manufacturers, importers, and distributors. If you are a device user facility, you must report deaths and serious injuries that a device has or may have caused or contributed to, establish and maintain adverse event files, and submit summary annual reports. If you are a manufacturer or importer, you must report deaths and serious injuries that your device has or may have caused or contributed to, you must report certain device malfunctions, and you must establish and maintain adverse event files**. If you are a manufacturer, you must also submit specified followup. **These reports help us to protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use.**

- 21 C.F.R. 803.10- (a) If you are a device user facility, **you must submit reports** (described in subpart C of this part), **as follows: (1) Submit reports of individual adverse events no later than 10 work days after the day that you become aware of a reportable event :(i) Submit reports of device-related deaths to us and to the manufacturer, if known; or (ii) Submit reports of device-related serious injuries to the manufacturers or**, if the manufacturer is unknown, submit reports to us.(2) Submit annual reports (described in 803.33) to us.(b) If you are an importer, you must submit reports (described in subpart D of this part), as follows:(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable event:(i) Submit reports of device-related deaths or serious injuries to us and to the manufacturer; or(ii) Submit reports of device-related malfunctions to the manufacturer.(2) [Reserved**](c) If you are a manufacturer, you must submit reports (described in subpart E of this part) to us, as follows:(1) Submit reports of individual adverse events no later than 30 calendar days after the day that you become aware of a reportable death, serious injury, or malfunction.(2) Submit reports of individual adverse events no later than 5 work days after the day that you become aware of:(i) A reportable event that requires remedial action to prevent an unreasonable risk of substantial harm to the public health,**

or(ii) A reportable event for which we made a written request.(3) Submit supplemental reports if you obtain information that you did not submit in an initial report.

- 21 C.F.R. 803.50(a)- (a) If you are a manufacturer, **you must report to us no later than 30 calendar days after the day that you receive or otherwise become aware of information**, from any source, that reasonably suggests that a device that you market:(1) **May have caused or contributed to a death or serious injury**; or(2) Has malfunctioned and this device or a similar device that you market would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur.(b) What information does FDA consider "reasonably known" to me?(1) You must submit all information required in this subpart E that is reasonably known to you. **We consider the following information to be reasonably known to you:(i) Any information that you can obtain by contacting a user facility, importer, or other initial reporter;(ii) Any information in your possession; or (iii) Any information that you can obtain by analysis, testing, or other evaluation of the device.**(2) You are responsible for obtaining and submitting to us information that is incomplete or missing from reports submitted by user facilities, importers, and other initial reporters.(3) **You are also responsible for conducting an investigation of each event and evaluating the cause of the event.** If you cannot submit complete information on a report, you must provide a statement explaining why this information was incomplete and the steps you took to obtain the information. If you later obtain any required information that was not available at the time you filed your initial report, you must submit this information in a supplemental report under 803.56.

- 21 C.F.R. 803.53- **You must submit a 5-day report** to us, on Form 3500A or an electronic equivalent approved under 803.14, **no later than 5 work days after the day that you become aware that:(a) An MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health.** You may become aware of the need for remedial action from any information, including any trend analysis; or(b) We have made a written request for the submission of a 5-day report. If you receive such a written request from us, you must submit, without further requests, a 5-day report for all subsequent events of the same nature that involve substantially similar devices for the time period specified in the written request. We may extend the time period stated in the original written request if we determine it is in the interest of the public health.

- 21 C.F.R. 806.10- (a) **Each device manufacturer or importer shall submit a written report to FDA of any correction or removal of a device initiated by such manufacturer or importer if the correction or removal was initiated:(1) To reduce a risk to health posed by the device; or(2) To remedy a violation of the act caused by the device which may present a risk to health unless the information has already been provided as set**

forth in paragraph (f) of this section or the corrective or removal action is exempt from the reporting requirements under 806.1(b).(b) The manufacturer or importer shall submit any report required by paragraph (a) of this section within 10-working days of initiating such correction or removal.(c) The manufacturer or importer shall include the following information in the report:(1) The seven digit registration number of the entity responsible for submission of the report of corrective or removal action (if applicable), the month, day, and year that the report is made, and a sequence number (i.e., 001 for the first report, 002 for the second report, 003 etc.), and the report type designation "C" or "R". For example, the complete number for the first correction report submitted on June 1, 1997, will appear as follows for a firm with the registration number 1234567: 1234567-6/1/97-001-C. The second correction report number submitted by the same firm on July 1, 1997, would be 1234567-7/1/97-002-C etc. For removals, the number will appear as follows: 1234567-6/1/97-001-R and 1234567-7/1/97-002-R, etc. Firms that do not have a seven digit registration number may use seven zeros followed by the month, date, year, and sequence number (i.e. 0000000-6/1/97-001-C for corrections and 0000000-7/1/97-001-R for removals). Reports received without a seven digit registration number will be assigned a seven digit central file number by the district office reviewing the reports.(2) The name, address, and telephone number of the manufacturer or importer, and the name, title, address, and telephone number of the manufacturer or importer representative responsible for conducting the device correction or removal.(3) The brand name and the common name, classification name, or usual name of the device and the intended use of the device.(4) Marketing status of the device, i.e., any applicable premarket notification number, premarket approval number, or indication that the device is a preamendments device, and the device listing number. A manufacturer or importer that does not have an FDA establishment registration number shall indicate in the report whether it has ever registered with FDA.(5) The unique device identifier (UDI) that appears on the device label or on the device package, or the device identifier, universal product code (UPC), model, catalog, or code number of the device and the manufacturing lot or serial number of the device or other identification number.(6) The manufacturer's name, address, telephone number, and contact person if different from that of the person submitting the report.(7) A description of the event(s) giving rise to the information reported and the corrective or removal actions that have been, and are expected to be taken.(8) Any illness or injuries that have occurred with use of the device. If applicable, include the medical device report numbers.(9) The total number of devices manufactured or distributed subject to the correction or removal and the number in the same batch, lot, or equivalent unit of production subject to the correction or removal.(10) The date of manufacture or distribution and the device's expiration date or expected life.(11) The names, addresses, and telephone numbers of all domestic and foreign consignees of the device and the dates and number of devices distributed to each such consignee.(12) A copy of all communications regarding the correction or removal and the names and

addresses of all recipients of the communications not provided in accordance with paragraph (c)(11) of this section.(13) If any required information is not immediately available, a statement as to why it is not available and when it will be submitted.(d) If, after submitting a report under this part, a manufacturer or importer determines that the same correction or removal should be extended to additional lots or batches of the same device, the manufacturer or importer shall within 10-working days of initiating the extension of the correction or removal, amend the report by submitting an amendment citing the original report number assigned according to paragraph (c)(1) of this section, all of the information required by paragraph (c)(2), and any information required by paragraphs (c)(3) through (c)(12) of this section that is different from the information submitted in the original report. The manufacturer or importer shall also provide a statement in accordance with paragraph (c)(13) of this section for any required information that is not readily available.(e) A report submitted by a manufacturer or importer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer, importer, or FDA that the report or information constitutes an admission that the device caused or contributed to a death or serious injury. A manufacturer or importer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the device caused or contributed to a death or serious injury.(f) No report of correction or removal is required under this part, if a report of the correction or removal is required and has been submitted under parts 803 or 1004 of this chapter.[62 FR 27191, May 19, 1997, as amended at 63 FR 42232, Aug. 7, 1998; 69 FR 11311, Mar. 10, 2004; 78 FR 55821, Sept. 24, 2013]

- 21 C.F.R. 814.84-(a) **The holder of an approved PMA shall** comply with the requirements of part 803 **and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device**.(b) Unless FDA specifies otherwise, **any periodic report shall:(1) Identify changes described in 814.39(a) and changes required to be reported to FDA under 814.39(b).(2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA:(i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.(ii) <u>Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant</u>.** If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted.(3) Identify changes made pursuant to an exception or alternative granted under 801.128 or 809.11 of this chapter.(4) Identify each device identifier currently in use for the device, and each device identifier for the device that has been discontinued since the previous periodic report. It is not necessary to identify any device identifier discontinued prior to December 23, 2013.

- 21 C.F.R. 820.65- **Each manufacturer of a device that is intended for surgical implant into the body** or to support or sustain life and whose failure to perform when properly used in accordance with instructions for use provided in the labeling can be reasonably expected to result in a significant injury to the user **shall establish and maintain procedures for identifying with a control number each unit, lot, or batch of finished devices and where appropriate components. The procedures shall facilitate corrective action.** Such identification shall be documented in the DHR.

- 21 C.F.R. 822-Post market surveillance- This part **implements section 522 of the Federal Food, Drug, and Cosmetic Act (the act) by providing procedures and requirements for postmarket surveillance of class II and class III devices** that meet any of the following criteria:(a) Failure of the device would be reasonably likely to have serious adverse health consequences**;**(b) **The device is intended to be implanted in the human body for more than 1 year;**… The purpose of this part is to implement our postmarket surveillance authority to maximize the likelihood that postmarket surveillance plans will result in the collection of useful data. These data can reveal unforeseen adverse events, the actual rate of anticipated adverse events, or other information necessary to protect the public health.

- 21 C.F.R. 820.100(a) 6 -7- Corrective and Preventive Action-(a) Each manufacturer **shall establish and maintain procedures for implementing corrective and preventive action.** The procedures **shall include requirements for:(1) Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.** Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;(2) Investigating the cause of nonconformities relating to product, processes, and the quality system;(3**) Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;(4) Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;(5) Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;(6) Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and(7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions**, for management review.(b) All activities required under this section, and their results, shall be documented.

- 21 C.F.R. 820.70(e)(h) (a) *General*. **Each manufacturer shall develop, conduct, control, and monitor production processes to ensure that a device conforms to its specifications. Where deviations from device specifications could occur as a result of the manufacturing process, the manufacturer shall establish and maintain process control procedures that describe any process controls necessary to ensure conformance to specifications. Where process controls are needed they shall include:(1) Documented instructions, standard operating procedures (SOP's), and methods that define and control the manner of production;**(2) Monitoring and control of process parameters and component and device characteristics during production;(3) Compliance with specified reference standards or codes;(4) The approval of processes and process equipment; and(5) Criteria for workmanship which shall be expressed in documented standards or by means of identified and approved representative samples. (b) *Production and process changes*. Each manufacturer shall establish and maintain procedures for changes to a specification, method, process, or procedure. Such changes shall be verified or where appropriate validated according to 820.75, before implementation and these activities shall be documented. Changes shall be approved in accordance with 820.40.(**e) *Contamination control.* Each manufacturer shall establish and maintain procedures to prevent contamination of equipment or product by substances that could reasonably be expected to have an adverse effect on product quality**.(h) *Manufacturing material.* **Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, the manufacturer shall establish and maintain procedures for the use and removal of such manufacturing material to ensure that it is removed or limited to an amount that does not adversely affect the device's quality. The removal or reduction of such manufacturing material shall be documented.**

- 21 C.F.R. 820.90-(a) ***Control of nonconforming product***. Each manufacturer **shall establish and maintain procedures to control product that does not conform to specified requirements**. The procedures shall address the identification, documentation, evaluation, segregation, and disposition of nonconforming product. The evaluation of nonconformance shall include a determination of the need for an investigation and notification of the persons or organizations responsible for the nonconformance. **The evaluation and any investigation shall be documented.** (b) *Nonconformity review and disposition.* (1) **Each manufacturer shall establish and maintain procedures that define the responsibility for review and the authority for the disposition of nonconforming product. The procedures shall set forth the review and disposition process. Disposition of nonconforming product shall be documented.** Documentation shall include the justification for use of nonconforming product and the signature of the individual(s) authorizing the use.(2) Each manufacturer shall establish and maintain procedures for rework, to include retesting and reevaluation of the nonconforming product after

rework, to ensure that the product meets its current approved specifications. Rework and reevaluation activities, including a determination of any adverse effect from the rework upon the product, shall be documented in the DHR.

- 21 C.F.R. 820.90-(a) Each manufacturer **shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination,** or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated product is used or distributed. When the quality of product deteriorates over time, it shall be stored in a manner to facilitate proper stock rotation, and its condition shall be assessed as appropriate.(b) Each manufacturer shall establish and maintain procedures that describe the methods for authorizing receipt from and dispatch to storage areas and stock rooms.

- 21 C.F.R. 820.180- **All records required by this part shall be maintained at the manufacturing establishment or other location that is reasonably accessible to responsible officials of the manufacturer and to employees of FDA designated to perform inspections. Such records, including those not stored at the inspected establishment, shall be made readily available** for review and copying by FDA employee(s). Such records shall be legible and shall be stored to minimize deterioration and to prevent loss. Those records stored in automated data processing systems shall be backed up.

- 21 C.F.R. 820.198-(a) **Each manufacturer shall maintain complaint files. Each manufacturer shall establish and maintain procedures for receiving, reviewing, and evaluating complaints by a formally designated unit. Such procedures shall ensure that:(1) All complaints are processed in a uniform and timely manner;(2) Oral complaints are documented upon receipt; and(3) Complaints are evaluated to determine whether the complaint represents an event which is required to be reported to FDA under part 803 of this chapter, Medical Device Reporting**.(b) Each manufacturer shall review and evaluate all complaints to determine whether an investigation is necessary. When no investigation is made, the manufacturer shall maintain a record that includes the reason no investigation was made and the name of the individual responsible for the decision not to investigate.(c) **Any complaint involving the possible failure of a device, labeling, or packaging to meet any of its specifications shall be reviewed, evaluated, and investigated, unless such investigation has already been performed for a similar complaint and another investigation is not necessary.**(d) **Any complaint that represents an event which must be reported to FDA under part 803 of this chapter shall be promptly reviewed, evaluated, and investigated by a designated individual(s) and shall be maintained in a separate portion of the complaint files or otherwise clearly identified.** In addition to the information required by 820.198(e), records of investigation under this paragraph shall include a determination of:(1) Whether the device failed to meet specifications;(2) Whether the device was being used for treatment or

diagnosis; and(3) The relationship, if any, of the device to the reported incident or adverse event.(e) When an investigation is made under this section, a record of the investigation shall be maintained by the formally designated unit identified in paragraph (a) of this section. The record of investigation shall include:(1) The name of the device;(2) The date the complaint was received;(3) Any unique device identifier (UDI) or universal product code (UPC), and any other device identification(s) and control number(s) used;(4) The name, address, and phone number of the complainant;(5) The nature and details of the complaint;(6) The dates and results of the investigation;(7) Any corrective action taken; and(8) Any reply to the complainant.(f) When the manufacturer's formally designated complaint unit is located at a site separate from the manufacturing establishment, the investigated complaint(s) and the record(s) of investigation shall be reasonably accessible to the manufacturing establishment.(g) If a manufacturer's formally designated complaint unit is located outside of the United States, records required by this section shall be reasonably accessible in the United States at either:(1) A location in the United States where the manufacturer's records are regularly kept; or(2) The location of the initial distributor.

- 21 C.F.R. 820.30 - Each manufacturer of any class III or class II device, and the class I devices listed in paragraph (a)(2) of this section**, shall establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met.**

- 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a)- **A drug or device shall be deemed to be misbranded…If its labeling is false or misleading. The following acts and the causing thereof are prohibited: the introduction or delivery for introduction into interstate commerce…any device that is adulterated or misbranded.**

- 21 U.S.C. 351(a) (h)- **A drug or device shall deemed to be adulterated**…if it has been prepared, packed, or held under insanitary conditions whereby it **may have been contaminated with filth….or its manufacturing, processing, packing, or holding do not conform with current good manufacturing practice…if is…not in conformity with…an applicable condition prescribed by an order.**

- 21 U.S.C. 352 (q) (r)- Restricted devices using false or misleading advertising or used in violation of regulations- **In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular,** or (2) it is sold, distributed, or used in violation of regulations prescribed under section 360j(e) of this title. **Restricted devices not carrying requisite accompanying statements in advertisements** and other descriptive printed matter. In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes **in all advertisements and other descriptive**

> **printed matter issued or caused to be issued by the manufacturer**, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

V. Violations of Federal Laws

In addition to violating the PMA Order on several occasions and submitting false medical records during the clinical trials, the holders also violated the above mentioned Federal laws by the following actions/inactions:

- The holders **failed to timely provide the FDA with reports** after twelve months, eighteen months and then a final report for one schedule. The holders also failed to timely submit post approval reports for its six month, one year, eighteen month **and** two year reports. All reports failed to meet the respective deadlines.

- The holders failed to document successful placement of Essure concealing the failure rates.

- The holders **failed to notice the FDA of several adverse reactions** and actively concealed the same. The holder **failed to report 8 perforations** which occurred as a result of Essure **and was cited for the same by the FDA** via Form 483.

- The holders **failed to report to the FDA information it received that reasonably suggested that the device may have caused or contributed to a serious injury**. Again, The holders **failed to report 8 perforations as adverse events which occurred as a result of Essure to the FDA as evidenced in** Form 483.

- As outlined in "Gross Consumer Deception Warranting Recall" *infra*, The holders' warranties were not truthful, accurate, and not misleading.

- The holders' warranties were not consistent with applicable Federal and State law.

- The holders failed to notice the FDA of their internal excel file containing **16,047 entries of complaints.**

- The holders **excluded the risk assessment for safety of loose coils in its Risk Management Plan** and stated the FDA found that The holders had violated the FD&C Act.

- erroneously **using non-conforming material** in the manufacturing of Essure;

- failing to use **pre-sterile and post-sterile cages;**

- manufacturing Essure **at an unlicensed facility**;

- manufacturing Essure for three years **without a license to do so**.

- Not reporting … complaints in **which their product migrated**;

- **Not considering these complaints in their risk analysis for the design** of Essure;

- **Failing to document CAPA activities** for a supplier corrective action;

- On January 6, 2011, the FDA issued a violation to The holder for the following: "An MDR report was not submitted within 30 days of receiving or otherwise becoming aware of information that reasonably suggests that a marketed device may have caused or contributed to a death or serious injury if the malfunction were to recur." **These failures included incidents regarding perforation of bowels, Essure coils breaking into pieces, and Essure coils migrating out of the fallopian tubes**. The holders were issued these violations for dates of incidents 9/1/10, 10/26/10, 5/11/10, 10/5/10, 10/1/10, 11/5/10, 11/16/10, and 11/3/10.

- The holders **had notice of 168 perforations but only disclosed 22** to the FDA.

- On January 6, 2011, **The holders were cited for their risk analysis of Essure being incomplete.** Specifically, the FDA found that the Design Failure Modes Effects Analysis for Essure didn't include as a potential failure mode or effect, location of the micro-insert coil in the peritoneal cavity.

- On January 6, 2011, **The holders were cited for not documenting Corrective and Preventive Action Activities.** Specifically, the FDA found that there **were failures in The holders' Design**. The FDA also found that The holders' CAPA did not mention the non-conformity of materials used in Essure or certain detachment failures. The FDA found that The holders' engineers learned of this and it was not documented.

- On July 7, 2003, The holders were cited for not analyzing to identify **existing and potential causes of non-conforming** product and **other quality problems.** Specifically, two lot history records showed rejected raw material which was not

documented on a quality assurance form, **which is used to track the data.** (Inner/outer coil subassemblies were rejected but then not documented, leading to the question of where the rejected components went)

- On July 7, 2003, The holders were cited for **not following procedures used to control products which did not conform to specifications.**

- The holders also breached this duty by requiring the implanting physician to purchase two (2) Essure "kits" per month **regardless of whether they used them or not** and by contracting with third parties from the hysteroscopic manufacturers to promote Essure who were not competent to perform the same.

- The holders also breached this duty by failing to disclose to Patients and her Implanting physician the fact that it **altered medical records to reflect less pain then was being reported during the clinical studies for Essure and changed the birth dates of others to obtain certain age requirements that were needed to go through the PMA process.**

The violations of federal law are memorialized in writing and attached as Exhibit "C."

VI. Gross Consumer Deception Warranting Recall

The Commissioner of Food and Drugs or designee may request a firm to initiate a recall when the following determinations have been made:

(1) That a product that has been distributed **presents a risk of illness or injury** or **gross consumer deception.**

(2) That the firm has not initiated a recall of the product.

(3) That an agency action is necessary to protect the public health and welfare. 21 C.F.R 7.45 Enforcement Policy-Recall:

According to 21 C.F.R. 814, governing premarket approval of medical devices, a *Statement of material fact* means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation **or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact**, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

Per 21 U.S.C. 352(q)(1) and 21 U.S.C. 331(a)- **A drug or device shall be deemed to be misbranded…If its labeling is false or misleading.** The following acts and the causing thereof are **prohibited:** the introduction or delivery for introduction into interstate commerce**…any device that is adulterated or misbranded.**

Per 21 U.S.C. 352 (q) (r)- Restricted devices using false or misleading advertising or used in violation of regulations- **In the case of any restricted device distributed or offered for sale in any State, if (1) its advertising is false or misleading in any particular,** or (2) it is sold,

distributed, or used in violation of regulations prescribed under section 360j(e) of this title. **Restricted devices not carrying requisite accompanying statements in advertisements** and other descriptive printed matter. In the case of any restricted device distributed or offered for sale in any State, unless the manufacturer, packer, or distributor thereof includes **in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer**, packer, or distributor with respect to that device (1) a true statement of the device's established name as defined in subsection (e) of this section, printed prominently and in type at least half as large as that used for any trade or brand name thereof, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications and, in the case of specific devices made subject to a finding by the Secretary after notice and opportunity for comment that such action is necessary to protect the public health, a full description of the components of such device or the formula showing quantitatively each ingredient of such device to the extent required in regulations which shall be issued by the Secretary after an opportunity for a hearing.

Lastly, the PMA Order reads, "Warranties are truthful, accurate, and not misleading… Warranties are consistent with applicable Federal and State law."

Notwithstanding the fact that the PMA Order was obtained via fraud, the representations made in connection with Essure are deceptive, misleading and inaccurate. Under Federal law, Essure is "misbranded," "adulterated," and "restricted" and the holders have made "false statements of material fact" relating to Essure. The following are warranties, representations, and advertisements that are deceptive, misleading, and inaccurate:

- Only FDA approved female sterilization procedure to have **zero** pregnancies in the clinical trials."

    i. However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. The holders concealed this information from Patients.

- "There were Zero pregnancies in the clinical trials."

    i. However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. The holders concealed this information from Patients.

- "Physicians must be signed-off to perform Essure procedures"

    i. However, the holders failed to abide by the FDA guidelines when training the implanting physician and "signed-off" on the implanting physician who did not have the requisite training. The holders concealed this information from Patients.

- "Surgery-free"

i. However, Essure is not "surgery-free", rather surgery is not required. Moreover, **all Essure procedures are done under hysteroscopy, which is a surgical procedure.**

- "Worry free: Once your doctor confirms that your tubes are blocked, you **never** have to worry about unplanned pregnancy"

i. However, several pregnancies have been reported subsequent to confirmation. The holders concealed this information from Patients.

ii. However, between 1997-2005, 64 pregnancies were reported to the holders. The holders concealed this information from Patients.

i. However, Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month Confirmation Test was confirmed. The holders concealed this information from Patients.

ii. However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked."

iii. However, women who have Essure have **10 times greater risk** of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost four (4) times greater[5].

iv. Yet, The holders' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described **by the holders** as "**painful and is also known to be highly inaccurate, with false-positive results in as many as 40%."**

- "Essure is the most effective permanent birth control available-even **more effective than tying your tubes or a vasectomy**."

i. Yet, the holders' SEC filings, Form 10-K show that no comparison to a vasectomy or tying of tubes was ever done by The holders. The holders stated, "**We did not conduct a clinical trial to compare the Essure procedure to laparoscopic tubal ligation**." The holders concealed this information from Patients.

ii. In fact, women who have Essure have 10 times greater risk of pregnancy after one year than those who use laparoscopic sterilization. At ten years, the risk of pregnancy is almost 4 times greater[6].

[5] *Probability of pregnancy after sterilization: a comparison of hysteroscopic versus laparoscopic sterilization,* Gariepy, Aileen. Medical Publication "Contraception." Elsevier 2014 attached as Exhibit " F."
[6] *Id.*

- "Correct placement…is **performed easily** because of the design of the micro-insert"

    i. However, the holders admitted that placement of the device requires a "skilled approach" and even admitted that their **own experts in hysteroscopy** (as compared to general gynecologists not on the same level as an expert hysteroscopist) failed to place the micro-inserts in 1 out of 7 clinical participants. The holders concealed this information from Patients.

- "In order to be trained in Essure you **must be a skilled operative hysteroscopist**. You will find the procedure easier to learn if you are already proficient in operative hysteroscopy and management of the awake patient. If your skills are minimal or out of date, you should attend a hysteroscopy course before learning Essure."

    i. However, the holders "signed off" on the implanting physician who was not a skilled operative hysteroscopist, in order to monopolize and capture the market, including the implanting physician. The holders concealed this information from Patients.

- "Essure is a surgery-free **permanent birth control**."

    i. However, Essure is not permanent as the coils migrate, perforate organs and are expelled by the body. Moreover, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

- "Zero pregnancies" in its clinical or pivotal trials.

    i. However, there were at least four pregnancies. The holders concealed this information from Patients.

- In order to be identified as a qualified Essure physician, a minimum of one Essure procedure must be performed every 6-8 weeks.

    i. However, the holders "signed off" on "Essure physicians" who did not perform the procedure every 6-8 weeks, including the implanting physician. The holders concealed this information from Patients.

- No pregnancies have occurred after a successful confirmation test in the Essure clinical studies at 4 and 5 years of follow up.

    i. However, there were at least four pregnancies. The holders concealed this information from Patients.

- Data from two clinical studies show that 99 percent of women who had the Essure procedure rated their long-term comfort with the micro-inserts as 'good,' 'very good' or 'excellent'."

    i. However, the actual choices given to the clinical participants were 'poor,' 'very good' or 'excellent.' The holders concealed this information from Patients.

    ii. Moreover, the holders altered medical records of trial participants to reflect favorable data.

- The holders' Senior Director of Global Professional Education represented to the public that "For the Essure procedure, the patient is not under anesthesia, therefore a **skilled approach** is crucial."

    i. Yet, The holders also claims that "Correct placement…is **performed easily** because of the design of the micro-insert"

- The holder's CEO stated: "Essure allows you to push away the constant worry about an unplanned pregnancy that's our message and that's our theme."

    i. However, there were actually **four pregnancies** during the clinical trials and five pregnancies during the first year of commercial experience. The holders concealed this information from Patients.

    ii. However, between 1997-2005, 64 pregnancies were reported to the holders. The holders concealed this information from Patients.

    iii. However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked."

    iv. Yet, The holders' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described **by the holders** as "painful and is also known to be **highly inaccurate**, with false-positive results in as many as 40%."

- Essure has been in use for over 5 years.

    i. However, Essure was only in use for 4 years at this time. The holders concealed this information from Patients.

- "The non-surgical permanent birth control for woman."

    i. However, the procedure is most commonly done with surgery. The holders concealed this information from patients.

ii. However, Essure is not permanent as the coils migrate, perforate organs and are expelled by the body.

iii. However, all Essure procedures are done under hysteroscopy, which is a surgical procedure, and billed as a surgery.

- The holders created a fake blog entitled "Diary of a Decision" in order to induce Patients to use Essure. The holders created a fictitious person, named "Judy" who pretended to have had the procedure and answered questions from patients.

  i. However, "Judy" never had the procedure as represented and was actually Debbie Donovan. The holders concealed this information from patients.

- The holders warranted that Essure "allows for visual confirmation of each insert's proper placement both during the procedure and during the Essure Confirmation Test."

  i. However, Essure does not allow for visual confirmation of proper placement during the procedure.

- "Worry free"

  i. However, the holders **actively concealed** and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in a** Form 483 issued by the FDA to The holders. The holders actively concealed this from patients.

  ii. Most egregiously, the holders were issued another Form 483 when it **"erroneously used non-conforming material."** The holders actively concealed this and were issued an additional Form 483 for "failing to adequately document the situation." The holders actively concealed this from patients.

  iii. However, the holders' facility was also issued a notice of violation as it **"no longer uses pre-sterile and post-sterile cages."** The holders actively concealed this from patients.

  iv. However, the holders also were issued a notice of violation when it **"failed to obtain a valid license…prior to manufacturing medical devices."** The holders were manufacturing devices for three years without a license. The holders actively concealed this from patients.

  v. However, the holders were also issued a notice of violation as it was manufacturing medical devices from 2005 at an unlicensed facility. The holders actively concealed this from patients.

vi. The holders failed to notice the FDA of their internal excel file containing **16,047 entries of complaints.**

vii. Yet, The holders' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described **by The holders** as "painful and is also known to be **highly inaccurate**, with false-positive results in as many as 40%."

viii. Yet, The holders were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

- "The Essure **inserts stay secure**, forming a long protective barrier against pregnancy. They also **remain visible outside your tubes**, so your doctor can confirm that they're properly in place."

  i. However, the micro-inserts do not remain secure but migrate and are expelled by the body. The holders actively concealed this information from Patients.

  ii. However, the holders actively concealed and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483 issued to The holders by the FDA.

  iii. Yet, The holders were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

- "The Essure inserts are made from the same trusted, silicone free material used in heart stents."

  i. However, the micro-inserts are not made from the same material as heart stents. Specifically, the micro-inserts are made of PET fibers which trigger inflammation and scar tissue growth. Heart stents do not elicit tissue growth. The holders actively concealed this from Patients.

  ii. PET fibers are not designed or manufactured for use in human implantation.

  iii. Moreover, The holders also warranted: "the long-term nature of the tissue response to the Essure micro-insert is not known."

iv. However, the PET fibers are made of the same materials as the PVT material in vaginal meshes which have a high rate of expulsion.

v. Most egregiously, The holders were issued another Form 483 when it **"erroneously used non-conforming material."** The holders actively concealed this and were issue another Form 483 for "failing to adequately document the situation."

- "Surgery free"

i. However, all Essure procedures are done under hysteroscopy, which is a surgical procedure.

- "Anesthesia-free"

i. However, Essure is not "anesthesia-free," rather anesthesia is not required.

- Step Two: "pregnancy **cannot** occur"; Step Three: The Confirmation.

i. However, The holders also state that it is only **after** "The Confirmation" pregnancy cannot occur. i.e. the complete opposite of what is warranted in the brochure.

ii. However, Adverse Event Report ESS 205 dated 10/3/2006 evidences a pregnancy after the three month confirmation test was confirmed.

iii. However, between 1997-2005, 64 pregnancies were reported to the holders. The holders concealed this information from Patients.

iv. However, there have been over 30 pregnancies after "doctors confirmed the tubes were blocked."

v. However, there have been incidents where the micro-inserts were expelled from the body even after the Confirmation Test.

- "Essure **eliminates** the risks, discomfort, and recovery time associated with surgical procedures."

i. However, Essure is not "surgery-free", rather surgery is required.

ii. Yet, the holders' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described **by the holders** as "painful and is also known to be **highly inaccurate**, with false-positive results in as many as 40%."

- The **PET fibers are what cause** the tissue growth.

    i. However, during the PMA meeting with the FDA, The holders represented that the **trauma** caused by the expanding coil striking the fallopian tubes i**s what caused the inflammatory response** of the tissue. The holders concealed this information from Patients.

    ii. However, in the patent for Essure it states that a galvanic battery causes the tissue growth.

- "The inserts are made from…**safe, trusted material**."

    i. However, the inserts are not made of safe, trusted material as they migrate, corrode, break, and contain drugs. In fact, The holders refer to Essure and classify it as a "drug."

- In January 2014, the holders warranted that over 750,000 procedures had been performed.

    i. However, ten months later the holders advised only 625,000 had been performed.

- "This viewable portion of the micro-insert serves to verify placement and **does not irritate the lining of the uterus."**

    i. However, the device does irritate the uterus as the device is left trailing into the uterus and continues to elicit tissue growth. the holders concealed this information from Patients.

    i. However, the holders actively concealed and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483.

    i. Yet, the holders were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

- "there was no cutting, **no pain,** no scars…"

    i. However, patients have experienced pain as a result of Essure. The holders concealed this information from Patients.

    ii. Yet, the holders' SEC filings, Form 10-K show that the HSG test used to confirm the tubes are blocked has been described **by The holders** as

"painful and is also known to be **highly inaccurate**, with false-positive results in as many as 40%."

iii. Yet, the holders were issued Form 483's for not disclosing MDR's to the FDA for pain.

iv. However, the holders altered the records of at least one trial participant to reflect less pain.

- "The Essure System provides permanent birth control without invasive surgery or general anesthesia, and their associated risks."

  i. However, Essure is not "surgery-free" or "anesthesia-free," rather surgery and anesthesia is not required.

- "In addition to the above benefits, none of the women in the Essure clinical trials became pregnant while relying on Essure for contraception."

  i. However, there were at least four pregnancies during the clinical trials. The holders concealed this information from Patients.

- "Namely, the Essure system is delivered hysteroscopically without general anesthesia."

  i. However, Essure is not "surgery-free" or "anesthesia-free", rather surgery and anesthesia is not required.

- The holders represented to Patients that it was the expanding coil and tissue growth which caused the coil to be attached to the tube, not any type of coating.

  i. Yet, in Supplement 18, The holders represented that "A doctor placed the coil at the uterine-fallopian tube junction, where **its coating caused it be attached** to the tube." The coating is a hydrophilic polymer coating produced by AST Products, Inc. The holders actively concealed this from Patients.

- The holders warranted that the Essure system has **"no risks"** for patients because…the Essure system does not involve the use of radiofrequency energy.

  i. At the same time, the holders also states that there are limited risks with Essure.

  ii. At the same time, the patent for Essure alleges that the coils act as a galvanic battery.

- "Our Mountain View, California facility underwent an International Organization for Standardization ("ISO") inspection in September 2011 which resulted in continuing approval and ISO certification through May 2013. In December 2010 / January 2011 we underwent an FDA audit; all findings from the audit were satisfactorily addressed." However, the holders actively concealed the following:

    i. However, the holders' site has been inspected 7 times since 06/25 - 07/09/2002. The most recent FDA audit occurred on 05/30 - 06/26/2013. The FDA has issued 4 Form 483 inspectional observations.

    ii. However, the holders actively concealed and **failed to report 8 perforations which occurred as a result of Essure to the FDA as evidenced in** Form 483.

    iii. Most egregiously, the holders were issued another Form 483 when it **"erroneously used non-conforming material."** The holders actively concealed this and were issued another Form 483 for "failing to adequately document the situation."

    iv. However, the holders' facility was also issued a violation as it **"no longer uses pre-sterile and post-sterile cages."**

    v. However, the holders also were issued a violation when it **"failed to obtain a valid license…prior to manufacturing medical devices."** The holders were manufacturing devices for three years without a license.

    vi. **The holders failed to provide the FDA with their internal excel file containing 16,047 entries of complaints.**

    vii. Yet, the holders were issued Form 483's for not disclosing MDR's to the FDA for perforations, migrations and instances where Essure broke into pieces; were cited for having an incomplete risk analysis, not documenting non-conforming products, not following procedures used to control non-confirming product, and other quality problems.

In addition, Bayer has been corresponding with patients who have filed adverse events and advising them that **Essure is a drug.** Essure was approved as a medical device, never a drug, and to represent this to patients **after** they have it implanted is unconscionable. See Exhibit "E."

Most egregious is the gross deception in **failing to disclose** the adverse reports mentioned above dealing with perforations and migrations to women across the United States who were, and currently not able to make informed decisions and to their doctors who were, and currently not able to discuss the true extent of adverse events.

Full disclosure is a necessity when deciding to implant a foreign device into one's body. The fact that Essure's PMA was obtained through fraud is one issue. Another whole issue is that Essure's PMA was maintained through concealment of adverse events. Although the PMA Order specifically reads, "CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty standards must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws", the FDA has the authority to recall a medical device where it presents gross consumer deception.

VII. Implications of Continued Marketing and Sale of Essure

Bayer should not be able to market and sell a medical device that was **approved by the FDA on fraudulent results** of its clinical trial and altered medical records. This puts the public in grave danger.

Bayer should not be able to maintain the PMA for Essure when the **PMA Order has been consistently violated over a period of years**, according to your findings. This puts the public in grave danger.

Bayer should not be able to maintain the PMA for Essure when several **federal laws have been violated**. This puts the public in grave danger.

Bayer should not be able to market Essure based on false and misleading information, deceiving the public. This puts the public in grave danger.

Bayer should not be able to market a "misbranded" and "adulterated" product. This puts the public in grave danger.

Bayer should not be able to unilaterally change the status of Essure from a "device" to a "drug." This puts the public in grave danger.

Holders of PMA orders do not have the luxury to "pick and choose" what events they disclose to the FDA and to the public. The holders **must** "report to the FDA whenever it receives information from any source that **reasonably suggests** that the device may have caused or contributed to a serious injury" per your PMA Order. Holders of PMA orders also must comply with all federal reporting laws outlined above as **"these reports help us protect the public health by helping to ensure that devices are not adulterated or misbranded and are safe and effective for their intended use."** 21 C.F.R. 803.1(a) This was not done.

How can the public expect Essure to be safe and effective when (1) there is evidence of fraud in the preapproval process; (2) adverse events are not being reported; (3) complaints are not being considered in Essure's risk analysis; (4) CAPA activities are not being documented; (5) Essure's risk analysis is incomplete; (6) quality assurance forms, used for tracking non-conforming product, were not used; and (7) Essure violated its own PMA Order and federal law?

VIII. Ramifications

- PMA Order

The PMA Order issued by the FDA, expressly states, "Failure to comply with the conditions of approval invalidates this approval order."

Here, the order for Essure leaves no room for discretion. As described above and pursuant to your findings, Essure failed to comply with several conditions. Accordingly, the PMA should be withdrawn or temporarily suspended until Bayer discloses to the public its failure to comply with the order and/or until a premarket approval process has been conducted, free from fraud.

- Federal law

21 C.F.R. 7.45 Enforcement Policy-Recall: The Commissioner of Food and Drugs or designee may request a firm to initiate a recall when the following determinations have been made:

(1) That a product that has been distributed **presents a risk of illness or injury** or **gross consumer deception.**

(2) That the firm has not initiated a recall of the product.

(3) That an agency action is necessary to protect the public health and welfare.

Here, Essure presents a risk of gross consumer deception. The expedited approval process was predicated on fraud. Medical records of the trial candidates were altered to reflect less pain than was being reported and were changed to reflect inaccurate birth dates needed to complete the study. This alone warrants gross consumer deception as Essure is being marketed as safe and effective because it has PMA by the FDA.

Moreover, there is gross consumer deception in the failure to disclose and active concealment of adverse events described above. The public has a right to know of the perforations and migrations that were not disclosed. Failing to disclose these adverse events not only is a violation of several federal laws and the PMA order, but it also places the public at grave risk as they are not able to make informed decisions on Essure. The firm has not initiated a recall of Essure. This action is necessary to protect the public health and welfare.

21 C.F.R. 814.46-Withdrawal of approval of a PMA:

(a) FDA may issue an order withdrawing approval of a PMA if, from any information available to the agency, FDA determines that:

(1) Any of the grounds under section 515(e)(1) (A)-(G) of the act applies.

(2) Any postapproval requirement imposed by the PMA approval order or by regulation has not been met.

(3) A nonclinical laboratory study that is described in the PMA and that is essential to show that the device is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good

laboratory practice regulations in part 58 and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(4) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in part 56 or informed consent regulations in part 50, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(b)(1) FDA may seek advice on scientific matters from any appropriate FDA advisory committee in deciding whether to withdraw approval of a PMA.

(2) **FDA may use information other than that submitted by the applicant** in deciding whether to withdraw approval of a PMA.

(c) Before issuing an order withdrawing approval of a PMA, FDA will issue the holder of the approved application a notice of opportunity for an informal hearing under part 16.

(d) If the applicant does not request a hearing or if after the part 16 hearing is held the agency decides to proceed with the withdrawal, FDA will issue to the holder of the approved application an order withdrawing approval of the application. The order will be issued under 814.17, will state each ground for withdrawing approval, and will include a notice of an opportunity for administrative review under section 515(e)(2) of the act.

(e) FDA will give the public notice of an order withdrawing approval of a PMA. The notice will be published in the Federal Register and will state that a detailed summary of information respecting the safety and effectiveness of the device, including information about any adverse effects of the device on health, has been placed on public display and that copies are available upon request. When a notice of withdrawal of approval is published, data and information in the PMA file will be available for public disclosure in accordance with 814.9.

Here, as described above and pursuant to your findings, the holders have failed to comply with several post-approval conditions. Accordingly, the PMA should be revoked or temporarily suspended until Bayer discloses to the public its failure to comply with the order and/or until a premarket approval process has been conducted, free from fraud.

Petitioner seeks the following, with exact wording for the proposed orders or amendments to the same outlined in quotations: (1) issue an order finding that PMA Order for the medical device known as Essure has been violated ("The FDA finds that the PMA Order P020014 has been violated."); (2) issue an order requiring Bayer to disclose the violations mentioned *infra* to the public ("The FDA finds that the PMA Order P020014 has been violated and orders Bayer to disclose all complaints to the public"); (3) issue an order finding that Essure is "adulterated" and/or "misbranded" and cannot be marketed, distributed, or advertised ("The FDA finds that the medical device Essure System, PMA Order P020014 is adulterated or misbranded and cannot be marketed, distributed, or advertised until further order from the FDA."); (4) issue an order requiring Bayer to withdraw and issue a notice of retraction of the misleading representations outlined *infra*-including that Essure is a "drug" ("The FDA orders Bayer to cease marketing of Essure and publish notices of retraction for its prior warranties."); (5) immediately revoke the PMA Order; ("The FDA hereby withdraws PMA Order P020014"); (6) immediately place a temporary suspension on the PMA until an approval process free from fraud is completed ("The

FDA hereby suspends PMA Order P020014."); (7) amend the PMA Order to require Bayer to disclose the concealed violations mentioned *infra* or to include a black box warning that the PMA has been suspended ("The FDA orders Bayer to disclose all complaints and/or to include a black box warning that its PMA P020014 has been suspended."); and/or (8) initiate a recall due to gross consumer deception ("The FDA hereby issues a recall on all Essure devices.").

C. ENVIORNMENTAL IMPACT

Pursuant to 21 C.F.R. § 25.30, this petition is categorically exempt from the requirement of an Environmental Assessment (EA) or an Environmental Impact Statement (EIS).

D. ECONOMIC IMPACT

Pursuant to 21 C.F.R. § 10.30(b), information on the economic impact of this petition will be provided upon request by the Commissioner of the Food and Drug Administration (FDA). **The petitioner has prepared an economic impact statement regarding Essure and the onerous economic burden it has placed on Medicare/Medicaid and on the taxpayers** and will provide it upon request.

E. CERTIFICATION

Pursuant to 21 C.F.R. § 10.30(b), the undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition. Lastly, if the administration needs any additional information or this petition is lacking in any regard, please do not hesitate to contact the undersigned at any time.

Respectfully submitted,

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