

Essure, (Lack of) Consent, the FDA, and the Nuremberg Code

10.23.2015

My name is Susan Bucher. I became a nurse because of the abuse that occurred to me with my tubal ligation in 1995. I am the founder of the Coalition for Post Tubal Women (Tubal.org). Since 1997 I have been working on issues of informed consent, protocol development, research and development in this area of female sterilization. I have personally communicated with thousands of women pre and post sterilization.

In early 2000, I, along with Dr. Vikki Hufnagel, worked to stop "STOP" (Selective Tubal Occlusion Procedure) which is what the Essure device was originally named by Conceptus. Dr. Hufnagel presented her data to the FDA on review protocol during the early 90's on the destructive nature of the field of sterilization and demanded a recall of Ovabloc. I learned about her scientific research and she encouraged me to get my RN degree to be able to have a stronger voice in women's health care issues.

It is historical that Essure has followed in the path of Ovabloc. I am requesting a full review of all the complications of Essure. At this point in time there appears to be more deaths and serious complication with Essure over those reported on Ovabloc and I am seriously concerned as to how this device has remained to be marketed today. The numbers of users and complications do not appear to be factual. It is likely that there is not full reporting of complications and there is a complete failure of the Med Watch Program which needs to take place immediately.

The FDA is charged by statute with the obligation of ensuring the protection of the rights, safety, and welfare of human subjects who participate in clinical investigations involving articles subject to section 505(i), 507(d), or 520(g) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 355(i), 357(d), or 360j(g)), as well as clinical investigations that support applications for research or marketing permits for products regulated by FDA, including food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products. <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm118434.htm>

Many have profited from the development, research, and premarket approval, and marketing of this product, (Conceptus/Conceptus stock holders, Bayer/Bayer stock holders, ACOG/OBGYN doctors, etc...), it was done so at the cost of vulnerable women needing special protection and ongoing informed consent. http://www.hhs.gov/ohrp/archive/irb/irb_chapter6.htm#g3

Is there reporting on the data as to anyone who works with the FDA as to the stock they own or is held in proxy for them. Does the FDA investigate its staff?

The Nuremberg Code, the Declaration of Helsinki (<http://www.raps.org/focus-online/news/news-article-view/article/4207/>), and The Belmont Report (<http://www.hhs.gov/ohrp/humansubjects/guidance/belmont.html>) all address voluntary informed consent as a requirement for the ethical conduct of human subjects research.

Recently the FDA suggested that more data was needed and suggested Bayer gather more data to analyze which leads one to infer that physicians are collecting information/data from women who have volunteered to be studied or not. This indicates that the study of this device is still ongoing but without any type of consent from those who have received the device. ALL OF THESE WOMEN NEED TO KNOW ABOUT THESE HEARINGS, NEED to be given a MedWatch Form, NEED to know the current data and the facts that include women have died at insertion, have had the device migrate, have developed nickel allergies,etc.

In reviewing the Nuremberg Code and what has occurred with the creation, development, research study/testing, and marketing of Essure, one sees many violations which requires the FDA to take immediate action to correct.

From: <http://www.cirp.org/library/ethics/nuremberg/> and (https://en.wikipedia.org/wiki/Nuremberg_Code)

1. The voluntary consent of the human subject is absolutely essential. This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment. The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs, or engages in the experiment/treatment. It is a personal duty and responsibility which may not be delegated to another with impunity. (Required is the voluntary, well-informed, understanding consent of the human subject in a full legal capacity.)

In the case of Essure (as well as other forms of sterilization), the decision of what type of sterilization will be done is decided and directed by the doctor performing the sterilization. Inconveniences, hazards and effects upon future health has not been and currently is not disclosed (nickel allergies, risk of device migrating, higher risk of hysterectomy, loss of ovarian function, etc...)

Women need to be able to select their own form of birth control or sterilization and not be influenced by marketing or sales, or by the doctor based on how much they will profit by selling and inserting the Essure device. She needs to have all data as part of informed consent including the number of deaths associated with Essure, the number of complications, as well as how much the doctor profits from inserting the device compared to a traditional tubal ligation or other forms of birth control, etc....

2. The experiment (treatment) should be such as to yield fruitful results for the good of society, unprocurable by other methods or means of study, and not random and unnecessary in nature. (The experiment should aim at positive results for society that cannot be procured in some other way).

Other forms of birth control and other forms of sterilization (tradition tubal ligation) are available.

3. The experiment (treatment) should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results justify the performance of the experiment. (It should be based on previous knowledge (like, an expectation derived from animal experiments) that justifies the experiment.)

Studies were done on rats and rabbits. As this is a device that is inserted into a woman's Fallopian tubes, criticism of this is animal studies done on cats or pigs may have been more appropriate and matched more closely a woman's anatomy.

4. The experiment (treatment) should be so conducted as to avoid all unnecessary physical and mental suffering and injury. (The experiment/treatment should be set up in a way that avoids unnecessary physical and mental suffering and injuries.)

Steps to avoid all unnecessary suffering and injury have not occurred and currently are not occurring. Reports of unbearable pain being compared to physical torture during insertion are common. This and the after effects of pain and bleeding have led to more mental suffering for many women of which they were not warned of. Women are not informed of the risk of nickel allergy developing and not offered pre-testing for nickel sensitivity. After when women return to their doctors with complaints they are told that the Essure device had no bearing on their current condition adding to emotional distress.

All the side effects are NOT told:

- *death at insertion*
- *rate of hysterectomies*
- *rate of hospitalization*
- *rate of tubes and ovaries being removed*
- *death of fetuses*

this all needs to be part of the consent.

The following is a typical example of an informed consent

Consent Form for Essure® Procedure

I understand that the Essure permanent birth control procedure has been clinically tested for four years and shown to be 99.8% effective in preventing pregnancy during that time period.

I understand that the Essure procedure involves placing a micro-insert (small, flexible coil) into each fallopian tube which over time causes the tubes to close, thereby preventing pregnancy.

I understand that to be sure the Essure micro-insert has worked to close off my fallopian tubes and that I can rely on the Essure procedure for my birth control, an Essure Confirmation Test (hysterosalpingogram (HSG)) must be performed three months following the procedure. During this test, a special fluid (dye) and x-ray will be used to show that my fallopian tubes are occluded and that the micro-inserts are in the correct location.

I understand that until the Essure Confirmation Test (HSG) has confirmed my tubes are closed another form of birth control must be used.

I understand that some women may not have successful placement of both Essure micro-inserts, and should this occur I should seek the advice of my physician.

I understand that should I become pregnant, I should immediately seek medical care for evaluation of the pregnancy.

I understand that the Essure procedure is considered to be permanent and cannot be reversed.

I understand that the other risks associated with placement of the Essure device include, but are not limited to: bleeding, infection, perforation, and pain similar to menstrual cramping.

I understand that Essure does not protect against sexually transmitted diseases and that barrier methods such as condoms should be used for protection against sexually transmitted diseases.

I have received the patient information booklet.

I have had the opportunity to ask questions regarding the Essure permanent birth control procedure and wish to proceed with the placement of the Essure devices.

I am not allergic to nickel or contrast media (dye).

Signature _____ Date _____ Witness _____ Date _____

No information about increased risk of Hysterectomy

Conceptus, Inc. is providing the information in this binder to you for informational and educational purposes only. Conceptus, Inc. makes no representations about the suitability of the information contained in this binder for your particular clinical purposes. You are encouraged to tailor any of the forms or protocols in this binder or replace them with those that are best suited, in your clinical judgment, for your practice and patients. You are solely responsible for ensuring that you and your staff have been properly trained in all aspects of providing the Essure procedure to your patients in the office setting, including administering appropriate anesthesia.

CC-1670 01Apr08F

5. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur; except, perhaps, in those experiments where the experimental physicians also serve as subjects. (It should not be conducted when there is any reason to believe that it implies a risk of death or disabling injury)

Deaths have occurred to both women and fetuses, yet the device is still presented to women as being their only option for permanent birth control. It was highly inferred (and even joked about) at the time of approval that the pregnancy rate would be found to be will be much higher than originally reported upon when gaining FDA approval.

See:

<https://www.facebook.com/angie.firmalino/videos/vb.1148784067/10203634200712765/?type=2&theater>

6. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment/treatment. (The risks of the experiment/treatment should be in proportion to (that is, not exceed) the expected humanitarian benefits)

Because there are other sterilization treatments available (traditional tubal ligation), anything with a higher risk of pregnancy, death, hysterectomy, allergies, etc... is NOT acceptable.

7. Proper preparations should be made and adequate facilities provided to protect the experimental subject (patient) against even remote possibilities of injury, disability or death. (Preparations and facilities must be provided that adequately protect the subjects against the experiment's risks.)

This is not occurring. Essure is promoted as being non-surgical despite being inserted surgically. Its promoted as being a device that can be (and often is) inserted into women in a private doctors office without any requirement of adequate emergency facilities, crash carts, or staff with ACLS training present.

8. The experiment/treatment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment. (The staff who conduct or take part in the experiment must be fully trained and scientifically qualified.)

With the Essure device, doctors have been learning how to insert the device and experimenting on women as they go.... Women are not told by their doctor prior to the placement of their Essure device how many Essure devices the doctor has inserted, how many placements were successful, how many insertions were not successful, etc.... Women trust and believe that their doctors are highly trained and experienced in placing the device when often they are not. This is FRAUD.

<http://medical-dictionary.thefreedictionary.com/fraud>

“the act of intentionally misleading or deceiving another person by any means so as to cause him or her legal injury, usually the loss of something valuable or the surrender of a legal right resulting from the action of that person on the misrepresentation.”

9. During the course of the experiment/treatment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

See #4 above. This has not been offered to women. The device is not reversible as is the case with traditional tubal ligation.

10. During the course of the experiment/treatment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgment required of him, that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject. (The medical staff must stop the experiment/treatment at any point when they observe that continuation would be dangerous.)

Going back to 2000, concerned medical personal have stepped forward to warn Conceptus, Bayer, and the FDA that continuing to offer and providing this device to women will result in injury, disability, and death to patients. This includes whistle blowers, obgyns who offered, sold, and inserted the Essure product in their private practice then stopped after seeing the mayhem it created as well as RN's, (one RN was involved as a study participant and reported a change in negative status change of her outcome).

Multiple trained medical personal and whistle blowers have called for the complete halt and recall of this product in order to ensure consumer safety and to promote women's health.