Crimes of Essure and the FDA

"Women need to be informed that with the use of Essure they will be at higher risk for hysterectomy, and of all the risks associated with hysterectomy."
~ Dr. Vikki Hufnagel

Position Paper

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Submitted publicly and directly to the FDA

The CRIMES OF ESSURE

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This POSITION PAPER is authored by Dr. Vikki Hufnagel.

This document was created for review and presentation for the September 24, 2015 public advisory committee of the Food and Drug Administration (FDA). The FDA is convening this committee to seek expert scientific and clinical opinion on the risks and benefits of the Essure System.

General Name of Committee: Obstetrics and Gynecology Devices Panel of the Medical Devices Advisory Committee. General Function of the Committee, Bayer HealthCare's Essure System

Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

This POSITION PAPER includes advice and recommendations regarding:
• Essure
• Informed Consent
• Women's Health rights
• Ethics in Medicine and FDA governance

REQUEST FOR NEW SYSTEM THAT PROVIDES A MEANS OF INPUT BY THOSE WITHOUT FUNDS OR FINANCIAL SUPPORT

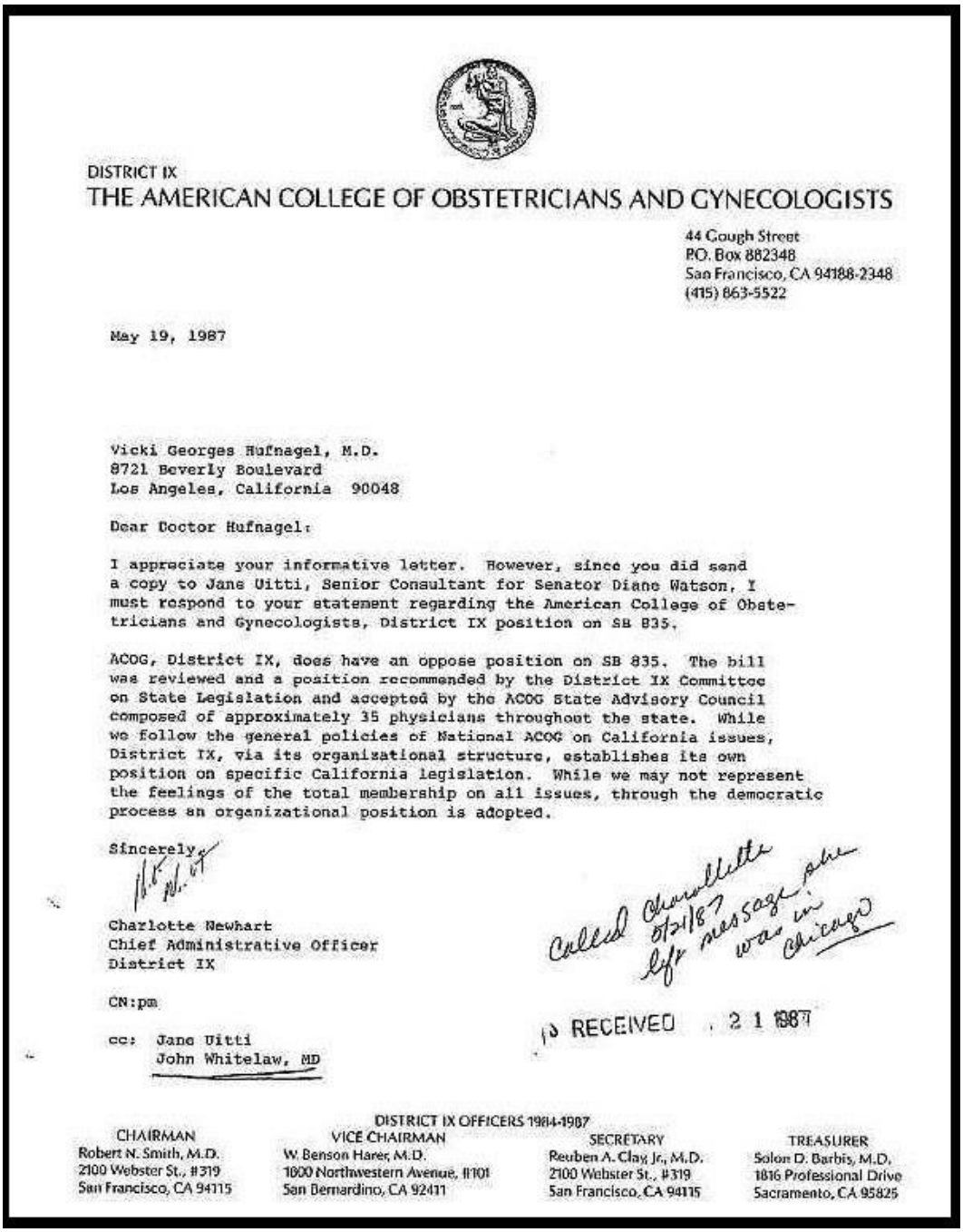
I supported my ethics in medicine work in the 80's by giving ⅓ of my income to create the Institute for Reproductive Health (IRH) [1]. The American College of Obstetricians and Gynecologists (ACOG) attacked me to destroy my means of income to shut me up. This was very successful. It kept my work from advancing and women have not had access to Female Reconstructive Surgery (FRS). Also this was an attack to kill the message by killing the messenger. I do not have income to do ethics work in women's medicine which is needed.

I live in California and have limited income and serious health conditions that prevents travel for all the FDA meetings I should attend. I am asking for the FDA to provide assistance so that I can attend all Women's Health Issues before the FDA. As the FDA is aware or should be I am a nationally known "whistle-blower" in women's health care. [2] [3]

The CIO of The Hufnagel Bioethics Institute (HBI) and I have direct knowledge of Essure and its complications. Susan Bucher RN created the Coalition for Post Tubal Women [4] and the first web site (tubal.org) on the complications of female sterilization. I am the physician who created the concept and scientific fact of Post Tubal Ligation Syndrome (PTLS) in the late 80's. I have reported and published many papers on this subject. Also, I wrote an informed consent law for sterilization which has not been introduced to the states. It needs to be in process because of the increased number of women injured by various devices and procedures to prevent pregnancy.

My work has been repressed because I have proven many abuses in this area of medicine. My book No More Tubal Ligations and more was literally stolen and destroyed by the California Medical Board (CMB). I am now publishing to expose abuses and crimes that have taken place by the FDA, ACOG and corporations and to look at why and how this has occurred at all levels from the power of money and greed and the psychology of institutions and the ignorance of the public at www.shadowofmedicine.com. This is the book I am writing currently to give insight into behaviors that cause harm in medicine.

In many cases, there is intentional misrepresentation of science and facts in order to sell a medical device, sell stock, flood a market to promote a device or procedure in order to make money knowing the science will actually injure or kill women as in the case of morcellation. I flew to the FDA in 1995 and explained that morcellation would KILL women based on our knowledge of oncology the time. How and why the FDA ignored SCIENCE is at issue in all of these cases.



DISTRICT IX
THE AMERICAN COLLEGE OF OBSTETRICIANS AND GYNECOLOGISTS

44 Gough Street
P.O. Box 882348
San Francisco, CA 94188-2348
(415) 863-5522

May 19, 1987

Vicki Georges Hufnagel, M.D.
8721 Beverly Boulevard
Los Angeles, California 90048

Dear Doctor Hufnagel:

I appreciate your informative letter. However, since you did send a copy to Jane Uitti, Senior Consultant for Senator Diane Watson, I must respond to your statement regarding the American College of Obstetricians and Gynecologists, District IX position on SB 835.

ACOG, District IX, does have an oppose position on SB 835. The bill was reviewed and a position recommended by the District IX Committee on State Legislation and accepted by the ACOG State Advisory Council composed of approximately 35 physicians throughout the state. While we follow the general policies of National ACOG on California issues, District IX, via its organizational structure, establishes its own position on specific California legislation. While we may not represent the feelings of the total membership on all issues, through the democratic process an organizational position is adopted.

Sincerely,

Charlotte Newhart
Chief Administrative Officer
District IX

CN:pm

cc: Jane Uitti
John Whitelaw, MD

Called Charlotte 5/21/87 left message she was in Chicago

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Letter from the ACOG to Dr. Hufnagel stating that they oppose law that would require "informed consent" for hysterectomy.

I have seen the ACOG lie and pay companies such as Abelson Taylor to astroturf and create disinformation against myself and my work. This occurs out of the fear of having the public learn about the politics of the ACOG and women's health care. I will be providing to the press this story that has been silenced for years by the ACOG.

TYPICAL EXAMPLES

The ACOG and the American Association of Gynecologic Laparoscopists (AAGL) supported **Dr. Jay Cooper** for years. He was a lead investigator for (and spoke many times to the FDA about) **STOP(TM)**, **Essure**, **Uterine Artery Embolization**, **NovaSure**, and **Ovabloc** which he was an owner. of the company.

The ACOG supported the sales and use of Ovabloc. Ovabloc was an **experimental medical device** designed to be a reversible rubber silicone plug placed in the fallopian tubes for the purpose of birth control. The Ovabloc ITD was described as being an *"Intratubal form-in-place" medical device that would form in situ after the intratubal administration of liquid silicone rubber mixed with catalyst in a mixer-dispenser. Radiopaque spherical silver powder was added to the silicone so that the ITD could be identified on X ray.*

Ovabloc was an experiment from hell.

This was a product that MDs thought they could get rich quick (as is the case with Essure). Hysteroscopy was not the issue. However many GYN's were not trained and allowed the salesmen to do the procedures which caused deaths to tale place. It was horrific and out of control. This device should have been recalled by the FDA early on. There was no control over the hot silicone spilling. It was not reversible as it was promoted. Jay Cooper was focused on the financial benefits of this device and not its safety.

I attended lectures and asked questions directly to Jay Cooper which he could not answer because basic science studies had not taken place.

- What was tubal volume average?
- What thermal damage could take place?
- How to avoid spillage?
- What direct damage to cilia would occur?

When I asked Cooper what was the normal size of a uterus in his lecture he did not know. Then I asked what was the average volume of a fallopian tube, then for a chart as to uterine and tubal volumes in females and he did not have one. I wanted to see how these changed by age, childbirth and weight.

After learning of the ***bad science*** I went to the Washington Post and the Congressional Paper to complain about this device and the lack of science that took place prior to placing it in women's bodies. National newspapers failed to report on this important story so that women who were victims and having complications had no idea that I had asked the FDA for a recall.

I gave notice to the FDA of the spillage of hot silicon into the pelvic abdominal cavity causing severe pain, burns, destruction of organs and hysterectomies for the many complications. There was a lack of proper rational scientific thought in the design of the device. It should have never gone to trial. Dr. Cooper and his team failed to do proper risk analysis.

None of these simple questions were asked. I asked for a recall of this device repeatedly to the FDA. **Not recalling this device is a crime.** A complete follow up was the ethical step to take. It still is the ethical step to take. I could not get the total number of women who had this device and I believe there were some 15,000 victims. Many have no idea what happened to them. I asked repeatedly for a recall which was wrongly denied. The FDA does not have follow up on the outcome of the some 15,000 women at risk.

If the FDA continues to be grounded in commerce and not science the public will become conscious that the FDAs current system needs to radically change and become an ethics based division in government. **Science and data need to be the foundation of review, not sales and profit to the corporations.** My staff and I need access to all FDA meetings through existing technology. Be it audio or audio visual the issues before the FDA need to be open to the public.

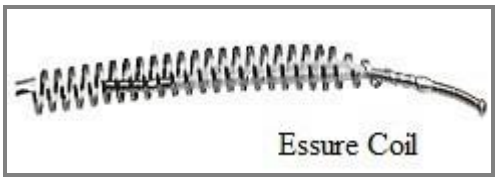
I would suggest that the public library system become a site for the public to meet and be able to communicate with the FDA. All libraries have computers cameras and audio can be added for a small cost to be able to connect with the FDA on these important issues. A woman who is suffering from problems with Essure is not a person who is healthy enough for travel and likely not a person who can afford the expense of travel to Maryland. HBI can help sponsor a national program to raise money for these much needed communication systems.

I want to speak on this issue because I have military training in creating protocols. I was cleared by the Office of the Inspector General (OIG) to operate at any military hospital after my license was revoked. **How did this take place?** The OIG reviewed what happened to me and found the actions of the California Medical Board (CMB) were not justified or fair, and lacked due process. My ability to write protocol has been proven over time. This is a skill needed by the FDA. My focus on ethics over business is essential in the FDA review process to help to balance evaluations.

The Hufnagel Bioethics Institute (HBI) has unique data on women's health issues. This information is based on experience and our direct contact with female victims of abuses and crimes since the early 80's. We also reach out over the globe on the issues of reproductive rights. Women are subjugated beyond their own conceptual knowledge. They lack the education in science/medicine and have no psychological assistance to move beyond the abuses they have learned to accept in their individual cultures. Women are taught to believe men in white coats are their loving and caring fathers who would never cause any harm to them. This "blind trust" is a common psychological paternalistic way of thinking for most women about their doctors. Women are slowly learning that men in white coats are just that and nothing more. Some men in white coats are loving father figures but this is a dwindling number. Most men in white coats are out to make money as their primary goal. The FDA needs to learn this reality as well and that the **welfare of the patient is the primary goal** for a member of the Hippocrates Society which today has only a few members. Simply ask a physician to recite the Hippocratic Oath and see what happens.

Here are some facts and the science on Essure which have been ignored despite the fact that these are all fundamental and should have been seriously examined prior to creating the device.

MATERIAL ANALYSIS



1. Essure is made of rigid materials. ***Ridged non-flexible material is known to perforate tissue.***

The anatomy and physiology of the uterus and fallopian tubes with the materials used **WILL CAUSE PERFORATION.** This is a scientific fact. **Thus damages were caused by intention by those involved.**

A. The fallopian tubes move constantly in the pelvic cavity (like a jelly fish in water)[5][6]. Movement to the uterus and fallopian tubes is caused by intromission of the penis during sex [7] as well as by orgasm alone. Motion and movement against a rigid object will cause injury, infection, scarring and perforation.

B. Ridged devices can perforate other organs including: bladder, rectum, and major blood vessels such as the AORTA and the VENA CAVA.
Ridged materials can cause bowel obstruction and all of its complications. Ridged materials can puncture through embryonic sacks.

Summary: It is not logical to place a rigid object inside a fallopian tube. Anyone with basic knowledge of physiology and anatomy would know this. This is a fundamental design flaw.

INTERIOR ANALYSIS

The fallopian tube has fine cilia that move inside with fluid production. Chemicals needed by the female body are produced here. They also contain receptor sites for production, function, and relay of hormones and co-factors [8] [9] [10] [11] [12] [13] [14]. These have many roles including reducing rheumatic diseases. Placement of a rigid object will cause inflammation and scarring and destroy all chemical processes. Physically the end of the tube at the fimbra will close off from inflammation. The fluid created will fill the tube and create hydrosalpinx (hydrosalpinges) [15]. This will cause chronic severe pelvic pain.

This is all logical and anyone with a basic knowledge of anatomy and physiology would know this.

Summary: An increased rate of rheumatoid disease would be predicated. Increased pelvic inflammatory disease is predicted. As an issue for informed consent these all would have to be part of the informed consent process.

Where women told the following?

The first issue is that this product was **NOT** designed to have a healthy outcome.

Women need to be told that perforation may occur. Also that a hysterectomy may have to be performed when a perforation takes place.

Women need to be informed that with the use of Essure they will be at higher risk for hysterectomy, and of all the risks associated with hysterectomy.

Informed consent is a right, <u>not</u> an option.

We at HBI need the numbers on the complications but it is clear that we do not have accurate statistics to provide to women because the data has not been properly kept in order to be able to give proper risk factors. However it is also not rational to perform an elective procedure on a female that could result in the loss of her sexual organs.

This design of Essure and its marketing is not a rational concept. **One can not offer to control pregnancy and at the same time inform that the total loss off the female organs may take place** yet this is the reality of this device and its failures. This is not logical nor is it ethical.

Protocol for the FDA needs to look at ethical issues. This is not taking place. The first step in evaluation is to review the **Hippocratic Oath**. The FDA and physicians have forgotten the Oath and why we have it.

1. **I will take care that they suffer no hurt or damage.**
   They key word here is NO, no negative outcome is permitted.
2. **I will comport myself and use my knowledge in a godly manner.**
   The knowledge is focused on healing not stock sales.
3. **I will willingly refrain from doing any injury or wrong from falsehood.** Falsehood is not giving females of any age full informed consent.
4. ***Primum non nocere***… "First do no harm".
5. **Whose illness may affect the person's family and economic stability.**
   The creation of pelvic pain can impact the entire family and is a significant issue in one's life. There is a general concept that pelvic pain is no big thing and does not impact the life of the female. In reality it can completely disable a female and cause enormous harm to the family. This includes loss of needed income to support the family, enormous medical costs, increased divorce rates, and even suicide.

There are many errors that take place by the FDA. However these errors are not made known to the public because of the fact that the media and press do not cover these issues with the matter of importance they carry. A major newspaper at most may do a series of 2 articles. The follow up is often lost and the "fire" of the material is never created to burn in the minds of the nation. The programs of disinformation are not made known to the public. I am sure many at the FDA are very much cognizant of the reality of crisis management disinformation marketing programs and others are totally ignorant. A educational program on lobbying, power structures, and disinformation needs to be known by all at the FDA.

The tabloids are best suited for getting a story out to millions and creating noise in all media. A half a page in the National Enquirer is likely to save more lives than a Pulitzer prize article in one of our finest papers. This is learned by decades of experience as a reporter and whistle-blower. It is better to reach more of the public and get the public to realize they are being hurt.

There is little fire in the victims of Essure. They believe that the way to change comes through being "good girls" to the patriarchs of medicine. They have been trying to appeal to the morals of physicians to see them as victims and have had a 180 degree change. This is because of the age of these women and the culture that they have been educated by. I am from the 60's and in my 60's and I know that the ACOG see's these women as flies they can swat. The ACOG destroyed me for speaking the truth. They are a machine that will do anything to protect itself.

The women victims of Essure have magical thinking that those who sell this device will have compassion for them and take care of them. All one has to do is read the history of this SCUM EVENT. Any male reading the history would make a fist and hit the enemy who harmed them. These females actually work on the belief all of this harm is caused by accident! The psychology of the shadow in medicine is totally unknown and needs to become well known by the public. I would have published this years ago had it not been stolen and destroyed by the CMB.

It is very difficult to explain the psychology of institutions to Americans that have grown up indoctrinated into a belief system that has magical thinking as it foundation and is celebrity driven. I will be sending the FDA my Position Papers on issues that have been covered up or forgotten that need action on. In this paper I am asking for a full recall of Ovabloc.

ESSURE with proper informed consent being written and given to women, I suspect no women would elect to use this device. The ACOG has made money on the device and created another product to harm women. They highly profit when the device is inserted and again in the sequel when women return with iatrogenic problems which often require hysterectomy. The point to be made here is that these physicians are supposed students of science. They (those who created the device and those who are trained in women's medicine) all know better as to anatomy and physiology of the female and the harm they are causing.

As a scientist I am concerned about the failures in the following areas:

1/lack of proper review of device prior to testing
2/What can go wrong when we put metal inside the human body

One of my papers which caused attacks on myself early in my career while at Cedars Sinai Medical Center concerned IUDs. The placement of metal in an IUD I saw as an added risk. Are women told today of the risk for NMR or other wavelength transmissions who have metal in their tubes or uterus? I would think one would look for inflammatory processes and immunological changes.

At the time no one considered the possibility of thermal damage by wave technology. An young male attending at UCLA attacked me repeatedly. I had been writing on the negative aspects of various birth control devices for my manual of FEMALE SURGICAL CONSENT. This document was 30 pages in length back in the early 80's. A copy was sent to the Texas Legislature when I was working on the informed consent law for hysterectomies at the time.

There was a tragic irony that took place. His wife "cooked" her uterus and had a serious complication. Microwaves are conducted and heat up and cause fires with metal objects. She wore heels and had a microwave unit that was in the range of her pelvic area. The unit was defective and the waves were transmitting beyond the containment. The damage showed that the metal exploded inside her uterus. He stopped bad mouthing me after that event. However, the fact she was injured and no one at UCLA organized to educate the public on this case I found deplorable. This should have been a published article. The case was kept silent with intention. The wife had the IUD put in at the UCLA clinic. One must realize that institutional medicine is constantly covering up scandals. This was never looked at by the FDA which is bizarre in our society today since we live in a time of extreme corruption because of our decay by financial crimes.

My request before the September 24, 2015 hearing:

Please provide me the data base system you are using for Essure.
How does one access the data for review?
Did you ask for an NIHS review? I did, some time ago, and NIHS has not responded (which is not protocol for them). Why are they not responding?
I need the consent form being used for review. Please provide this for my review.
All copies of Medwatch complaints filed concerning Essure for my review.
All lawsuit information against Essure and access to all the documents filed by Essure with the FDA.

I volunteer to help the FDA create a Bioethics review process.

I warn that most Bioethics experts are not physicians and fail to know the many complex issues that prevent a clear and powerful review. I have sat on committees in Bioethics and watched cover-ups take place.

The ACOG and others see me as the enemy. That is fine with me because you need to keep your friends close, and your enemies even closer.

"Essure" Nickel Labeling, FDA & Issues of Consent

Seeing "RED FLAGS" with the Changes in the Standard of Care

*Those who withhold information about the known risks of **"Essure"** prior to its use are committing fraud. Withholding information constitutes forced (fraudulent) consent which can lead to battery. ~ Dr. VGH*

Essure Nickel Labeling and Warning:

The Essure device is made of a nickel-titanium alloy. Originally, women were advised via product labeling instructions for use (IFU) that in vitro testing demonstrated that nickel is released from this device. Women were advised to test for nickel allergy prior to having the Essure implanted. Women found to be hypersensitive to nickel were advised not to have the product placed.

After the product was on the market for some time, Conceptus lobbied the FDA to remove the contraindication for patients with known hypersensitivity to nickel as confirmed by a skin test. **This should have been a big red flag for the FDA,** but instead of seeing the red flag, the FDA gave Conceptus the green light. In August 2011, Conceptus removed important information and warnings relating to Nickel from their IFU having gained the FDAs approval to do so.

How did this happen?

This was **NOT** an action of consumer safety or protection on the part of the FDA. This was an action of giving the green light to a manufacture and obgyns to withhold important information from women at the time of consent.

This information was removed and withheld with the intent to persuade women to make the decision that the manufacture and doctor wants them to make. **Withholding information from women at the time of consent is an intentional fraud.** Doctors/organizations/medical device manufactures who withhold information, or who state that pre-testing for nickel allergy is not important and not necessary prior to the use of the Essure product are committing intentional fraud and misrepresentation. **Withholding information constitutes forced (fraudulent) consent.**

Co$t and Profit$:

When comparing the cost of performing a skin test for nickel allergy compared to the cost of losing a sale/surgery, and compared to the cost of future medical care needed for women finding out after the fact they do have an allergy to nickel is **NOT** equal. **The cost of loss of health to the woman far outweighs the other.**

Nickel hypersensitivity can cause:

• pulmonary asthma
• eosinophilic pneumonitis
• conjunctivitis
• inflammatory reactions around the nickel-containing implants
• anaphylactoid reactions after parenteral injection of nickel-contaminated medications

NICKLE ALLERGIES ARE REAL:

It is time the FDA alerts America to the fact that allergies to materials used in the human body do exist. In 1995 I spoke before the FDA DEVICE COMMITTEE and gave evidence of the Human Leukocyte Antigen (HLA) being linked to allergies with silicone and its use in BREAST IMPLANTS. The fact that this data has not been made public for decades is another reason that powerful institutions took my voice. This is unethical and simply flat out wrong. For progress in medicine to take place we must know what is not working and not cover it up. I am adding to the Hippocratic Oath my own statement **"What you do not know can kill you"**.

Physicians have a duty to not cover up and not be silent about the wrongs they witness. This includes also the things they do wrong. It is best to admit all mistakes and wrongdoings. As I reveal in Shadow of Medicine many lives would of been saved had others joined me in speaking out. But they saw me being burned at the stake and turned their eyes away .

I consider the addition of nickel into this product completely insane. Why would anyone put nickel into a woman's body? I have stated, as have others, that **nickel should NEVER be used in any type of gynecologic implant.**

Nickel is **NOT** a metal that has been shown to have NO NEGATIVE effects on the human body. People can be sensitized to nickel and have allergic reactions. **It is criminal that the requirement for pretesting for nickel allergen was removed from the Essure product labeling and many women have been injured by this action.**

For the record, **POLYESTER FIBERS (PET) ALLERGIES ARE ALSO REAL:** (I will write more on this at a later time)

Past and Continuing FDA FAILURES…

As I stated earlier, the FDA has failed in the past to inform the public that silicone can cause allergies. Certain HLA types have reaction to silicone. The FDA has publicly stated that there is no reaction to silicone breast implants. However that is not actual truth, the NIH has studies showing that some HLA types do have allergic reactions to silicone. However, this has not been made a proper part of informed consent which is a major issue that needs to be corrected. Silicone is not 100% safe. I reported this in 1995 with surgical cases to the FDA. I did a series of surgical breast implant removals with 100% improvement in patient condition with all symptoms of allergy and pain removed but also no breast deformity. No new implants needed to be placed as I showed the committee for Female Reconstructive Surgery (FRS) for breast operations. Also

I showed the FDA that all breast implants cause **chest wall deformity**. None of this has been made public. It is time to reveal this data.

It is not ethical to not provide the patient with ANY and ALL complications to any device. This is a need that the FDA is not providing.

ALL is they keyword.

The patient must have ALL the information to make their consent or not.

Do not confuse *"consent"* with *"informed consent"*. **Batteries occur when information is withheld** in order to coerce a women into signing a form and then she suffers bodily harm (of a known risk which was not disclosed). A form stating that the women was "informed" or told of the risks is not valid without details of what she was specifically told or informed of.

I advise all women who believe or know that they have been a victim of a battery to file a police report. The fact that the battery took place in a medical setting has no bearing and does not change that a crime of battery has been committed. It is not for the police to decide if they should or should not take your report. If you are reporting a battery their job is to take your report.

The FDA allowed Conceptus and doctors to alter and with-hold important information about nickel allergy pretesting. This fact paints the picture that the FDA is working more-so for the device manufacture and their profits instead of protecting the public. **This goes against all ethics.**

Pretesting for nickel allergy is a legal and ethic requirement before use with of this product. Women also need to be informed in writing (via an informed consent document which she signs) that with use of this product she will be at higher risk for hysterectomy, and of all the risks associated with hysterectomy… and MORE.

The marketing pressure to not give 100% complete consent needs to end immediately for all products, devices and procedures.

"Transvaginal Ultrasound" (TVU) replacing "Hysterosalpingogram" (HSG) as the 3 Month Essure Confirmation Test

Another "Red Flag"

First of all, with Essure, some perforations will take place during the insertion procedure. This is because there is no A-Assessment. No lab studies for contraindication have been done. No RISK ASSESSMENT has been done. No view into the pelvis. No STD work up! This is not the practice of medicine… this is the sales of a "magic pill" to women who are not educated and are always looking for that magic pill. This is true for most of the American population. The quick fix seekers. Hysterosalpingogram (HSG) shows only if the tube is open (or closed) and some of the internal tube condition. Transvaginal Ultrasound (TVU) shows where the NICKEL is. And where are the studies on nickel and ultrasound (US)? Without contrast the tube being open or not is not able to be determined. Again, I need to remind the medical community that by 1980 I was a published expert and researcher in ultrasound (US) for OB/GYN. I have never been attacked for my lack of skills or training. I am attacked because I tell the truth.

The current standard of care with Essure until recently was for all women to undergo a **hysterosalpingogram (HSG) as a confirmation test three (3) months after** the device is implanted to determine if the fallopian tubes are blocked by tissue in-growth around the coil inserts. What this means is that SEVERE INFLAMMATION AND SCAR TISSUE had resulted from the ESSURE. That the function of creating factors and co-factors needed for the female system have been destroyed by this action. This is an issue of informed consent women are not told… that they may have a higher risk of rheumatoid problems or have chronic pelvic pain with hydrosalphinx.

It was announced on July 1, 2015, that the **FDA approved transvaginal ultrasound (TVU) to be the NEW primary confirmation test** to be performed 3 months after Essure placement to check if the device had been "placed properly" (3 months after it was placed). In my science world this is malpractice. At the time of the insertion placement should be documented.

The 3 month TVU is to be done NOT in addition to a HSG test but as the primary confirmation test. As explained by Bayer, the TVU will be performed by the physician (after training) and only if the physician is unable to confirm correct placement with TVU, an HSG will have to be performed (by a radiologist).

This plan shows those behind it lack medical science knowledge. How is Bayer going to train a MD in an entire field of medicine that takes years of learning? Answer is: They are not. It also shows that the technology of intraoperative US is not known to the ACOG, FDA or Bayer and I could go on about what should be done… but that is ***INSANE*** since **this entire "ESSURE" project is one I ETHICALLY CONDEMN.**

While HSG tests confirms with dye and x-ray if the tubes are occluded or blocked (and alternative birth control is no longer needed) the TVU only checks for "placement". This is also vague since the device could be in the correct plane but already have perforated out the tube.

This new rule did not just come on its own by the FDA. Bayer and obgyns had to make the request for this new protocol to be approved and had to lobby the FDA for its approval. The request from the manufacturer, the ACOG, and OBGYNs to forgo the HSG and replace it with a TVU 3 months after placement should have been **another "Red Flag" for the FDA**.

I challenge Bayer and the so called OBGYNS. Who the hell are these people?

1/ Hired guns for the project 2/ Stock holders 3/the devil?

The reality is only laparoscopy is a way of visualization and diagnosis for the many complications that women have reported.

The problems with this new protocol:

1. TVUs are often **fuzzy and hard to read**.
2. The TVU will **NOT confirm that the tubes are occluded**.
3. TVUs **do not detail as an x-ray HSG does** as to how many coils are present or if they are bent/broken.
4. Tissue **pathology is not determined**.
5. The physicians who promote, sell (**profit**), and place the Essure device are proposed and anticipated to be the ones who will be trained/certified to do the Essure TVU "confirmation of placement" test. (This means MORE money for the e-doctors as they will be able to charge $$$ for performing the TVU) (Currently obgyns do not perform or profit from the HSG as TVU are performed by radiologists). As the doctors inserting the device already highly profit by charging "surgical fee" rate$ for inserting the device (which causes a conflict of interest over suggesting/offering other forms of birth control…) the fact that they will further profit by performing the TVU only **compounds this conflict**.
6. When doctors insert the Essure it is done so visually (using a hysteroscope) so it should **be known at the time of insertion** if the devise was properly placed. **X-ray should be done at the time of insertion to confirm the device did not break while being inserted and for future reference.**
7. Checking for "proper" placement via TVU 3 months later is **NOT** done to see IF it was properly placed. It is done to see if it is still properly placed or has it migrated. How can this be determined if there are not before images to compare them to? Proper placement does not mean that the tubes are occluded, it just means the device is where the doctor wants it to be (which with TVU could be subjective).
8. In the news article **Bayer describes the Essure® insert as "soft and flexible"**. The metal coil is not soft and it is not micro as they have described in the past. The insert can be seen with the naked eye and the coil is made of metal. Calling the coil micro, soft and flexible is **marketing fraud** done to mislead women and the public.
9. The proper placement of Essure is for it not to be placed to begin with based on **all the complications that have occurred and the lack of ethics and science** in the development of this device.

My belief is that **Bayer and OBGYNs would prefer the TVU over the HSG** as they are visually less dramatic (as women are posting copies of their misplaced and migrated HSGs on the internet), and they give less information (which goes along with withholding information from women as is done with the nickel information).

I am the gyn who created intraoperative ultrasound in the early 1980's. I presented this at the ACOG annual meeting. Thus I can speak to this issue as a world expert. The gyn community is not trained in intraoperative ultrasound nor in TVU. Thus adding ultrasound to Essure either at the time of insertion or 3 months after it is placed will **NOT** have any change in how it is placed, its migration, or in the iatrogenic sequel caused by the device.

The ACOG failed to create a program to advance this technology when I created intraoperative GYN US in 1981. I sent a teaching program to the ACOG who responded by stating that gynecologists should not learn this technology and it should stay in the radiologists control. I disagreed with the ACOG's decision. Thus the addition of US for insertion or confirmation of device placement by a physician will not be able to take place. The public is unaware that meetings take place in which it is decided who is in power over technology in the medical industry. In this issue I was pushing for the establishment of GYN intraoperative ultrasound. The ACOG sat down with the heads of the American College of Radiologists and split how things would be done for economic reasons and to prevent territory fights.

The reason we do not have virtual colonoscopy today and much needed technology to reduce colon cancer is the fact that a territory fight has been going on for decades. Thus, virtual colonoscopy has not advanced as it should have for decades. This is a territory fight issue. It is based on money. **The FDA is aware of these issues as well.**

It takes time to find out the money issues that are behind this crime against women. I currently do not have the time to do this. However I can oversee a group of women who would volunteer to get to the bottom of these issues. I have found that the victims are not logical and in fear and are acting out as a result of these crimes. This is an area in medicine and finance that is not discussed. Victims cannot be true advocates for themselves because there is NO SUPPORT SYSTEM for them. The actions they take are emotional and often not logical. This is a true psychological condition taking place. There is no current therapy available and no experts working on this condition. I am first to describe this in the medical literature. I have seen the lack of focus and disorganization when these crimes take place. I am working on the psychological issues of the female victims of Bill Cosby. There are direct similarities in these cases. **Women expect to have help.** The medical community (those who make, sell, insert, and approve the use of Essure) take action to cover-up. Then they find out no one (family and friends) believes them. Then they become labeled by society as doing wrong or being mentally ill. This is a very difficult situation. Why have the women not gone after the **patent holders** of Essure? Why are they not filing police reports because with the lack of consent **they all have been victims of a battery**? They are not logical and are emotionally not able to separate so they can take action. They are totally overwhelmed (due to their negative iatrogenic condition, caring for young children, work, etc…). And in trying to work with them is difficult because they find comfort in "fun events" such as Facebook posting and social rallies (as opposed to writing Congress, attending NOW meetings, filing police reports, marching/protesting). The concept of hard work on these issues is not on the table for them. Some women have shame because they consented to the implantation of Essure. They know they were buying the magical pill and should have been more of an advocate for themselves. These women have not even come forth.

"Essure" and Hormone Health

"Women need to be informed that with the use of "ESSURE" they will be at higher risk for hysterectomy, and of all the risks associated with hysterectomy." ~Dr. Vikki Hufnagel

Since the 80's I have lobbied and advocated for **baseline hormone testing** not only for post tubal ligation and sterilized women but **for ALL women as a standard of care to promote hormone health.** *This has been a major focus of my work.* I have had NO support since my mentors died. No one in the OBGYN community has assisted me in this issue. I have been attacked repeatedly for my opinion which in this area is **based on science and proven to be correct over the decades.**

My protocol directs baseline hormone testing for **ALL women** starting at age twenty-five as a **standard screening test** in the same way that mammograms are for women at age forty. This was based on hundreds of patients I studied and presented showing that hormone levels are necessary for the **standard of care for ALL women**. In some cases of disease hormone studies are needed before age 25.

Loss of hormone production, hormone imbalance, and **hormone shock** (sudden loss or abrupt change of hormones triggering physical shock and manifesting with shock related symptoms) can affect both a woman's physical and mental health (a few examples include bone health, cardiac health, memory, REM sleep and libido).

In the United States, a woman's odds are more then one in four of one day having a tubal ligation (female sterilization) or hysterectomy. A woman's chance of one day having a surgery that could affect her hormone production or possibly castrate her is much higher (1 in 4) then getting breast cancer (1 in 8), yet women are not routinely offered hormone testing as they are with mammograms.

The ACOG et al have repeatedly refused to inform women about hormone testing and about hormones being sold to them. The ACOG knows that many hormones are the cause of breast cancer by the formulas being used and the manner in which the hormones are given. My work was intentionally suppressed by the ACOG in collusion with the CA division of the AMA, and the CMB. The GYN community has told lies to women patients for decades. These lies have caused morbidity and mortality. One lie is that a woman only needs one ovary to function. This story is not based in science. The GYNS failed to study these women for decades. Also GYNS have failed to study women with appendectomies. I studied women with lost ovarian function after an appendectomy. The loss of one ovary is common.

My neighbor is a typical female patient. She was put on manufactured hormones. She never had hormone studies. She now has ductal carcinoma. She never had a ductal cell study. She never had a risk assessment for breast cancer. This is the condition in the standard of care in the upper class in Beverly Hills Ca. You can imagine the care the poor are getting.

Women are not informed about or offered hormone testing. A woman having this information about what her levels are when she is in the prime of life and feeling her best is **essential** information to have in her medical files. A base line is **needed for all women** should she need NCH tm NATURAL CYCLIC HORMONES then it can be provided to fit her personal hormone state.

The **Hormone Profile Protocol** **I created in the 80's** (for which the CMB stated I was a criminal and women did not need hormone testing) **directs for the following plan of care:**

All women (including women younger then age 25) should be hormone tested before all surgical procedures or medical treatments which could affect her hormone levels short term or long term: This would include being tested before a hysterectomy, tubal ligation/female sterilization **("ESSURE")**, uterine fibroid embolization, prior to donating eggs, Lupron shots, prior to starting hormone replacement therapy or taking the birth control pill, etc…

In any operation blood supply to organs can be lost causing loss to the organ. Thus a cesarean section can cause loss of ovarian function. Thus any disease, device, procedure or operation can stop hormone production. Testing before and after is a scientific fact that needs to be a standard of care and I am sorry that the ACOG and CMB have caused so much harm to so many. The FDA needs to be science based. Tests need to be done before an action and then after. **The fact this is not done is medical negligence and medical malpractice.** In 1995 I discussed this issue at the medical device committee meeting. **The failure to test female hormones is a crime by anyone who practices medicine.**

Women who are experiencing **irregular periods or cycles** (regardless of age). This would include **missing cycles** (in the absence of pregnancy), experiencing **long periods** (longer then 10 days of bleeding) **long or short cycles** (having two periods in a month, going 45 days between cycles). Any cycle that has new symptoms associated with it also needs investigation.

All women who have undergone **any form of female sterilization**/tubal ligation (Essure), tubal reversal, Essure removal, hysterectomy, uterine fibroid embolization, one or both ovaries removed, one or both fallopian tubes removed, or **any type of surgical or medical treatment that could have affected her hormone production** (regardless of age).

It is not scientific to allow a device to be used without hormone studies. This is a continuation of a business protocol to sell a device and not be thinking at all times of the welfare of women. Again, **the FDA needs to use a science and ethics protocol.** A business protocol can be used after you have created a safe product. It is clear that this ESSURE, Morcellation which kills women, UAE (UFE), Mesh Implants and Breast Implants all are not as they should be. I will prove that Morcellation was allowed and is now allowed and that any reasonable person would condemn this device and condemn how it came into use. If the FDA does not evolve into using a science and ethics protocol in time the public will take action. It takes time and hard work to uncover wrongs. It took me 30 years to expose Bill Cosby. Do not believe that the FDA is more powerful than truth. No one is more powerful than truth.

Women are not offered hormone studies because the ACOG has lied to women for decades about hormones. It has lied about the fact only one ovary is needed for normal function. There is no science behind their statements. As women evolve and become educated they will learn they cannot trust those who lie and fail to teach. The ACOG failed to educate women or offer hormone studies in a proper way for too long of a time for anyone to trust them. They have made public statements which inform the public that the tests for hormones are unreliable and not necessary. This is not true.

There is a cost to run hormone tests. However had this been done for decades the cost would of decreased. I went to China in 1996 to create hormones that would be safe. That same year the ACOG and CMB attacked me to stop my work. My neighbor who has breast cancer was never given risk assessment, never has any hormones studies. She is like millions of women she trusted her GYN. Women are not having baseline hormone studies which is negligence in the provision of hormones to women. Yet, across America women are get hormones from physicians without proper testing.

The other side of this issue is women are in fear of hormones and refuse them. Many of the women refusing hormones will also suffer. This is an area in women's medicine that is corrupt. The manufacturers of patent drugs run this. The ACOG has not done any education of women to learn about hormones and has fought me for decades on routine testing. However I will not give up. Routine testing of hormones is the same as having routine testing of your blood pressure or a pap smear. **It is basic and essential.** Thus any action that can change hormones needs to be studied. And this refers to all the medications, devices and procedures being reviewed by the FDA.

Hormone studies need to be done in depth. I can tell you that most GYN's do not even know all the hormones the female body creates. For example getting a FSH follicle stimulating hormone test is not enough information. When ESSURE came to the FDA they should have been concerned about the co-factors and chemicals created within the fallopian tube. Why were they not? This is the question I ask and the reality was they were not working with a scientific model. **I offer to provide an educational program on female hormones to the FDA.**

Thus, in evaluating ESSURE one cannot offer safety because the studies on hormone effects has not taken place. This is another issue of lack of informed consent and failure of FDA protocol. **Patients should not have this research after the fact.** It should have been done during the testing phase.

I will be sending a FOIA on the files of several issues I wish to investigate. **On this section I want to see all of the studies done before insertion of ESSURE and after: toxicology, allergy, immunological, general blood chemistry, rheumatoid studies, hormone studies, nickel studies and inflammatory studies.**

As a Bioethics Surgeon and Physician I am asking to see **the toxicology studies for ESSURE.** All those for ESSURE would needed to have had an allergy and immunological baseline studies prior to insertion of Essure. Then follow up studies for changes.

CONCEPT OF REVIEW:

It appears that the FDA needs to reevaluate its process. If a device has complications the etiology of these needs to be examined. The current PATCH policy is not scientific. The FDA current suggestion, for example, is to add Ultrasound. This is a patch bandage you are adding which is not logical and not science. In science one does not outline problems then put bandages on them. In science one goes back to the start and reviews the entire process. This is the scientific process

which the FDA needs to work on as its protocol type. Currently the process used is a business review not a science review. I do not have the time to review the entire May hearing this year. I believe it was great because it is bringing transparency to the FDA. But in all the talks the foundation was in a business model review. The FDA attempts to support the device and the company to make the device work. This is done through business model concepts. This is not science or ethics and is a business position which is not what is needed. A complete scientific and ethics review is needed. A protocol needs development and I suggest that the FDA ask NASA for assistance in this process. I continue to study Aerospace Medicine because it is grounded in science and protocols. Use of ultrasound may in fact, with Essure, have complications with the nickel element.

I offer my services to corporations and to FDA and other government authority because of my skills and experience. **I am not the enemy and never have been. But I am not silent and I do have a very different point of view.** This point of view caused me and my family great harm but it also created new operations that I hope to document for the future to save lives. **Follow the Hippocratic Oath and do good.** Thank you for this act of transparency in allowing me to speak on these issues.

~ BE OF VALOR

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