Does FDA Preemption Trump Informed Consent?

By Dr. Julio Cesar Novoa, M.D.

Informed Consent is a fundamental right of every patient. Violation of this right not only constitutes a breach of the patient-physician relationship and medical malpractice, but also constitutes violations of State law and the civil rights of the patient as protected by Federal law.

What is Patient Informed Consent?

Informed consent is a process of obtaining “permission” or “consent” from the patient before conducting a healthcare intervention.

A health care provider must ask a patient to consent to receive medical care, therapy or undergo surgery before providing it, or a clinical researcher must ask a patient to participate in a research study before enrolling that person into a clinical trial.

Informed consent is collected according to guidelines from the fields of medical ethics and research ethics.

An informed consent can only be given based upon a clear appreciation and understanding of the facts, implications, and consequences of an action.

In order to give informed consent, the individual concerned must have adequate reasoning faculties and be in possession of all relevant facts.


What legal recourse does a patient have when Informed Consent is not obtained?

1. State Civil and Criminal regulations regarding Informed Consent

   a. Violation of the Patient-Physician Relationship
      i. Complaint to the State Medical Board for unprofessional conduct and ethics violation.
      ii. Civil lawsuit for medical malpractice

   b. Criminal Complaint for Assault and Battery
2. Federal Law Violation of Title 21 and/or Title 42 of the United States Code. Title 42, Section 1983, Violation of Civil Rights


What is FDA Preemption?

In regards to this discussion, FDA Preemption refers to legal protection provided to the manufacturer of a Class III medical device.

The FDA classifies medical devices based on a specified level of risk. Devices are either Class I, II or III. In the case of Class III devices, the FDA requires a premarket approval (PMA) evaluation before the medical device can be sold in the US market.

Once a medical device is granted Class III, PMA protection, the manufacturer of the device cannot be held liable for damages caused by the medical device even if the device is proven to be defective or at fault for an injury to the patient.

Federal courts have ruled that since FDA regulations provide legal protection for Class III medical devices to their respective manufacturer, this provides federal protection to the manufacturer which “preempts” State laws.

- In law, the term “preemption” refers to situations in which a law passed by a higher authority takes precedence over a law passed by a lower one. Usually, “preemption” is used interchangeably with “federal preemption,” meaning that a law passed by the U.S. Congress must be applied if it conflicts or overrules a law passed by a state legislature on the same subject.


Why is the FDA PMA Classification Allowed to Preempt State Regulations?

Under the United States Code of Federal Regulation (CFR) Title 21, the US Congress gives the Food and Drug Administration (FDA) the authority to regulate medical devices.

Specifically, Under:

CFR TITLE 21 (FOOD AND DRUGS)

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH AND HUMAN SERVICES

SUBCHAPTER H-MEDICAL DEVICES
THE ESSURE PERMANENT STERILIZATION DEVICE IS CLASSIFIED BY THE FDA AS A CLASS III HIGH RISK MEDICAL DEVICE.

Therefore, under Title 21, Class III Medical Device PMA regulations preempt State regulations, thus, generally preventing patients from seeking any legal recourse from a device manufacturer at a State level for damages caused by Class III medical devices.

How does Title 21, Class III PMA Preemption conflict with a patient’s civil rights regarding Informed Consent?

The US Congress protects the rights of patients regarding medical research and practices in CFR Titles 21 and 42.

Title 21, Chapter 1, Subchapter A, Part 50, Subpart B, Sec 50.25, delineates the specifications of Informed Consent but only for research volunteers. More interestingly, is the fact that it specifies that research patients cannot be forced or allowed to waive their rights, even during experimental studies, in regards to negligence, yet once a device obtains Class III PMA, patients no longer have this right.

Sec. 50.25 Elements of informed consent.

(a) Basic elements of informed consent. In seeking informed consent, the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject’s participation, a description of the procedures to be followed, and identification of any procedures which are experimental.

(2) A description of any reasonably foreseeable risks or discomforts to the subject.

(3) A description of any benefits to the subject or to others, which may reasonably be expected from the research.

(4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject.

(5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained and that notes the possibility that the Food and Drug Administration may inspect the records.

(6) For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

(7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects’ rights, and whom to contact in the event of a research-related injury to the subject.
Should Title 21, Class III PMA Preemption Trump

Title 42 Informed Consent for Sterilization?

NO! Title 42 affords protection to federally funded insurance programs, specifically Medicare and Medicaid. In the case of the ESSURE permanent sterilization device, a patient who is sterilized using the ESSURE device must sign an Informed Consent specifically approved by the Secretary of the Department of Health and Human Services (DHHS).

Title 42 › Chapter IV › Subchapter C › Part 441 › Subpart F › Section 441.257

§ 441.257 Informed consent.

(a) Informing the individual. For purposes of this subpart, an individual has given informed consent only if:

(1) The person who obtained consent for the sterilization procedure offered to answer any questions the individual to be sterilized may have concerning the procedure, provided a copy of the consent form and provided orally all of the following information or advice to the individual to be sterilized:

(i) Advice that the individual is free to withhold or withdraw consent to the procedure at any time before the sterilization without affecting the right to future care or treatment and without loss or withdrawal of any federally funded program benefits to which the individual might be otherwise entitled.

(ii) A description of available alternative methods of family planning and birth control.

(iii) Advice that the sterilization procedure is considered to be irreversible.

(iv) A thorough explanation of the specific sterilization procedure to be performed.

(v) A full description of the discomfarts and risks that may accompany or follow the performing of the procedure, including an explanation of the type and possible effects of any anesthetic to be used.

(vi) A full description of the benefits or advantages that may be expected as a result of the sterilization.

(vii) Advice that the sterilization will not be performed for at least 30 days, except under the circumstances specified in § 441.253(c).

(2) Suitable arrangements were made to insure that the information specified in paragraph (a)(1) of this section was effectively communicated to any individual who is blind, deaf, or otherwise handicapped;

(3) An interpreter was provided if the individual to be sterilized did not understand the language used on the consent form or the language used by the person obtaining consent;
(4) The individual to be sterilized was permitted to have a witness of his or her choice present when consent was obtained;

(5) The consent form requirements of § 441.258 were met; and

(6) Any additional requirement of State or local law for obtaining consent, except a requirement for spousal consent, was followed.

(b) *When informed consent may not be obtained.* Informed consent may not be obtained while the individual to be sterilized is:

(1) In labor or childbirth;

(2) Seeking to obtain or obtaining an abortion; or

(3) Under the influence of alcohol or other substances that affect the individual's state of awareness.

§ 441.258 Consent form requirements.

(a) *Content of consent form.* The consent form must be a copy of the form appended to this subpart or another form approved by the Secretary.

(b) *Required signatures.* The consent form must be signed and dated by:

(1) The individual to be sterilized;

(2) The interpreter, if one was provided;

(3) The person who obtained the consent; and

(4) The physician who performed the sterilization procedure.

(c) *Required certifications.*

(1) The person securing the consent must certify, by signing the consent form, that

(i) Before the individual to be sterilized signed the consent form, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual to be sterilized appeared mentally competent and knowingly and voluntarily consented to be sterilized.

(2) The physician performing the sterilization must certify, by signing the consent form, that:

(i) Shortly before the performance of sterilization, he or she advised the individual to be sterilized that no Federal benefits may be withdrawn because of the decision not to be sterilized;

(ii) He or she explained orally the requirements for informed consent as set forth on the consent form; and

(iii) To the best of his or her knowledge and belief, the individual appeared mentally competent and knowingly and voluntarily consented to be sterilized.
Except in the case of premature delivery or emergency abdominal surgery, the physician must further certify that at least 30 days have passed between the date of the individual’s signature on the consent form and the date upon which the sterilization was performed.

(3) In the case of premature delivery or emergency abdominal surgery performed within 30 days of consent, the physician must certify that the sterilization was performed less than 30 days, but not less than 72 hours after informed consent was obtained because of premature delivery or emergency abdominal surgery and -

(i) In the case of premature delivery, must state the expected date of delivery; or

(ii) In the case of abdominal surgery, must describe the emergency.

(4) If an interpreter is provided, the interpreter must certify that he or she translated the information and advice presented orally and read the consent form and explained its contents to the individual to be sterilized and that, to the best of the interpreter’s knowledge and belief, the individual understood what the interpreter told him or her.

Does Title 21 Conflict with Title 42?

It appears that a conflict may exist in regards to the protection awarded to a medical device manufacturer under Title 21 (Class III PMA federal preemption) as compared to the protection of civil rights guaranteed to a patient under Title 42, Informed Consent for Sterilization.

This situation is unique in terms of Class III PMA preemption, because, unlike other types of medical devices, the ESSURE device is the only Class III medical device used for sterilization. And, since the ESSURE is used specifically to sterilize a patient, Title 42 provides specific protection under federal law which is not available to patients with other types of Class III medical devices.

Therefore, in the specific scenario of Medicaid sponsored sterilization, Title 21 may not preempt Title 42 in regards to the ESSURE device and Informed Consent for Sterilization.

Unlike where Title 21 preempts State law(s), in this situation, you have one Federal law, Title 42, which may challenge another Federal law, Title 21, if Title 42 is violated.

If such is the case, which Federal law preempts the other?

Federal Preemption of State Law, Failure to Warn

Both state law and product liability (tort) lawsuits regulate medical devices, as well as, prescription drugs.

Generally, a medical device manufacturer has a duty to warn physicians of any dangerous effects that the manufacturer is aware of or has reason to know are inherent in the use of medical device. A manufacturer that fails to warn a physician can be held liable for breach of duty. State law product liability lawsuits based on this failure are referred to as “failure to warn” lawsuits.

However, “failure to warn” obligations, such as in the case of a medical device involving the manufacturer, physician and patient, are not as easy to litigate against either the manufacturer or the physician as thought.
In the case of Class III PMA medical devices, “failure to warn” obligations by the manufacturer are met by the product labeling required by and accepted by the FDA prior to marketing. In fact, a manufacturer is forbidden from adding any additional information to the product labeling or altering product labeling in any way without the expressed written approval by the FDA. In other words, even if a manufacturer were aware of a product defect or potential risk of injury, it is required to get approval for a product label change from the FDA before this information can be added to the labeling prior to sale to physicians.

Therefore, as written, manufacturers of medical devices with Class III PMA classification are generally protected from liability claims on a State level due to the fact that Title 21 awards protection against “failure to warn” claims because the FDA acceptance of the product labeling is considered “enough warning” regarding the medical device.

https://www.mayerbrown.com/files/News/77b19e3e-587a-410f-a2c0-568a2a28c6db/Presentation/NewsAttachment/620480df-7958-4ea2-9f80-fecb66c41b37/How%20to%20Argue%20Medical%20Device%20Preemption%20For%20the%20Defense%20October%202012.pdf

In cases of Class I and II medical devices, manufacturers are not protected from liability as compared to Class III PMA medical devices; however, liability can be mitigated by the concept known as “Learned Intermediary Doctrine.”

In situations where the medical product is recommended or prescribed to the patient by a learned third party, such as a physician or clinician, an exception to the duty to warn exists. This exception is known as the learned intermediary doctrine. The learned intermediary (physician) has a duty to warn the patient of all risks and benefits associated with the recommended product. “Entrusted with the duty to properly advise patients of the benefits and risks associated with prescribed drugs, if a clinician is aware of a side-effect and yet still elects to prescribe that drug, a manufacturer’s duty to warn may be discharged if a court deems that the learned intermediary exception applies.”

http://druganddeviceblog.com/category/duty-to-warn/

Therefore, aside from the protection provided to the manufacturer of Class III PMA classification which preempts State law; some state laws free a manufacturer from liability by entrusting the patient’s physician with providing adequate warning in place of the manufacturer.

Is there a loophole in Title 42?

Unfortunately, the protection granted by Congress in Title 42 does not specifically obligate a manufacturer to obtain Informed Consent from the patient since the wording in the criteria for obtaining Informed Consent refers to the entity obtaining Informed Consent from the “patient” as a “person or physician.” There is no specific acknowledgment of responsibility to obtain Informed Consent by the manufacturer.

§ 441.258 Consent form requirements.

(a) Content of consent form. The consent form must be a copy of the form appended to this subpart or another form approved by the Secretary.

(b) Required signatures. The consent form must be signed and dated by -

(1) The individual to be sterilized;
(2) The interpreter, if one was provided;
(3) The person who obtained the consent; and
(4) The physician who performed the sterilization procedure.

Legal Challenges to Title 21 and Title 42

Challenges of Title 21: Federal courts have ruled that, expressed or implied preemption, to State law does not allow a patient to sue for Failure to Warn which is preempted by the Class III PMA classification. Specifically, the FDA labeling of a device is sufficient to defend against most Failure to Warn claims.

However, the courts have ruled in favor of manufacturers by accepting an unrealistically broad assumption. Specifically, that proper labeling as delineated by the FDA are sufficient warning to the consumer of the risks, benefits, indications and alternatives to the use of a device.

Aside from the labeling on a device, such as in the case of the ESSURE, the FDA does not require any specific written confirmation of Informed Consent regarding a Class III PMA device.

In comparison, during clinical trials, written and extensive informed consent is required by law, but once a device gets Class III PMA, no written informed consent is required by the FDA. This is strictly left up to the physician who places the device.

Challenges of Title 42. Obtaining Informed Consent is strictly left up to a “person and physician,” not a manufacturer of a medical device.

WHAT IS THE LEGAL DEFENSE UNDER TITLE 21 AND TITLE 42 WHEN THE PATIENT IS UNAWARE AND/OR HAS NEVER SEEN THE LABELING OF THE ESSURE DEVICE IN ORDER TO BE INFORMED OR GIVE INFORMED CONSENT?

Why would the courts feel that adequate warning exists when a patient is unable to read or completely unaware of what the FDA labeling on the product says?

Consider the general manner in which the ESSURE is bought, sold and placed in a patient.

The ESSURE is marketed directly for sale to the physician, not to the patient. Current federal regulations prevent the sale the ESSURE device to patients; instead, they are sold directly to physicians.

Any FDA literature of the device is available directly to the doctor. Few patients are aware of the FDA website or ESSURE website and do not obtain or confirm any information regarding the ESSURE outside of what they are told by their doctor.

Further, few patients are able or allowed to see the actual labeling on the ESSURE device since this is not provided to the patient prior to its insertion.

Unlike a consumer that goes to the store and is able to read the label on a food package, or a consumer who goes to buy a car and is able to read the owner’s manual or physically touch the product before they buy it,
patients are not allowed to touch either the box or ESSURE device before it is placed inside of their bodies. An extremely small number of patients are even aware of the labeling on the device packaging.

Therefore, if a patient is unaware of the FDA labeling, how are they able to be appropriately advised and warned regarding the risks of the device and how is Informed Consent confirmed so that an obvious failure to warn situation doesn’t exist?

We have to remember that patients cannot purchase these devices directly from the manufacturer and Class III PMA does not require confirmation that the patient has seen, read or understands the labeling or risks of the product.

As such, despite Class III PMA classification, the manufacturer should be obligated to confirm that the patient has read the product labeling aside from any confirmation from the doctor since, in this regard, the doctor is acting as a distributor/wholesaler and retail agent of the manufacturer during the sale of the product.

Further, labeling of the device can also include information regarding the PMA status of the device.

Previously, it was a prohibited act to have the premarket approval application (PMA) number on the device labeling. The FDA Modernization Act of 1997 (FDAMA) repealed the restriction in Section 301(l) of the FFDCA, which prohibited reference to FDA approval in the labeling or advertising of medical devices that have an approved PMA.


Since information regarding the PMA status is allowed on the device labeling, it would seem only logical that a patient should be informed regarding what PMA actually means.

FDA regulations requires that labeling not be ambiguous or misleading as to the risks of a device. Further, the FDA classifies the ESSURE as a HIGH RISK device. Therefore, by the minimal standards of product labeling, patients should be made aware of the device’s risk classification in order to be properly informed.

Whether relying on a physician interpretation or patient interpretation of informed consent, few would opine that not knowing the risk classification of a product and the fact that a patient waives their rights to compensation for damages should the product later be found to be either unsafe or ineffective, is not a critical piece of information necessary for a patient to make an Informed Consent. On the contrary, this should always be the first and most in depth piece of information discussed as part of Informed Consent.

In regards to the PHYSICIAN, if Bayer failed to provide information about the risks of the ESSURE, including its Class III PMA classification which would have been a critical piece of information to pass on to their patient, isn’t a FAILURE TO WARN an even more obvious situation?
If the physician, acting as the wholesale purchaser and the retail seller of the ESSURE and the agent obtaining informed consent from the patient, is not informed as to the risks and problems with the ESSURE, how is failure to warn not an obvious and consistent occurrence?

In this recurring scenario, if the doctor is improperly warned and the patient, as a layperson, who has no direct information from either the FDA or a Class III PMA medical device manufacturer, is even less informed than the doctor. Therefore, there cannot be any reasonable expectation that the patient can make an informed decision or give Informed Consent.

So, I go back to my point that despite the fact that the courts have relied on the FDA product labeling to provide adequate documentation of the risks of a device which serves as a defense against Failure to Warn liability, the fact remains that a low percentage of patients and doctors are ever made aware of Class III product labeling, and, on the contrary, are not warned at all.

Most interestingly is the fact that the recent draft BBW and physician informed consent recommendations are indirect written confirmation that Informed Consent has never been properly obtained since no such information was available for the doctor or patient to review which was critical information for the patient to have as a knowledge base for their decision making process. Further, even with the new proposals, the FDA is still not requiring that patients be informed that the ESSURE is classified as a Class III PMA HIGH RISK device, which prevents a patient from making an Informed Consent, and, thus violates a patient’s civil rights.

Sadly, even if both the black box warning and draft recommendations are adopted, it is estimated that less than 50% of doctors will pass all of the BBW information on to their patients and the fact remains that patients will still have no direct access to product labeling since the newest recommendation for informed consent will be strictly voluntarily.


As things currently exist, there is a fundamental absence of critical information required for either a physician (under the concept of Learned Intermediary Doctrine) or the patient to make an Informed Decision about a Class III device if INFORMATION about its HIGH RISK STATUS is not present on the product labeling or if this is not given to the patient by either the doctor or the manufacturer. Therefore, its absence in any written informed consent document is an absolute violation of a patient’s civil rights.

Further, these violations disproportionately affect women within ethnic minorities (such as Hispanics and African Americans) and lower financial status, especially when patients are specifically targeted for marketing if they have Medicaid.

If such a violation were done by a person, local government or representative of a State or the Federal government, then a patient could seek legal relief under Section 1983 of Title 42. Should we, therefore, not hold the Commissioner of the FDA and/or the Secretary of the DHHS legally accountable for these violations?
Possible Solutions to Title 21 and Title 42 Issues

1. Contact the Secretary of the Department of Health and Human Services (DHHS).

   It is obvious that the Legislative and Judicial branches of the US government have failed to protect patients. Neither Title 21 nor Title 42 provides any of the fundamental protection that they should in order to protect or reduce the risk of harm to patients.

   Interestingly, Title 21, which grants the FDA regulatory control over medical devices, and Title 42, which provides patients in federally sponsored programs protection in regards to Informed Consent, are BOTH overseen by the same entity, which is the Secretary of the Department of Health and Human Services (DHHS).

   For clarification, the FDA is a department within the DHHS, and, therefore, the FDA Commissioner reports to the Secretary of the DHHS.

   Therefore, it is imperative that while changes are made at the "grass-roots" level through patient and physician awareness, and concerns addressed to the FDA, all patients and their families should make their feelings known directly to the Secretary of the DHHS.

   The FDA is not the final say in changing the requirements for providing adequate Informed Consent to the patient.

   The Secretary should be made aware of these problems and demands for new regulations that guarantee that patients are made aware of the risks of using the ESSURE.

   Specifically, the FDA and product manufacturers are in the best legal position to guarantee that minimal standards regarding Informed Consent, to include an explanation of Class III PMA classification and an acknowledgment by the patient that they are waiving their rights to sue under product liability laws, are in place. ALL patients should be required to sign a document approved by the FDA and provided by the manufacturer and signed by a patient’s doctor and the patient that states the following:

   - I have been advised by my doctor and Bayer of the following Food and Drug Administration (FDA) BLACK BOX WARNING (BBW) and draft guidance recommendations regarding the ESSURE.

   "WARNING: Some patients implanted with the ESSURE System for Permanent Birth Control have reported adverse events, including perforation of the uterus and/or fallopian tubes, intra-abdominal or pelvic device migration, persistent pain, and allergy or hypersensitivity reactions. Some of these reported events resulted in device removal that required abdominal surgery. This information should be shared with patients considering sterilization with the ESSURE device during discussion of the benefits and risks of the device."
I have been advised by my doctor and Bayer that the ESSURE System is classified as a Class III, HIGH RISK device by 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. Due to the level of risk associated with Class III devices, FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices.”

Due to its Class III classification, if the device were to cause any harm for reasons found to be associated with the device, I am aware that I would have little or no recourse to seek monetary compensation for injuries caused by the device from the manufacturer of the device, which is the Bayer Corporation.

2. Notify the Inspector General of the Department of Health and Human Services of the violation of your civil rights by failing to obtain Informed Consent as a violation under Title 42, Section 1983 for the failure to warn you (by the FDA and the manufacturer of Class III PMA products) of the Class III HIGH RISK classification of the ESSURE and the waiver of your rights to seek legal recourse for injury or emotional distress caused by the device.

NOTE: EXPERT TESTIMONY IS NOT REQUIRED WHEN SEEKING COMPENSATION FOR EMOTION DISTRESS UNDER SECTION 1983.

Department of Health and Human Services
The Honorable Daniel Levinson, Inspector General
Main Phone Number: (202) 619-3148
Mailing Address: 330 Independence Avenue, S.W.; Washington, D.C. 20201
Hotline Number: (800) 447-8477; HOTLINE:
https://forms.oig.hhs.gov/hotlineoperations/?ref=widget
Hotline Email: hhstips@oig.hhs.gov (link sends e-mail)

Twitter, YouTube
URL:

http://oig.hhs.gov/

3. Request that the Secretary of the Department of Health and Human Services (DHHS) place a temporary moratorium on the marketing, use or sale of the ESSURE permanent sterilization device, based on:

(1) current review of clinical studies,
(2) a review of the significant increase in complaints filed in the Manufacturer and User Facility Device Experience (MAUDE) databank,
(3) increasing number of unplanned pregnancies, fetal and maternal deaths,
(4) draft review of a BLACK BOX WARNING (BBW), and 
(5) additional post market clinical study of the ESSURE by the FDA rendering the ESSURE as an 
experimental device requiring continued research under Title 21, Chapter 1, Subchapter A, Part 
50, Subpart B.

4. Support the Fitzpatrick-Slaughter Bills, including Ariel Grace’s Law and the Medical Device 
Guardian Act.

a. Fitzpatrick Bill aims to ban the use the ESSURE device from the US market.

“While many medical devices prove lifesaving, we know that some can cause harm and have 
devastating consequences on patient I think everyone would agree that when a medical device is 
found to be unsafe, there needs to be an effective process in place to track these failures, to remove 
devices from the market, and provide legal recourse for those impacted. Currently, that process is 
falling us, and our constituents are paying the price,” said Fitzpatrick. “It’s time we reform the FDA, 
its processes and procedures to allow for maximum innovation and maximum safety. Agencies, 
physicians and lawmakers should all be committed to this common cause, and open to these 
bipartisan solutions.”

b. Ariel Grace’s Law

The permanent sterilization device ESSURE has led to the death of at least four women and nearly 
300 unborn children, including Ariel Grace who was stillborn following failure of the device. However, 
under current law, the manufacturer cannot be held liable for her death or the harm and suffering 
the device has inflicted upon tens of thousands of other victims.

Ariel Grace’s Law resolves this injustice by allowing victims to seek legal recourse and ensures medical 
device manufacturers are incentivized to maintain the safest and most effective products for all 
patients.

reform-bills

c. Medical Device Guardians Act of 2016

A bill designed to amend the Federal Food, Drug, and Cosmetic Act to require physicians and 
physician’s offices to be treated as covered device users required to report on certain adverse 
events involving medical devices, and for other purposes.


Laparoscopic power morcellators are used for hysterectomies and to treat uterine fibroids by 
grinding, or morcellating, them. However, if the blades hit an undetectable fibroid cancer, it will 
spread the cancer throughout the body, like shrapnel – taking Stage 1 cancers immediately to 
Stage 4.

Despite this, no one reported this deadly defect to the FDA, until Amy Reed, a mother of six, and 
a doctor underwent morcellation and her cancer spread throughout her body. Dr. Reed’s 
patient report to the FDA was the first adverse event report received by the FDA regarding 
morcellators, despite her same hospital having has a patient harmed by a morcellator one year 
earlier. After the initial report from Dr. Reed, hundreds of other safety reports began to flow into 
the FDA.

But it should not have fallen upon the patients to bring this to the FDA’s attention. The Medical 
Device Guardians Act codifies an existing mandate of the American Medical Association’s 
Code of Medical Ethics, which recognizes that physicians are in the best position to identify and
report unsafe devices. Additionally, the bill adds physicians’ reports to the list of groups, such as hospitals, already protected from having their reporting to the FDA used against them in a civil case.


Example Letter for Patients to Send to the Secretary of the Department of Health and Human Services and the Inspector General, Department of Health and Human Services

Dear Inspector General,

I am writing this letter as a formal complaint against the Food and Drug Administration (FDA) for a violation of Title 21 and Title 42 of the United States Codes of Federal Regulations.

This complaint is filed under Title 42, section 1983, as a civil rights violation.

Titles 21 and 42 requires that a patient give Informed Consent before undergoing a medical sterilization.

Under current FDA policy, a manufacturer nor physician is required to inform a patient that a FDA Class III medical device is classified as HIGH RISK by the FDA and that a patient granting permission to have this device inserted into their body waives all rights to seek legal recourse when this HIGH RISK device injures a patient.

Under Title 42, Chapter IV, Subchapter C, Part 441, Subpart FDA, Section 441.257(iv, v), federal law mandates that a patient giving Informed Consent, must have:

- "a thorough explanation of the specific sterilization procedure to be performed."
- "a full description of the discomforts and risks that may accompany or follow the performing of the procedure, including an explanation of the types and possible effects of any anesthetic to be used."

I consider the classification of the ESSURE permanent sterilization device as a Class III HIGH RISK device, and the fact that I unknowingly waived all rights to sue the manufacturer for product defects or related injuries when allowing this device to be placed in my body, as mandatory and critical information to my decision making process that was not given to me.

As a point of fact, had I known that the ESSURE device was classified as a HIGH RISK device by the FDA, and my waiver of rights to sue for damages caused by the device, I WOULD HAVE NEVER CONSENTED TO HAVE THE ESSURE PLACED IN MY BODY.
Under the FDA Modernization Act of 1997, the FDA allows for the PMA status of a medical device to be added to the labeling or advertising of a medical device. HOWEVER, the FDA (1) failed to require that this information be added to the ESSURE product labeling, (2) failed to require the manufacturer notify my doctor of the HIGH RISK nature of the device, and (3) failed to notify me of the HIGH RISK nature of the device.

On February 29, 2016, the FDA attempted to mitigate its error in providing Informed Consent to my doctor and myself by issuing draft recommendations to doctors and required the placement of a BLACK BOX WARNING on the ESSURE device. HOWEVER, despite 6 months of delay, the FDA has failed to make a final decision on these proposals. FURTHER, even if these recommendations are adopted, they are strictly voluntarily. As such, it continues to fail to guarantee the minimum requirements for Informed Consent under Title 42, Informed Consent for Sterilization.

The Commissioner of the FDA has been made aware of these violations of Title 21 and 42 and yet continues to allow the dissemination of ambiguous and misleading labeling of the ESSURE device.

Further, the FDA continues to allow misleading and deceptive marketing of the ESSURE device as a non-surgical procedure.

Original marketing of the ESSURE device by the Conceptus corporation (original manufacturer of the ESSURE) appropriately advertised the device as a surgical procedure. However, the FDA is allowing the Bayer corporation (current manufacturer of the device) to advertise and market the ESSURE as a non-surgical procedure.

Placement of the ESSURE device is unequivocally a surgical procedure. Its placement requires (1) anesthesia, (2) requires the use of an operative (surgical) hysteroscope by a surgeon considered proficient in surgical hysteroscopic procedures including the placement of the ESSURE, (3) requires Informed Consent as a surgical procedure, and (4) is classified and billed under ICD 10 and CPT codes as a surgical procedure.

Despite recommendations from an FDA advisory committee, dated September 2015, requiring the correct marketing of the ESSURE device as a surgical procedure, this has not been included in the draft recommendations under review.

Allowing the ESSURE to be marketed as a non-surgical procedure is not only misleading and deceptive but is an additional violation of my right to know about the risks of the device since I believe the ESSURE is intentionally marketed as a non-surgical procedure in order to reduce the perceived or awareness of the potentially life threatening risks of this type of surgery.

Had I known that the ESSURE is a surgical procedure, I would not have consented to having it placed in my body.
The ESSURE device has caused me physical, emotional and financial harm which would not have occurred if I had been informed of its HIGH RISK CLASSIFICATION or my inability to seek any legal recourse for the damages the device has caused me as a Class III medical device.

Because of these events, I believe the Commissioner of the FDA and the Secretary of Health and Human Services should be held accountable for my injuries, which is the reason I wish to file a complaint under Title 42, section 1983.

I respectfully request the Secretary of the Department of Health and Human Services and the Inspector General of the HHS to immediately investigate my complaint and until policy changes are made, I would like the Secretary to order a temporary moratorium of the placement, sale or marketing of the ESSURE device in support of the current legislation in Congress presented by the Fitzpatrick/Slaughter bills banning the device from use due to its documented high incidence of device failure and unacceptably HIGH RISK of complications leading to additional HIGH RISK surgeries to remove it, as well as, risks of patient and fetal death.

Sincerely,

Name
Address
Contact Number
Email Address