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Review Article

Medicolegal Review: Essure Lawsuits and Legal Strategies Adverse to Gynecologists

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ABSTRACT The minimally invasive Essure procedure for hysteroscopic sterilization is an ongoing target for litigation. Although efficacious, this device has been scrutinized by the US Food and Drug Administration (FDA) owing to alleged complications. Patients affected by these potential complications are filing lawsuits against Bayer, the manufacturer of Essure. Many of these lawsuits have been barred by preemption, a legal doctrine that limits what can be required of a product by state lawsuits once the FDA approves it; however, in the lawsuits that have been allowed to proceed, the manufacturer has used a legal strategy termed the "learned intermediary doctrine" in an effort to shift blame to the gynecologist to absolve itself of liability. The learned intermediary only requires that a manufacturer inform the gynecologist of the risks associated with the device, and the gynecologist, in turn, must notify the patients through adequate informed consent. To incorporate the necessary components of informed consent, a gynecologist should include what a reasonable practitioner would consider pertinent to the discussion, as well as what a prudent patient would want to know to make a treatment decision. This disclosure entails explaining the risks, benefits, and alternatives, which should be clearly documented in the medical records. Understanding the importance of proper documentation and the legal strategies used in suits will help gynecologists lessen liability exposure when using a medical device, such as Essure, that is being targeted for litigation. Journal of Minimally Invasive Gynecology (2017) 24, 727–730 © 2017 AAGL. All rights reserved.

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The minimally invasive procedure of hysteroscopic sterilization became available in 2002 when the US Food and Drug Administration (FDA) approved the Essure device. The use of this device offers many advantages over the traditional open or laparoscopic approach: it can be performed in-office, requires no general anesthesia, and has minimal recovery time. Recently, Essure has become a target of litigation for both the manufacturer and gynecologists using the device, owing to its association with numerous alleged complications. The FDA has recently reviewed this product's safety and, in response to concerns raised by this review, has initiated the process to improve Essure outcomes.

When new medical procedures are associated with complications, legal repercussions inevitability follow. With the litigious claims, patients have a financial incentive to declare complications, whether legitimate or not. This review shows how manufacturers of medical devices involved in litigation have historically shifted blame to gynecologists in similar lawsuits, as well as how Bayer, the manufacturer of Essure, has already begun this process. The "learned intermediary doctrine" and preemption are explained, to inform gynecologists of how these cases are constructed. In our opinion, Essure is a safe, long-term, effective contraception option for women that should not be discontinued out of fear of legal repercussions. Nevertheless, because plaintiffs' attorneys are targeting both Bayer and the gynecologists providing Essure services, gynecologists who continue to insert the Essure device in the face of litigation need to be cautious. Unfortunately, even when using this FDA-approved product for its intended purpose, gynecologists can still be named in lawsuits.

A survey conducted by ACOG revealed that nearly 1 of 5 ob-gyns (19%) decreased the overall number of gynecologic

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surgical procedures owing to fears of being sued [1]. Unfortunately, medical device litigation involving other products besides Essure, including uterine morcellators, Norplant, and transvaginal mesh, has become part of gynecologic practice today. Medical device lawsuits not only expose gynecologists to financial liability, but also deter gynecologists from using medical devices subject to litigation, which directly impacts the care and options available to patients. The aim of this medical legal review is to make gynecologists aware of the legal strategies used in lawsuits to extend legal liability to gynecologists, as well as to emphasize the importance of documenting informed consent in the medical record.

Materials and Methods

We used the LexisNexis legal search engine to review legal documents from Essure-related cases. LexisNexis is a legal database used by attorneys, judges, and law students to find past cases that reinforce legal arguments. The US judicial system operates under the principle of "stare decisis," which uses legal precedents to ensure consistency in rulings from the courts on similar legal issues. Thus, prior rulings are helpful to courts in deciding cases.

We also used the MAUDE (Manufacturer and User Facility Device Experience) database to retrieve statistics and information surrounding the adverse events of the Essure product. MAUDE is an online database containing the medical device reports submitted to the FDA by consumers/patients, healthcare professionals, manufacturers, and device user facilities.

Background

The Essure device consists of an outer coil composed of stainless steel and an inner coil composed of a nickel titanium alloy integrated with polyethylene terephthalate. The coils are placed under hysteroscopic guidance in the fallopian tubes, ultimately resulting in tubal occlusion. Essure has proven to be very efficacious, with a 5-year effectiveness rate of 99.8% [2]. Essure was originally marketed by Conceptus; however, in 2013, Bayer acquired Conceptus to expand its offerings in women's health. Although Essure has been on the market since 2002, the bulk of the litigation did not appear until after its acquisition by Bayer. The likely explanation is that Bayer acquired Conceptus for a mere $1.1 billion, whereas Bayer's market capitalization was listed at $102.5 billion in 2016, making it a more prosperous target for plaintiffs.

In November 2015, after receiving numerous complaints through the MAUDE database, the FDA convened a meeting to review Essure. The focus was on safety and efficacy, risks versus benefits, and patients' concerns and experiences with the device. Importantly, the FDA advisory committee also sought recommendations for improving physician training, patient counseling, and education of both parties [3]. This advisory committee meeting resulted in several notable outcomes. First, the FDA ordered Bayer to conduct a postmarket surveillance study to obtain more data regarding Essure's benefits and risks. Second, the FDA required a boxed warning on the device's packaging with information for both patients and providers on possible side effects and adverse outcomes associated with Essure, which was finalized on October 31, 2016. The FDA also proposed a decision checklist for presentation to patients prior before the Essure insertion procedure, to improve informed consent. In addition, the meeting addressed a trade complaint filed in February 2015. A trade complaint is filed through the Federal Trade Commission to address unfair and misleading business practices. The allegations suggested that Bayer altered trial records to suggest more favorable experiences. This trade complaint was investigated by the FDA and ultimately extinguished in favor of Bayer [3].

Reported Complaints About Essure

To evaluate the safety and efficacy of Essure, the FDA reviewed reports submitted through the MAUDE database since the device's approval in 2002. A total of 9900 medical device reports related to Essure had been received at the time of the FDA review. Importantly, the FDA commented on the limitations of this method of data acquisition, including its questionable validity, given that it is unverified and potentially biased. The FDA stated:

> The most frequently reported patient problems during this period were pain/abdominal pain, heavier menses/menstrual irregularities, headache, fatigue, and weight fluctuations. The most frequent device problems reported were patient–device incompatibility (for example, possible nickel allergy), migration of the device or device component, device operating differently than expected, device breakage, device difficult to remove, malposition of the device, and device difficult to insert [3].

Aside from the MAUDE database, patients have looked to various social media outlets to express their concerns with Essure, including a widely used Facebook group. Unfortunately, many of the patient complaints associated with Essure are difficult to demonstrate with objective findings, which puts manufacturers, the FDA, and gynecologists in a problematic situation.

Preemption

In March 2016, a federal judge in the Eastern District of Pennsylvania ruled that several counts in 5 civil action lawsuits (McLaughlin, Ruble, Stremil, et al vs Bayer Corporation) were allowed to proceed against Bayer [4]. Although many of the counts were dismissed, those that were allowed to proceed claimed negligent manufacture, negligent risk

management, breach of express warranty, negligent training, and fraudulent manufacture.

This ruling is considered paramount to the initiation of Essure lawsuits, given that many previous rulings were barred by preemption. A legal doctrine used by medical device manufacturers to protect themselves from litigation, preemption essentially states that federal law is the supreme law of the land. There are 2 types of preemption: express preemption and implied preemption. In express preemption, Congress has adopted a statute that explicitly displaces state law. In implied preemption, Congress has not explicitly displaced state law, but if conflict exists between federal law and state law, federal law preempts state law. Express preemption applies to medical device lawsuits in that once a device has received premarket approval, the manufacturer cannot make any changes to design specifications, manufacturing processes, labeling, or any other attribute that would affect the device's safety or effectiveness without FDA permission. No state can impose any further requirements on the device manufacturer. Even if the state law claim does not mandate additional requirements for the device manufacturer, it may be implicitly preempted. Therefore, the US Supreme Court states that any person suing the device manufacturer for negligence must prove that this negligence violated federal law. Because this is difficult to prove, this defense strategy is effective. Most lawyers waited to see whether these first trials were preempted before filing their own cases. The Supreme Court's ruling has opened the doors to a plethora of lawsuits against Essure across the country.

Legal Strategies Used by Plaintiff Attorneys and Medical Device Manufacturers that Adversely Impact Gynecologists

The learned intermediary doctrine is a defense strategy stating that a manufacturer has a duty to warn physicians of dangerous propensities of a drug or device. Subsequently, physicians have a duty to pass on this warning to patients, making the physicians "learned intermediaries." The manufacturer discharges its duty to warn consumers by reasonably warning physicians of the risks associated with the device. The rationale for this lies in the fact that physicians know both a patient's medical history and the risks of a drug or device. Bayer, the manufacture of Essure, previously used the learned intermediary doctrine in an attempt to diminish its liability in Mirena lawsuits. For example, in the case of Gonzalez vs Bayer Pharmaceuticals and Planned Parenthood of Houston and Southeast Texas [5], Bayer was targeted for providing inadequate warning to the patient. However, Bayer responded by shifting liability to the gynecologist by stating that the claim was barred by the learned intermediary doctrine, given that Mirena is available only by prescription from a licensed gynecologist. Bayer is also now applying the learned intermediary doctrine in the Essure lawsuits. In the 2016 McLaughlin, Ruble, Strimel, et al vs Bayer case [4], Bayer successfully used the learned intermediary doctrine in an effort to resolve itself of liability for alleged complications from the Essure medical device. In this case, the plaintiff claimed that Bayer is liable for failure to disclose adverse events; however, the court in this case found Bayer was protected under the provisions of the learned intermediary doctrine, stating that the medical device manufacturer has a duty to warn the gynecologist and no duty to warn patients directly, making the physician the learned intermediary.

Courts use a 2-pronged test when the learned intermediary doctrine is applicable to determine whether the manufacturer is at fault. The plaintiff must demonstrate that first, the defendant (the manufacturer) failed to warn the physician of a risk regarding the product, and second, that this failure to warn was the cause of the plaintiff's injury. The plaintiff must demonstrate that had a treating physician been appropriately warned of this risk, she would not have used the product.

It is not uncommon for plaintiffs' attorneys to use a so-called "shotgun" approach as their legal strategy. In this scenario, the attorney lists the physician, the manufacturer, and the medical institution where the event occurred in the lawsuit. The financial gain is much greater when the plaintiff attorneys of patients with alleged injuries target parties with "deeper pockets," such as the manufacturer compared with the gynecologist. There are also additional legal logistic and strategic benefits for the plaintiff attorneys to name multiple parties in the lawsuit. For example, naming multiple parties expands the options of permissible locations in which to file the suit. Civil suits may be filed in either the defendants' place of business or residence or the location of the business transaction, one of which may offer a more amiable locale. Naming the gynecologist will often keep the lawsuit in the state court as opposed to the federal court, which could be advantageous to the plaintiff attorney as well. Also, as a legal strategy, plaintiff attorneys will often name multiple parties in a lawsuit with the hope they will testify against one another in the process of defending themselves. If they each testify against the other, this ultimately strengthens the plaintiff's case.

Protecting Gynecologists From Legal Repercussion

The most commonly used claim by plaintiff attorneys against gynecologists in these medical device lawsuits is an alternative cause of action known as lack of informed consent. They make this claim because it is difficult for plaintiff attorneys to prevail with a traditional medical malpractice claim if an FDA-approved product is used for its intended purpose and the alleged complication is a known risk associated with the procedure. Thus, plaintiff attorneys will argue that the patient with the alleged injuries was not informed of the risks and alternatives, and that had she been informed, she would not have agreed to the procedure. To prevail, plaintiff attorneys must show that the lack of

informed consent was a significant factor leading to the patient's injuries.

Depending on the jurisdiction, most courts use one of two standards to determine whether informed consent was adequate. The first of these, the "reasonable practitioner" standard, refers to what a reasonable physician would consider important to include. The second, the "prudent patient" standard, refers to whether the information included is what a reasonable person would want to know to make a treatment decision. Therefore, it is essential that practicing physicians have a comprehensive understanding of all aspects of informed consent.

Informed consent incorporates 5 elements: capacity, voluntarism, disclosure, understanding, and decision [6–10]. Whereas most of these elements are relatively straightforward, disclosure warrants further elaboration. First, a patient must have adequate information to understand what the procedure is and why it is being performed. The physician should clearly outline risks, benefits, and alternative treatments. All information should be conveyed using simple terms easily understood by a nonmedical person. Dangerous and irreversible risks should be stated, as should common complications, regardless of severity [7,8]. Not only should this conversation be complete and patient-centered, but it also should be clearly documented with written informed consent.

Bayer's website for Essure provides a sample informed consent document to be adapted by gynecologists in the office [11]. In addition to the risks listed in the sample document, we suggest adding the following statement: "Other reported patient problems include pain/abdominal pain, heavier menses/menstrual irregularities, headache, fatigue, and weight fluctuations." It is important to understand, however, that regardless of the precise wording of the consent document, the potential for a lack of informed consent claim remains. By having the patient sign a consent document, the presumption is highly in the gynecologist's favor that the patient was properly informed of the risk; however, this is a rebuttable presumption, and the patient can still claim that she was not adequately informed of the risk associated with the procedure.

Conclusion

Essure remains an excellent sterilization option for women and should continue to be offered even though it is now subject to ongoing litigation. However, gynecologists who choose to continue to insert the Essure coils despite ongoing litigation need to be particularly cautious. Gynecologists should have a basic understanding of the legal strategies being used by plaintiff attorneys, as well by the attorneys representing the manufacturer of Essure. Even though plaintiff attorneys representing patients are interested in going after the financially deeper pockets of a medical device manufacturer, they may name the medical provider as a party to the lawsuit in an attempt to obtain a more sympathetic venue for court. Moreover, by naming the medical provider as a party, plaintiff attorneys hope that the medical provider and the medical device manufacturer will point the blame at each other, creating favorable witnesses for the plaintiff attorneys.

In addition to legal strategies used by plaintiff attorneys representing patients, gynecologists also should be aware of legal strategies used by attorneys representing medical device manufacturers, such as the manufacturer of Essure, that attempt to absolve the manufacturer of liability by using the learned intermediary doctrine. This doctrine shifts liability from the device manufacturer to the medical provider by arguing that once the manufacturer lists the complications associated with its device, it is the duty of the medical provider to inform the patient of the risks associated with the device. Thus, clear documentation in the medical record indicating that the patient was informed of the risks and alternatives becomes crucial when using a medical device, such as Essure, that is currently being targeted for litigation. By clearly documenting informed consent in the medical records, gynecologists can decrease their chance of being named as a party in an Essure lawsuit and, if named, should hopefully be able to prevail in a lack of informed consent claim.

References

1. American Congress of Obstetricians and Gynecologists. Medical liability climate hurts patients and ob-gyns: survey reveals continuing trend. Available at: http://www.acog.org/About-ACOG/News-Room/News-Releases/2012/Medical-Liability-Climate-Hurts-Patients-and-Ob-Gyns. Accessed February 28, 2017.
2. Conceptus, Inc. Essure effectiveness report, version 2, page 8. Mountain View, CA: Conceptus, Inc; 2002.
3. US Food and Drug Administration. September 2015 advisory committee to discuss Essure safety and effectiveness. Available at: www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/EssurePermanentBirthControl/ucm452254.htm. Accessed October 1, 2016.
4. McLaughlin, Ruble, Strimel, et al v Bayer Corporation. 14-7315 through 14-7318, 15–384 (Pa. 2016).
5. Gonzalez v Bayer Healthcare Pharmaceuticals, Inc, and Planned Parenthood of Houston and Southeast Texas. H-12–1412, 2013 U.S. Dist., Lexis 33585 (Tex. 2013).
6. Faden RR, Beauchamp TL. *A History and Theory of Informed Consent*. New York: Oxford University Press; 1986.
7. Beauchamp TL, Childress JF. *Principles of Biomedical Ethics*. 3rd ed. New York: Oxford University Press; 1989.
8. Emanuel EJ, Joffe S. Ethics in oncology. In: Bast RC, Kufe DW, Pollock RE, et al., editors. *Cancer Medicine*. 5th ed. Hamilton, Canada: BC Decker; 2000. p. 1145–1163.
9. Meisel A, Roth LH, Lidz CW. Toward a model of the legal doctrine of informed consent. *Am J Psychiatry*. 1977;134:285–289.
10. Berg JW, Applebaum PS, Lidz CW, Parker LS. *Informed Consent: Legal Theory and Clinical Practice*. Oxford, UK: Oxford University Press; 2001.
11. Bayer Corporation. Essure procedure consent form (example). Available at: http://www.hcp.essure-us.com/assets/doc/Consent_Form_Example.docx. Accessed February 28, 2017.