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Essure: The IUD Story We Should Have Seen Coming

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Essure: The IUD Story We Should Have Seen Coming

by

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HCS Capstone

Submitted to:

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Richmond, VA

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Introduction:

Female sterilization is the second most common contraceptive method used by women in the U.S.. Historically, the procedure was done via laparoscopic surgery. However, in 2002, Bayer's new female contraceptive device called Essure was approved by the FDA, allowing hysteroscopic sterilization. The Essure device is essentially a small metal coil that is inserted into each fallopian tube with the intention of causing swelling and scarring that closes off the tubes. The device was attractive for many women and physicians because the procedure could be performed in a doctor's office rather than an operating room. As of 2015, 750,000 women had received Essure (Dhruva et. al., 2015, p. e17(1)).

Although Essure may be the first device of its kind in terms of the specific mechanism by which it interferes with conception, it is certainly not the first intrauterine device (IUD). It is believed that people have been intrigued by the contraceptive potential of IUDs for a very long time. According to legend, the first attempts at contraception via inserting objects into the uterus were performed by Arab and Turkish camel drivers who inserted small stones in their camels' uteri so they couldn't get pregnant on long journeys across the desert (Perry & Dawson, 1985, p. 8). Other early IUDs were fashioned out of wood, glass, ebony, ivory, wool, pewter, even diamond studded platinum. In the 17th century, Italian adventurer Casanova suggested using a gold ball. The most similar precursor to the modern IUD, however, is the cervico-uterine pessary - a T-shaped device made out of metal. The device was derived from the common vaginal pessary - initially designed to treat prolapsed uteri, a condition that results when the uterus slips into the vagina or even out of the body. Flipping this device upside down so the stem sticks into the uterus was found to have contraceptive functions (i.e. the cervico-uterine pessary). According to Perry and Dawson, "Soon, women were having pessaries inserted for contraceptive reasons

alone, although neither they nor their doctors openly admitted to it. In America, dispensing contraceptive devices - or even information on the subject - was against the Comstock Law of 1873 ... The law made it a crime to disseminate any information about birth control; it remained in effect for more than 50 years” (p. 9). Women who received this device were taking a significant risk - both legally and with their health. Inserting any device into the uterus has the potential to introduce bacteria from the vagina into the sterile uterus, causing severe infection. Not to mention, this was well before the discovery of Penicillin, the first antibiotic, in 1928 so infections tended to be significantly more detrimental.

In 1909, Dr. Richard Richter who practiced in Poland, near modern day Breslau, developed an IUD that consisted of two or three looped rings of silkworm gut - a material commonly used to suture wounds at the time. “The loops were joined together by a short piece of aluminum-bronze wire, which, with the silken ends of the loops, formed a kind of ‘tail.’ The entire device was poked into the uterus with the aid of a wooden stick” (p. 10). However, Richter released nearly no data on infections, bleeding, or other complications likely because the device was illegal, and these records would have further incriminated him. Richter’s device was largely ignored by the medical community, most likely due to its illegality.

In 1923, Dr. Karl Pust of Germany developed a new IUD. He used three twisted strands of silkworm gut to create a device shaped somewhat like a baby’s pacifier. The device had a tail of dangling silken strings that was wrapped tightly with another silk thread and then attached to a button of glass. He claimed that he followed 453 women who had the device and none got pregnant or had serious complications. However, the silk wrapped tail allowed bacteria from the vagina to enter the uterus and cause severe infections. “More than 20,000 of Pust’s IUDs were distributed before the device was finally condemned by the medical profession. How many of

those women became ill or died is not known. “Several aspects of the Pust episode - the glowing initial reports from the inventor, the tail strings causing infection, the injuries to women - were hauntingly similar to events that would occur 50 years later with the Dalkon shield” (p. 11). In fact, this was a narrative that would be all too familiar, continuing all the way up to the development of Essure in the 21st century.

Despite Pust’s device’s failings, interest in IUDs grew. Doctors felt the growing acceptance of IUDs allowed them to experiment more, and feminist movements applauded the invention’s ability to free women from the burden of childbearing or too many children if they should so choose. In 1930, Dr. Ernst Grafenberg of Germany created a new IUD. The device was a ring of “German silver” - a mixture of copper, zinc, and silver. Grafenberg’s ring had no tail strings like previous devices, given a number of doctors believed the strings were to blame for infections. Grafenberg reported that he inserted the rings in 600 women and less than 2% became pregnant but did not mention infection. He was also the first doctor to provide instructions on how the devices were to be inserted and removed. He emphasized the use of sterile equipment, advised against anesthetic, and against use of the device for women with preexisting infections (i.e. gonorrhea) (p. 12). His device was not well received in Germany; with the rise of Nazi party, birth control was largely phased out in an attempt to produce as many Aryan children as possible. However, the device did gain traction elsewhere, at least initially. But soon enough, doctors started telling the all too familiar stories of bleeding, pain, and infections. In 1937, Grafenberg fled the Nazis and came to the U.S. where his device was still quite controversial. While he continued to use the device in private practice, he instead prescribed cervical caps and diaphragms in public practice (p. 13).

In 1936, Comstock Law was overturned, and it became legal to distribute information about birth control. Dr. Tenrei Ota of Japan had been experimenting with many iterations of an IUD device since 1920, and in 1934, he announced that he had used his most recent Ota ring, “a coiled ring of either silver, gold, or plastic with two or three radial arms suspended within it,” in 73 women and just one became pregnant. Although Ota neglected to mention infection, the device became popular among Japanese gynecologists. In 1959, Israeli doctor Willi Oppenheimer announced that he had been using two ring devices, including the Ota ring, in several hundred private practice patients since 1930 with very good results (p. 15). Similar reports about the Ota ring came out of Japan, but the number of patients wearing the devices was in the thousands. This information, along with the discovery of penicillin and other antibiotics, dramatically changed the way the western world thought about IUDs. Doctors went on to develop a whole range of IUDs with many physicians being especially excited about plastic IUDs because their flexibility meant doctors could insert the devices without dilating the cervix - a process that often required anesthesia which poses its own risks (rash, asthma flares, sometimes even stroke or heart attack). Over the next several years, many women unknowingly went on to become guinea pigs for these new devices, often at the cost of serious complications, namely pain, bleeding, uterus and sometimes bowel perforation, expelled devices, and permanent sterilization.

In 1962, the first international conference on intrauterine contraception was held. Only a few years prior, IUDs were out of the question for many gynecologists - “the unpopular contraceptive devices had been plagued by persistent reports that they caused bleeding and dangerous infections in the women who used them” (p. 7). At the conference, success stories like those of Dr. Lazar Margulies of New York City and Dr. Jack Lippes of Buffalo were shared with

little to no mention of complications (p. 16). Following the conference, IUD production soared throughout the 1960s, largely due to panic about the world's rapidly growing population; IUDs were believed to be the solution to this crisis, and they were strongly supported by the Population Council. This council was an organization founded in 1952 by John D. Rockefeller III and supported by the United Nations Fund for Population Activities and the Ford and Rockefeller foundations. The Population Council believed that "the problem of unchecked population growth is as urgently important as any facing mankind today... it becomes a central task of our time to stabilize this growth soon enough to avoid its smothering consequences."

Shortly after the IUD conference of 1962, the Population Council put together their own meeting. There was a frenzy of excitement over the potential for IUDs to be the solution to the population crisis. However, according to Dawson and Perry,

"This zealotry resulted in a very lopsided gathering. Negative reports about IUDs were quickly brushed aside as being unfounded, unreasonable, and uninformed. The conference organizers said the goal of the meeting was 'fact finding,' but as the conference proceeded it seemed clear that participants would only find those facts that they wanted to find. The evidence against IUDs was there, but it just didn't sink in. Sweeping statements were made at the conference about the safety of IUDs, statements that today seem insensitive at best" (p. 17).

Women's experiences of pain were grossly minimized, and Dr. Oppenheimer claimed that excessive bleeding was a result of anxiety about the device and underlying neurosis. He said that doctors who were hesitant about IUDs were biased (p. 18). Oppenheimer stated, "I have never seen any complications caused by the ring - no inflammation, no fever, no heavy bleeding, and no sterility when the patient wanted to become pregnant again." Yet, he did see all of these complications; he just attributed them all to other underlying conditions and not to the ring. Physicians at the conference understood basic female reproductive anatomy but did not know why IUDs worked. Despite being willing to confess ignorance here, there were no such

confessions of ignorance regarding the link between IUDs and infection (pp. 20-21). “The ability to ignore, explain away, and even cover-up the medical realities of IUDs would reach new heights with the inventors and manufacturers of the Dalkon shield,” and these would in turn set similar precedents for the manufacturers of future devices like Norplant and Essure (p. 19).

Perhaps the greatest risk posed by IUDs is their connection to pelvic inflammatory disease (PID). Several studies have shown that women who wear IUDs have between a 1.7 and 9.3 percent greater risk of contracting PID than women who do not have IUDs (p. 21). PID can present differently in different women, as Dawson and Perry explain.

PID may come on slowly and subtly. A woman may simply feel like she is coming down with a cold or flu: with fever, chills, and a nagging discomfort in her abdomen. The symptoms may appear and disappear for many weeks or months before she realizes she has an infection. Or the symptoms may come on suddenly; with persistent and very painful cramps, high fever, nausea, fast pulse, abnormal discharge or bleeding from the vagina. If proper medical care isn't received immediately, the disease can spread into the bloodstream, causing the formation of dangerous blood clots (a condition called thrombophlebitis) or blood poisoning (a condition called sepsis). Both conditions can be fatal.

Although death from PID is relatively rare in the U.S. because most people have at least decent access to medical care, complications from it are not uncommon. PID complications often result in infertility as a consequence of scar tissue in the uterus or fallopian tubes that block eggs from reaching the uterus and becoming fertilized. Despite Grafenberg's warnings that tail strings increased the risk of PID by allowing bacteria from the vagina to enter the uterus, many IUDs went back to having these strings. The tails allowed the woman and the doctor to check and make sure the device was still in place and made the removal process for doctors easier (pp. 21-22).

In addition to population control motives, doctors and inventors were highly motivated by the potential these devices had to make them very wealthy. Michael Burnhill, an early IUD

inventor admits “everyone thought they were going to get five percent royalties on a million sales a year.” IUDs cost between 20 and 80 cents per device to manufacture yet are sold to private physicians for at least \$15 each. The profit margin is typically lower overseas, but this is compensated for by the sheer volume of devices sold to developing countries. In fact, most physicians hoped to do trials of the devices in developing countries where malpractice laws were “more lenient or nonexistent.” Along these lines, many women who received IUDs did not even sign consent forms and some were inserted by doctors without their knowledge. Clearly, the profit motivation coupled with the population control hysteria facilitated a number of ethical oversights. This trend is laid bare in the closing statements of the 1962 IUD conference:

We have to stop functioning like doctors, thinking about the one patient with pelvic inflammatory disease; or the one patient, who might develop this, that, or the other complication from an intrauterine device; and think of the need for this in general ... Suppose [a woman patient] does develop an intrauterine infection and suppose she does end up with a hysterectomy and [infections]. How serious is that for that particular patient and for the population of the world in general? Not very. Perhaps we have to stop thinking in terms of individual patients and change our direction a bit ... If we look at this from an overall, long-range view - these are things that I have never said out loud before and I don't know how it is going to sound - perhaps the individual patient is expendable in the general scheme of things, particularly if the infection she acquires is sterilizing, but not lethal (p. 23).

Although this particular physician does not expressly contextualize this view in racial terms, many physicians, population council members, legislators, and ordinary citizens were comfortable subscribing to this perspective because black women were those most at risk of harm from contraceptive devices both abroad and domestically. It was as a result of this growing ideology, in fact, that black women founded the reproductive justice movement in 1994, the primary goal of which was to combat white supremacy and population control. The movement was and continues to be centered on three core reproductive principles: every woman has the

human right to have a child, not have a child, and parent her child (Ross, 2021). As the case of Essure will demonstrate, we are still very much in need of this movement for all women.

This history of failure to consider the harmful effects of intrauterine devices on women's bodies follows through to the main topic of this paper, Essure. In subsequent chapters, it will be demonstrated that the 2002 approval process for the sterilization device Essure was inadequate. Because many women are experiencing adverse responses to the device resulting in hysterectomy, salpingectomy, and unplanned pregnancy, it will be concluded that the initial trials were insufficient due to their exclusively short-term evaluations of a device intended to be permanent. Further, the case of Essure will be used to underscore larger issues in the FDA's approval process for medical devices in general, such as the lack of a requirement to have control groups included in clinical trials as is standard in pharmaceutical trials.

Literature Review:

There are three main classes of medical devices under the FDA. Class I devices pose "low risk of injury or illness" and about $\frac{3}{4}$ of these devices qualify for "exempt" status, meaning they do not have to prove their safety through studies or clinical trials. Class II devices pose "moderate risk of injury or illness" and while a few may qualify for "exempt" status, the majority must go through the standard premarket notification (PMN) process. This process usually does not require substantial clinical evidence. Finally, Class III devices are those that pose the highest risk of injury or illness to patients. Most of these devices require pre-market approval (PMA) which needs significant clinical evidence. However, if a device is considered a predicate device because it is similar enough to an already approved device, it's possible to avoid the PMA process (Van Norman, 2016, pp. 278-79). The documentary *The Bleeding Edge*

discusses the rapid growth of the medical device industry. While these devices have the potential to save and vastly improve the quality of human life, they also have the ability to cause significant harm if not used correctly. In many ways, the technology is charging ahead faster than we are understanding the actual science behind it. In the last 10 years, more than 70 million Americans have had a medical device implanted. The documentary talks about how the system for medical device approval has become backwards in the sense that the vast majority of devices are approved on a predicate rule (98%) that was intended to be an exception but has instead become the norm. If a manufacturer can argue that their device is equivalent to a previously approved device, they can avoid the PMA process. The problem is that these devices continue to get approved in this way, and thus we end up with devices that are nothing like the original device they are supposedly equivalent to. Even if a device is recalled from the market on account of its failing or safety threats, manufacturers can still get their device approved if they can argue substantial equivalence to that recalled device. Just 2% of devices coming onto the market actually go through the PMA process (Ziering & Herdy, 2018).

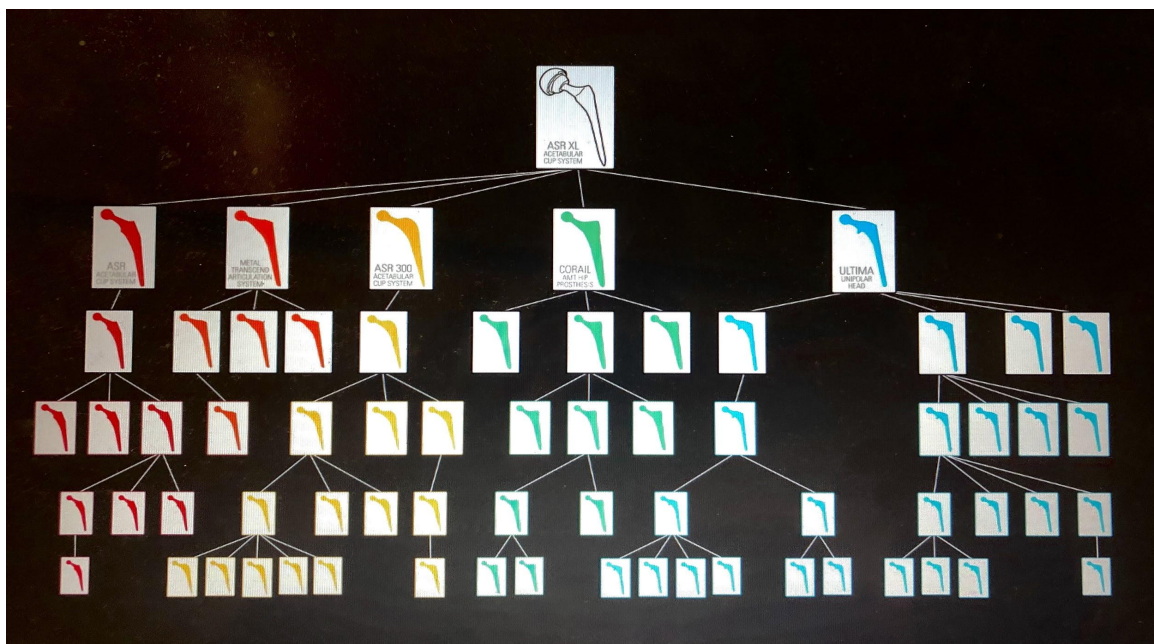


Figure 1. Visual representation of the predicate rule (Ziering & Herdy, 2018).

Much of this seems to be due to the overlap between the FDA and industry, with many people involved having vested interests. Dr. Diane Zuckerman (President, National Center for Health Research) comments on this: “When they go to work at the companies, they can tell the companies all the tricks of how to get around FDA regulations, how to get what you want. Almost all the heads of the FDA went on to work for industry” (Ziering & Herdy, 2018).

Although Essure did go through the longer PMA process, several concerning conclusions were made in every stage of the clinical trials. According to the Phase I trial results, 72% of women experienced at least “some pain” during the insertion procedure, even though all but one participant received at least one analgesic. A table in the article documenting “comfort with wearing the device” shows dramatically declining n values over time with 109 women responding at 3 months and just 25 responding at 18 months.

Table 3 Tolerance to wearing the Essure™ pbc micro-insert

Month of follow-up	Excellent	Very good	Good	Fair	Poor
	n (%)	n (%)	n (%)	n (%)	n (%)
3 months n = 109	106 (97)	2 (2)	0	1 (1)	0
6 months n = 106	103 (97)	2 (2)	0	1 (1)	0
12 months n = 78	74 (95)	2 (3)	2 (3)	0	0
18 months n = 25	23 (92)	1 (4)	1 (4)	0	0

*Review of women wearing the Essure™ pbc micro-inserts at 12 and 18 months out to five years will increase as they arrive for evaluation at these time points.

Figure 2. Table from Phase I Clinical Trial Article (Kerin et. al., 2001, 367).

Further, “Of the 130 women undergoing a placement attempt, nine (7%) experienced an adverse event in the study; six (4.6%) were ultimately unable to rely on the devices for contraception as a result of this adverse event” (Kerin et. al., 2001, pp. 367-68). Failure to achieve bilateral micro-insert placement happened in 15% of participants - an outcome not classified as an adverse

event. The report attributes many of these placement failures and adverse events such as tubal perforation to “tubal anatomic abnormalities” rather than to the physicians performing the insertion or to the device itself, which is supposedly a “one size fits all” device. Finally, the article was written by investigators who were “closely involved with the conception and development of this device.”

The second phase of Essure’s clinical trials presented similarly concerning data as seen in Phase I. To begin with, 27 women had bilateral placement failure out of 227 attempts which is nearly 12% (Kerin et. al., 2003, p. 1226). However, even if successful bilateral placement was not achieved, the devices that were incorrectly placed are typically left inside the women and can cause harm that this study surely does not account for (*The Bleeding Edge*). Additionally, the study continues to refer to “anatomic abnormalities” as sources of placement failure. As in Phase I, the majority of women (67%) reported pain during the procedure, and 76% reported pain afterwards. Women were asked to complete a questionnaire rating the severity of their pain yet there is no discussion of these results in the paper. Seven percent of women had an adverse reaction to the device, ranging from vasovagal response, expulsion, perforation, unsatisfactory device placement, or broken device tip. Women were also asked to rate their satisfaction with wearing the micro-insert over time, but these results are reported without n values, therefore making it impossible to tell if the women responding over time declines as in Phase I. Finally, the paper relies on cumulative months women have worn the device as a measure of success rather than months that each individual wore the device (Kerin et. al., 2003, pp. 1226-1227).

The final phase of clinical trials for the Essure device raised some of the same concerns as Phases I and II, as well as some new concerns. To begin with, the financial disclosure reveals that one of the authors of the paper is an employee at Conceptus, the manufacturer of Essure, and

two of the other authors are shareholders in Conceptus, suggesting major conflicts of interest. The article also notes that “with Food and Drug Administration approval came product labeling that allows for removal of micro inserts that have 18 or more coils trailing into the uterine cavity, and this should significantly reduce the risk of expulsions in the routine clinical setting” (Cooper et. al., 2003, pp. 59-67). Perhaps most importantly, however, is that the third phase of Essure’s clinical trials led to FDA approval of the device, contingent on the women participating in the trial being followed for an additional 4 years to obtain data on 5-year safety, effectiveness, and reliability of the microinsert.

While the 2002 FDA approval was contingent on 5 year follow up studies given that Essure is intended to remain implanted in women throughout their lifetime, one of these studies had yet to be published in 2015, and the other was published 13 years after the initial device approval (Dhurva et. al., 2015, p. e17(2)). However, the published study seems to overstate the safety and effectiveness of Essure, probably because it excluded women who did not have successful bilateral implantation, women who became pregnant within 3 months of the implantation, and women who had hysterectomies following implantation. The published study began with 518 previously fertile women seeking permanent contraception, yet the numbers referenced at the five-year mark only include responses from 385 women (Chudnoff et. al., 2015, pp. 951-960).

Additionally, testimony from two Essure clinical trial participants suggest that the integrity of the trial results may have been further complicated by pressure on participants to answer questions favorably about the device. Kimberly Hudak said “The first time I saw the question: rate your comfort of wearing the device, I said what does this mean? I’m not wearing anything; this is something that is implanted inside of my body. The nurse said can you feel it?

And I said I can feel pain inside of my abdomen. Where that pain is coming from, I don't know. And she said, then you need to rate it as excellent" (Ziering & Herdy, 2018). Similarly, Kimberly Huddelson shares her experience as a trial participant: "They would say, are you happy with the product? I would say no. And they would say but you're not pregnant? And I would say no. And they would say, then it's doing its job so you have to be happy with it." Not only was there inappropriate pressure on participants, but participants noted that Bayer actually changed participants survey responses regarding pain. Where women had reported pain, they crossed it out and wrote "no pain." Kimberly Hudak questioned Bayer about this and was told the practice was absolutely customary in a clinical trial (Ziering & Herdy, 2018).

The following quotation from Dhurva et. al. effectively summarizes the problems with the device's path to FDA approval:

The premarketing approval of Essure in 2002 was based on two nonrandomized, nonblinded, prospective studies that lacked a comparator group and enrolled a total of 926 women. The FDA review concluded that 97% of women with bilateral Essure placement could rely on the device. This determination of reliability, however, was not based on an intention-to-treat analysis and considered only women who successfully underwent the procedure and had 3-month hysterosalpingograms showing correct Essure placement and bilateral tubal occlusion (data presented to the FDA described a 14% failure rate for the first attempt at bilateral coil placement). Because of these exclusions, the declared reliability rate was based on only 664 (89%) of the 745 women who underwent an implantation attempt and did not account for 181 enrolled women who subsequently chose not to undergo the procedure (for unstated reasons), did not pass screening tests, or were excluded for not meeting other criteria. Among the 745 women who underwent an attempted Essure procedure, only 632 (85%) were followed up at 1 year for effectiveness outcomes and 682 (92%) for safety outcomes. Just 197 (25%) were followed for effectiveness at 2 years, which further limited the evaluation of adverse events and device safety (2015, pp. e17(1)-e17(2)).

In addition to insufficient and compromised clinical trials, Essure is associated with a vast range of adverse health outcomes. For example, in a study of 10 Essure recipients (8 of

whom went on to have hysterectomies and 2 of whom went on to have salpingectomies), metal particles were found in all ten women. “In five of the 10 patients, tin particles were observed in fallopian tube or uterine horn tissues with inflammatory cell reactions. In the other five cases, iron, chromium, nickel or platinum particles were observed. For implants, major deterioration of the weld zone was observed with either destroyed appearance or the presence of an organic coating containing numerous particles” (Catinon et. al., 2020, p. 162).

Take another example: the case study of a 39-year-old Essure implant recipient. At the time of the implantation, the procedure was deemed to have gone successfully. At the 3 month radiology follow-up, full tubal occlusion was described. Three years later, she presented with a number of symptoms, including back and pelvic pain, heavy menstruation, dysmenorrhea, hives, hot flashes, and night sweats. A pelvic exam revealed that one of her Essure devices was now sticking into the myometrium (the smooth tissue of the uterus). The lumen of the left fallopian tube associated with the mispositioned device was destroyed and showed signs of fibrosis. The right fallopian tube had a correctly placed device but was not occluded. The patient subsequently underwent a full hysterectomy with salpingectomy, which did relieve the symptoms (Hou, 2016, pp. 1-2).

According to the FDA’s own website *Problems Reported with Essure*, a wide variety of adverse effects were reported among Essure recipients.

From 2002 through 2019, the most frequently-reported patient problems were pain/abdominal pain (32,901), heavier menses/menstrual irregularities (14,573), headache (8,570), foreign body/device fragment in patient (8,501), perforation (7,825), fatigue (7,083), weight fluctuations (5,980), depression/anxiety (5,366), hypersensitivity/rash (5,077), and hair loss (4,999). Most of the reports received listed multiple patient problems in each report. The most frequent device problems reported were patient-device incompatibility/biocompatibility (for example, possible nickel allergy or patient’s

anatomy related to failure) (7,515), migration of the device or device component (4,535), device breakage/material fragmentation/fracture (2,297), dislodged or dislocated device (1,797), device operating differently than expected, for example, implant failure or pregnancy (1,058), malposition of the device (381), device difficult to remove (343), and device difficult to insert (335). Multiple device problems can also be listed in each report (FDA, 2020).

As was seen in some of the prior cases, many women went on to have hysterectomies and/or salpingectomies in attempts to resolve pain amongst a range of other device-related symptoms. Given that the Essure devices often cannot be removed via hysteroscopy because of their tendency to break and leave fragments in the fallopian tubes and/or uterus that can exacerbate or cause pain and other adverse symptoms, the device removal often means more invasive procedure to remove the uterus and fallopian tubes entirely (Ziering & Herdy, 2018). This is further demonstrated by a study evaluating the type of follow up surgeries in women who had Essure and the mean time between hysteroscopy and the surgeries. Surgeries were classified as “hysterectomy” if any part of the uterine corpus and fallopian tubes were removed and “device only” if laparoscopic methods were used to remove the coils and parts of the fallopian tube but left the uterus intact. The researchers obtained survey participants from the Essure Problems facebook group, and ultimately found that of the 3,803 women responded to the survey, 2468 women had hysterectomies, while 1035 had device removal and 300 had other surgeries (Sills et. al., 2017, pp. 298-99).

While these surgeries often ameliorated symptoms, this was not the case for all women who underwent them. In a case study of 11 women who had their Essure devices removed at Brigham and Women’s Hospital in Boston between 2012 and 2014, 10 of the 11 women reported pelvic pain, 6 of the 11 reported persistent bleeding, and 5 of 11 reported pain associated with intercourse prior to removal. Following the removal of the devices by hysteroscopy,

hysterectomy, or salpingectomy, 8 of the 11 participants reported improvement in their symptoms while 3 women continued to experience pain, bleeding, and/or dyspareunia (Brito et. al, 2015, p. 4).

In a study comparing hysteroscopic sterilization with Essure to laparoscopic sterilization surgery, it was found that the risk of reoperation was higher among Essure recipients. The authors write:

In our study, we found an over 10-fold higher risk of reoperation associated with hysteroscopic sterilization with the Essure device compared to laparoscopic sterilization, translating into about 21 additional reoperations per 1000 patients undergoing surgery. Meanwhile, the occurrence of unintended pregnancy was not different in the two groups. We also found that the use of device based hysteroscopic sterilization increased from 0.6% of all surgeries in 2005 to 25.9% in 2013 and was more often performed in older patients and those with higher comorbidity compared with laparoscopic tubal ligation (Mao et. al., 2015, p. 5).

Further, they found that patients who underwent hysteroscopic sterilization were eight times more likely to undergo reoperation two years after their initial procedure and six times more likely at three years after their initial procedure (p. 4).

In addition to adverse health effects and a vast number of follow up surgeries, the devices also lead to a number of unplanned pregnancies. After device implantation, women were advised to rely on alternative forms of contraception for three months until successful tubal occlusion was confirmed at a follow-up appointment. This unprotected period increases the likelihood that women will get pregnant with hysteroscopic sterilization with Essure rather than with laparoscopic sterilization. According to one study,

The likelihood of achieving successful bilateral coil placement on first attempt varies from 76% to 96% [8–22]. In addition, unlike laparoscopic sterilization, hysteroscopic sterilization is not immediately effective; at least 3 months is required for tubal fibrosis

and occlusion to occur for the procedure to be effective. During these 3 months, women need to use alternative contraception until they can undergo a post-procedure hysterosalpingogram (HSG) to confirm bilateral tubal blockage [23]. Prior research has shown that some (6–87%) women never return for their HSGs [8,10,12–14,16–19,24] and that blockage does not occur in 5–16% of HSG evaluations 3 months post-procedure (Garipey et. al., 2014, p. 175).

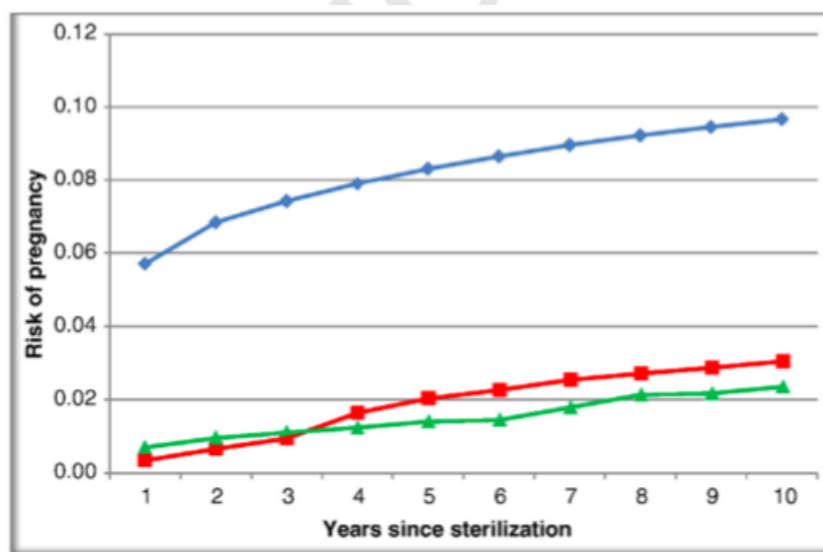


Figure 3. Comparison of hysteroscopic sterilization with Essure (blue) to laparoscopic surgery using silicone band application (green) or bipolar coagulation (red). After 10 years post sterilization, women who had the hysteroscopic procedure have a 99 out of 1000 risk of pregnancy as compared to 24 and 30 for silicone band application and bipolar coagulation, respectively (p. 179).

Even when women did successfully attend the 3 month follow up and receive confirmation of tubal occlusion, pregnancy was still possible. Take, for example, the case study of a 39-year-old Essure implant recipient. At the time of the implantation, the procedure was deemed to have gone successfully. At the 3 month radiology follow-up, full tubal occlusion was described. However, one year after implantation, the woman became pregnant, and terminated the pregnancy (Hou, 2016, p. 1).

In a retrospective analysis of pregnancies after device placement, it was found that “In total, in 212 of 508 pregnancies (41.7%) HSGs were determined to have been misinterpreted,

including 24 (4.7%) missed micro-insert expulsions and 95 (18.7%) perforations in which at least 1 micro-insert penetrated the fallopian tube, cornua, or uterine corpus” (Munroe et. al., 2015, pp. 245-251). Many Essure confirmations were misread because the physician/radiologist were only focused on tubal occlusion without concern for the actual micro-insert location. This likely contributed to oversight of device migration, perforation, or other dangerous malfunctions.

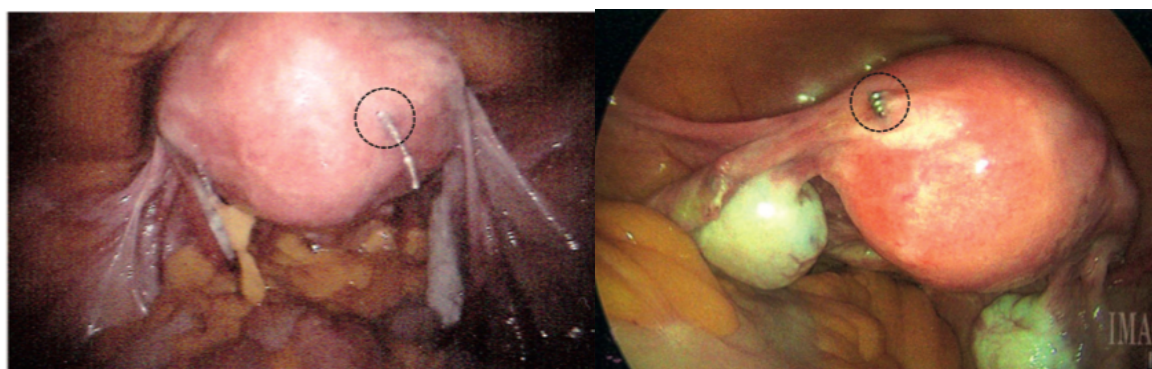


Figure 4. Left: “Intraoperative photograph obtained during laparoscopic assisted vaginal hysterectomy, performed approximately 1 year after hysteroscopic sterilisation showing fundal puncture by Essure device (circle).” Right: “Intraoperative photograph obtained during laparoscopic salpingectomy and removal of foreign body 2, showing left fundal puncture by Essure device (circle)” (Sills & Dalton, 2016, p. 231).

In a similar study, researchers made a survey available to women who had a medically confirmed pregnancy following HS with Essure. These women were a part of a closed, invitation-only support group for patients who underwent HS and had at least one subsequent unplanned pregnancy. The researchers found that the recommended hysterosalpingogram (HSG) three months post procedure was obtained by 66% (68 of 103) of women in this group. Additionally, of the 103 respondents, it was found that “mean (\pm SD) interval between the HS procedure and positive pregnancy test was 19.6 ± 14.9 (range, 2 to 84) months, although peak incidence (mode) for pregnancy was recorded 10 months after HS. Only three of 103 unplanned pregnancies (2.9%) occurred within the initial three months following HS.” Seventy-three

percent of women (n=76) reported compliance with using an alternate method of birth control between the procedure and the 3 month follow up (Sills et. al., 2015, pp. 298-300).

In addition to adverse health outcomes, follow up surgeries, and unplanned pregnancies, hysteroscopic sterilization with Essure has adverse economic consequences. In a study evaluating the 5 year expected costs of the Essure system provided in an office setting to laparoscopic BTL (LBTL) provided in a hospital outpatient setting, it was found that “For the outcomes subtree, the base case expected costs are \$4764 for Essure®, \$6186 for LBTL” and “In a two-way sensitivity analysis comparing costs for Essure® and LBTL, Essure® had lower expected costs across all values” (Kraemer et. al., 2009, p. 258). However, many of the adverse effects of Essure continue past 5 years. Further, a number of hysteroscopic sterilizations end up being performed in hospital outpatient settings anyways with many participants receiving general anesthesia. In a related study, Sills et. al. found:

Essure patients in the US revealed that unplanned conception and pregnancy termination after Essure, assuming a device failure rate of 5.7%, was associated with an economic impact of >\$1.5M in lost wages. If the 10-year Essure failure rate of 9.6% were used, the economic impact of unplanned pregnancy would be >\$2.5M in lost wages. Likewise, for women choosing to continue pregnancy after Essure failure with frequency at 5.7% (and total time missed from work = 65 days), this was associated with an economic impact of \$49.2M in lost wages during the exposure interval. In the scenario where Essure fails at this same rate (5.7%) but the employee avails of more time off work after delivery (100 days), cumulative lost wages would exceed \$75.7M. When all unintended pregnancies after HS failure in the US are considered irrespective of outcome (i.e., the sum of pregnancy terminations plus deliveries after Essure), this would result in ~\$130M in lost productivity in aggregate, assuming the 10-year failure rate (9.6%) were applied with a 100-day absence for each pregnancy conceived and delivered in the US (Figure 2) (2016, p. 35).

Findings:

From the literature, three major findings have become apparent. First, the clinical trials upon which the FDA based their approval of Essure were insufficient and unreliable, despite their being conducted under the traditionally more thorough, pre-market approval process. Second, Essure has caused harm to many women at many stages in the device's history from the initial insertion procedure to adverse health outcomes many years later. Third, laparoscopic sterilization is a safer and more effective sterilization method than hysteroscopic sterilization with the Essure device.

Essure's clinical trials were deeply flawed for a number of reasons. Perhaps the most egregious safety breach in this process was the failure to follow a large enough sample of participants over time. Despite the intention for the device to remain in place for the rest of a woman's life, the device was approved to enter the market based on how women tolerated the device over the first one to two years post implantation. Furthermore, in the published report on the first phase of the clinical trials, "tolerance to wearing the Essure pbc micro-insert" was reported at 3, 6, 12, and 18 months post procedure. However, despite surveying 109 women at 3 months, just 25 women were surveyed at 18 months (Kerin et. al., 2001, p. 367). In the published reports on the phase II and III clinical trials, no n values are reported for this same measure of tolerance wearing the device, so it cannot be known how many women were included in these surveys over time. A quote from OB/GYN Dr. Scott Sills summarizes these challenges.

It really wasn't tested for a sufficient amount of time. Most patients who had the Essure device were followed for about 12-18 months and the manufacturer reported very satisfactory results from it. But for a product that's supposed to be a lifelong implant, to cut off the study window at about a year and a half left a lot of questions unanswered (Ziering, 2018).

Given the permanent nature of the device, the FDA's market approval of Essure was contingent on a 5 year follow up study of the early trial participants. Despite coming onto the market in 2002, one of these such studies had yet to be published as of 2015 and the other was published 13 years after the initial device approval. However, the published study seems to overstate the safety and effectiveness of Essure, likely because it excluded women who did not have successful bilateral implantation, women who became pregnant within 3 months of the implantation, and women who had hysterectomies following implantation (Dhruva et. al, 2015, p. e17(2)).

Another contributing factor to the lack of reliability and sufficiency in the clinical trials is the widespread financial interests of people closely involved. In the first phase of the trials, the published article notes that it was written by investigators who were "closely involved with the conception and development of this device" (Kerin et. al., 2001, p. 370). The second article, regarding the phase II clinical trial results, was similarly published by the same three authors as the first, in addition to 3 others (Kerin et. al., 2003). In the final article, the financial disclosure reveals that one of the authors of the paper is an employee at Conceptus, the manufacturer of Essure, and two of the other authors are shareholders in Conceptus. In other words, all but one investigator in this trial had financial interests in the success of the product (Cooper et. al., 2003, pp. 59-67).

In addition to exclusively short-term data and glaring financial conflicts of interest, Essure's clinical trial lacked a control group. A New York Times article from 2015 focuses on recent publication of long term Essure complication data and how this data played a role in increasing skepticism around the device. The article explains,

Because there is no other device like Essure on the market, and because Bayer will not say how many American women have it, experts find it difficult to judge whether the

risks are disproportionate. Manufacturers are not required to include control groups in clinical trials, as is standard in drug trials, so there is no comparison group (Rabin, 2015).

It seems hard to believe that any proper study could be acceptable without control groups. In the case of Essure, comparing long-term health outcomes (pain, unplanned pregnancy, etc.) to laparoscopic sterilization - the standard female sterilization procedure - seems like an obvious path.

Finally, the testimony of several clinical trial participants points to serious issues of integrity with the trial procedures. As seen in the literary review chapter, there was significant pressure on women from nurses and investigators to answer questions about the device favorably, regardless of the women's actual experience with the procedure and the device. In combination with the trials' other flaws, it seems apparent that these trials were not sufficient enough to justify the device's market approval by the FDA in 2002.

In addition to the insufficiency and unreliability of the Essure clinical trials, it is made clear by the literature that this device caused harm to many women over its 15 years on the global market and its 17 years on the United States' market. The harm associated with the device began at the implantation procedure. According to the article regarding the phase I clinical trials, 72% of women experienced at least "some pain" during the insertion procedure, even though all but one participant received at least one analgesic (Kerin et. al., 2001, p. 367). Similarly, in the phase II clinical trials, 67% reported pain during the procedure and 76% reported pain after (Kerin et. al., 2003, p. 1226).

Not only was pain during the initial procedure commonplace, but so were a large range of adverse events up to several years following implantation. Pelvic pain, pelvic bloating, fatigue, dyspareunia, dysmenorrhea, dysuria, chronic headache, and persistent bleeding were some of the

most widespread events described in the literature. These adverse events contributed to many women pursuing reoperation, often hysterectomy and/or salpingectomy.

As well as the insufficiency and unreliability of the clinical trials and the vast range of harms Essure caused many women, the literature review presents a third major finding: laparoscopic sterilization is safer and more effective than Essure. One of the most appealing aspects of the Essure device was its advertised ability to be inserted in an office-setting. However, the literature reveals that many women had their devices implanted in surgical settings. For example, one retrospective cohort study of 638 patients found that 57% of HS procedures were performed in an operating room as opposed to a doctor's office (Sills et. al., 2015, 491). Similarly, the device was advertised to be minimally invasive, and yet, due to the coils tendency to break and fragment, it cannot effectively be removed without potentially harmful and more invasive surgeries (ex. hysterectomy, salpingectomy) than laparoscopic sterilization (Ziering & Herdy, 2018). Furthermore, in comparative studies between hysteroscopic sterilization with Essure and laparoscopic sterilization, Essure was found to be associated with a higher incidence of unplanned pregnancies.

Analysis

The deeply flawed clinical trials upon which Essure was approved and the widespread harm caused to recipients of the device reveals larger issues in the medical device industry and the FDA's approval processes for such devices. The corruption in the industry is illuminated by the case of Essure but is by no means limited to it. For example, Scott Gottlieb was the Commissioner of the FDA from 2017-2019 as appointed by President Donald Trump. Gottlieb's company, New Enterprise Associates, funded the development of Essure in the early 2000s.

While serving as the Commissioner of the FDA, Gottlieb hired a new lead attorney for the FDA - someone who used to represent Bayer (Essure's manufacturer) against patients harmed by medical devices (Ziering & Herdy, 2018). While these egregious conflicts of interest may seem shocking, they are not unique. According to Dr. Adriane Fugh-Berman, Professor of Physiology and Pharmacology at Georgetown University, it used to be that 70% of biomedical research was funded by the government, now about 70% is funded by industry. While the medical device industry has substantial influence in Washington, D.C., funding political campaigns, think tanks, and patient advocacy groups among other things, Ziering and Herdy caution that there is a more significant risk at play: "Perhaps an even worse problem is the revolving door. A number of FDA officials have both come from industry and then go back to industry after they're at FDA." When companies that invest in these medical devices stand to make enormous profits from their success, and the people running those companies are well-versed in FDA approval processes, it is relatively unsurprising that we see safety concerns being dismissed.

The case of Essure also serves to highlight the lack of accountability required of the institutions involved in this business. Despite Essure's removal from the European market in 2017, it remained available in the U.S. until 2019. Bayer's exit from the European market was hastened by the European equivalent of the FDA which asked for more safety data. Rather than admit they couldn't provide the data, Bayer pulled out of the European market, pinning the decision on "a lack of interest" (Ziering & Herdy, 2018).

The legal action taken against Bayer by the women harmed by the device was classified as a mass tort litigation where "a large number of people who were injured by the same medication, device, or product sue the entities responsible for creating and distributing that medication, device, or product. The individual cases filed are all handled together, since they

have so many similarities” (*Mass Tort Litigation*, 2020). Mass tort litigations are unique from class action suits in that many individual lawsuits are filed together as opposed to many plaintiffs in a single lawsuit. According to Trammell PC Attorneys at Law, “Those lawsuits are eventually grouped by the courts and brought before the same judge in a single venue. Since trying all of those cases individually could take many years, courts frequently pick out a few cases they believe are representative and hold trials for those cases. The results of those trials give both sides an idea of how other cases like them might go, and that knowledge helps both sides decide whether to settle and what the cases are worth.” Gathering evidence for mass tort lawsuits can take a long time because for several reasons including needing a large amount of information for each case, finding experts in medicine, economics, etc. who can speak to the injuries, arguing with the defense about whether the experts are qualified to speak on the issue, travel to meetings (often held in federal courts), and the defense resisting to release necessary documents or releasing a lot of information at once that is difficult to sort through.

Although Conceptus was the original manufacturer of Essure, the company was acquired by Bayer in 2013. In 2016, the FDA required Bayer to add a blackbox warning to Essure - the highest warning labels for devices that can cause serious injury and even death. Despite this action’s strong suggestion that the FDA knew Essure was dangerous, the device remained on the market for an additional two years. Over the years since its market approval in 2002, nearly 39,000 lawsuits were filed against Bayer by women who received the device. The plaintiffs accused Bayer of failing to report the numerous complaints of injuries related to Essure - a requirement of the FDA’s MDR regulation (*Mass Tort Update*, 2020). Additionally, Bayer was accused of not taking the complaints recorded with the FDA into account when deciding to continue marketing the device, being negligent in pushing the device on physicians with no

training, making false statements in its express warranty that the product was safe and effective, and wanting to protect profits at the expense of patients' health. Bayer sought to defend against these claims by citing the preemption provision (the conditional premarket approval) under the Medical Devices Act. "Bayer argued that the FDA's approval of the medical device protected the company from any claims by plaintiffs that the company failed to warn about the risks involved in using the device." In August 2020, Bayer announced its agreement reached with plaintiff's law firms to settle roughly 90% of Essure claims. In the settlement, Bayer does not admit wrongdoing or liability and maintains its previous claim that Essure is safe and effective.

Further,

The company agrees to pay \$1.6 billion to cover 90% of U.S. cases in jurisdictions that have significant filings against Bayer. The settlement requires plaintiffs to either dismiss their cases or not to file the cases. No other settlement terms were released. The U.S. settlement with respect to Bayer's Essure birth control device will have no effect on litigation in other countries. Bayer's decision to settle the cases was based on U.S. law factors (*Mass Tort Update*, 2020).

Despite the payments Bayer made in the settlement, the women who were violated by this device do not even get the satisfaction of the company admitting their wrongdoing. Considering how dramatically this device impacted so many women's lives, the settlement feels, much like the device's clinical trials, rather insufficient.

Take for example, Angie Fimilino's story. Fimilino suffered intense pain during the insertion of the devices and shortly thereafter developed chronic headaches that prevented her from being able to function - she couldn't take care of her kids, go camping, be active, etc. She went on to have about a dozen subsequent surgeries including one to remove the devices that were expelled into her uterus, a tubal ligation, a hysterectomy, and a number of other joint surgeries. Her joint problems are a result of the fractured devices leaving particles in the body

that can trigger an autoimmune response. Firmilino devoted a significant amount of her time to researching the device, its pathway to market approval, and even founded a Facebook support group that grew rapidly. Through this group, Firmilino found that many women were suffering from similar autoimmune disorders and found many stories of women getting pregnant after being implanted with the Essure devices. She reports health issues in those babies, devices having punctured the amniotic sac and caused preterm labor (which not all babies survive), and more than 800 failed pregnancies associated with Essure. Firmilino also discovered that many women are ending up with 5-7 devices because doctors are told by manufacturer representatives (who are not doctors) to just load up another one if the first misfires and misses the fallopian tube. Also stories of women's ruined sex lives, broken relationships, and suicidal thoughts are abundant in this online group. "There's nobody paying attention. We are keeping those records because nobody else is," Firmilino explains (Ziering & Herdy, 2018).

Another heartbreaking story is that of Ana Fuentes, who received Essure at 35 years old. According to Fuentes, she had never previously been hospitalized in her life, except when she was pregnant. After her Essure implantation, she was in and out of the hospital repeatedly for pain and continual bleeding to the point where she had to wear diapers. Her doctors told her that her severe menstrual problems were due to the fact that she was Latina. Ultimately, Fuentes had a hysterectomy to address the bleeding, but the chronic pain continued and caused her to lose her job. Shortly thereafter, her husband left her and she ultimately had to place her three girls in the care of a foster family because she couldn't support them.

Gaby Avina, née Martinez, has a similar story. She was a nurse and became a spokesperson for Essure after getting the device herself. Avina went on to experience chronic fatigue and began falling due to her legs giving out. She was told by her doctors that this was an

immune response to something - although she did not initially know it was to her Essure devices. Avina was also part of the clinical studies and reports never being asked how she was feeling or how her health was (Ziering & Herdy, 2018).

Unfortunately, Firmilino, Fuentes, and Avina's stories are not unique to women's experiences with Essure, nor with other similar devices. Two female contraceptive devices that preceded Essure, the Dalkon Shield and Norplant, follow similar story lines. The Dalkon Shield was an intrauterine device (IUD) for women that was manufactured and sold from January 1971 to October 1974 by the A. H. Robins Company (Kolb, 2018, pp. 813-814). The device was invented in 1968 by Dr. Hugh Davis and Irwin Lerner. They promoted the device at medical meetings and in February of 1970, Davis published an article in the American Journal of Obstetrics and Gynecology. The article detailed a study of 640 women using the device, and a pregnancy rate of just 1.1%. Davis described the Dalkon Shield as "modern," having "superior performance," and being a "first choice method" - unusual language for scientific studies. In 1969, Robins bought the manufacturing rights to the device for royalties and \$750,000. He proceeded to hire Davis as a consultant, and modify the design by adding a small amount of copper and a multifilament wick.

At the time, there were more than 70 IUDs on the market, so Robins began an aggressive marketing campaign to doctors and clinics, touting the device as safer, easier, and more painless to insert and as having the lowest pregnancy rate. They also used Davis's article as a marketing tool, without disclosing his ties to the company. Because the shield was a device and not a drug, it was not subject to the extensive testing required by the FDA. Problems began in 1971 with patients becoming infected and/or pregnant. By June 1974, there had been four deaths linked to the shield as well as countless spontaneous abortions and pelvic infections leading to continuous pain and sometimes sterility. Many studies showed that the pregnancy rate was much higher than originally thought, some showing it at 5.5% or even higher (pp. 813-814).

Despite being removed from the U.S. market in 1984, the Dalkon Shield remained available in foreign countries for an additional 9 months.

A number of women have similarly haunting stories about their experiences with the Dalkon shield. Take, for example, Pam Van Duyn, a 26 year old student finishing her undergraduate work in Eugene, Oregon in preparation for law school. Pam had been married to her husband Jim for 4 years. Although the couple hoped to have a family one day, they planned to finish school and work for a while first so Pam decided to have an IUD implanted - the Dalkon Shield. Shortly after getting the device, Pam was up in Portland with her younger sister visiting friends for the weekend while Jim was 400 miles away in a small town working on a project for the State Historic Preservation Office. The first night in Portland, after getting home from a concert, Pam felt flu-like symptoms coming on, and went to bed. However, a few hours later, she had a temperature of 102 and was experiencing severe abdominal pain. “‘I literally wanted to die,’ Pam remembers” (Perry & Dawson, 1985, p. 2). A general practitioner in Portland gave her a shot of penicillin and antibiotic pills, thinking she was suffering from food poisoning. “For the next five days, she lived in agony. Her temperature rose to 104 degrees. The pain was so great she couldn’t eat. She lay in the house in a semi-conscious state, praying for the drugs to start working, wondering why it was taking so long” (p. 3). On the fifth day since she had seen the doctor in Portland, she spoke on the phone with her husband Jim who realized she was losing her ability to think clearly and told her to go to the doctor right away. Pam and Jim didn’t have a family doctor or health insurance, so Pam searched for a doctor she could see. She found Dr. Randall Lewis, a 32 year old OBGYN who had recently completed his residency at the Mayo Clinic. Dr. Lewis quickly performed a pelvic exam and removed the IUD. He diagnosed Pam with an acute case of pelvic inflammatory disease and put her in the hospital where she was

found to have a significantly elevated white blood cell count. Her “X-rays revealed a large, tender mass the size of an orange attached to Pam’s left ovary and Fallopian tube. This was where the ovary and tube had become stretched, distended, and matted with pus from the infection” (p. 4). Jim drove home early to meet Pam. “She was completely dehydrated. Her lips were parched. She had no color. She was listless” said Jim. Lewis told Pam he may have to perform a hysterectomy to save her life if they couldn’t get the infection under control but Lewis waited and waited because Pam begged him and because the Mayo clinic taught him to be conservative around operations. They were ultimately able to identify the bacteria and gave more targeted antibiotics. After 9 days in the hospital, Pam finally went home. “She still had her uterus and Fallopian tubes, but they had been badly damaged. Her right Fallopian tube and ovary were heavily scarred from the infection. And the orange-sized mass of distended tissue, although no longer containing pus, remained attached to her left ovary and Fallopian tube. It was like carrying a time bomb. It might heal itself, as Lewis had seen in other patients at the Mayo Clinic; or it might flare up and send Pam back to the hospital” (p. 5). As she was leaving the hospital, Lewis told her it was unlikely she would be able to have a child due to the scarring and damage the infection had left behind.

Unfortunately, Pam’s story is not unique. Linda Towle and her best friend Gail Bennett flipped a coin to see who would get their IUD first; they were just twenty years old at the time. Linda came with Gail to her appointment with Dr. Hugh Davis. After waiting for quite a while, “Gail finally stepped into the waiting room. But she looked much different than she had a few minutes earlier. She was pale and crying, her face contorted with pain. ‘It hurts like hell,’ she told Linda” (p. 37). Dr. Davis said the pain would go away. On the way to the car, Gail had to stop because the pain was too intense. She began to vomit and then fainted, blood seeping

through her clothes. Linda took her back to the hospital, first to the ER, but was sent back to Davis' clinic where he gave Gail a tranquilizer and a pill to lessen the pain, then sent her home, again telling her the pain would disappear in a few days. Linda was scared by Gail's experience but was more scared of getting pregnant - she also thought that maybe things would be different for her given she was strong physically and mentally, and had always had easy periods (p. 38). Gail's IUD continued to cause her severe pain, and almost constant bleeding - she would have it removed in just a few weeks. When Linda went for her own appointment, Dr. Davis walked in and gave her the same speech he had given Gail about the safety of the device and how it was better than the pill. Then, without asking her permission, 6 people were let into the room to watch the insertion. Davis spoke only to them from then on, even when Linda cried out in pain as the device passed through her cervix and she began to cry. "The pain was awful. It felt like a pitchfork being thrust into her body. And there were all these strange people standing in the room, staring into her vagina" (p. 39). She recalls, "I was just a piece of meat laying on the table... if I live to be 100, I won't forget that." Linda continued to have pain and bleed. Her symptoms finally subsided, but returned even worse with her next period. She was told by Davis it wouldn't last more than her next period - but it did. She insisted on seeing him but he insisted that nothing was wrong. Linda continued to wear the device for about a year while the chronic pain and bleeding continued, becoming unbearable during her periods at which time she couldn't work, sleep, or eat. She lost 25 pounds and the blood loss made her anemic. Her marriage was fraying too - she was constantly ill and disinterested in sex (p. 40). In July of 1971, she went to go stay with her mother and happened to get her period during the stay. Distressed, her mother called their family friend who was a gynecologist. He saw Linda in his office the next day and removed the device, although that too was excruciatingly painful for Linda. Despite feeling

extremely weak for a few days, Linda finally began to feel better. In 1975, after nearly 5 years of good health, Linda came down with severe stomach pains which her doctors believed to be gastritis and sent her home. After that, she began to run a low-grade chronic fever and have bouts of abdominal pain. In 1977, Linda was remarried to a man named Joe who had two children from a previous marriage, but Linda decided she wanted a child of her own too. Ironically, just several months after this decision, she developed severe abdominal pain and a high fever and was diagnosed with PID. Scar tissue was found all over her uterus, but Linda proceeded to see a fertility specialist and underwent 8 surgeries over the next four years. Despite her significant efforts, Linda was ultimately unable to conceive (p. 41).

The Norplant device was a series of six silicone rods implanted in a women's arm. The device released a synthetic form of progesterone over five years with the goal of preventing pregnancy. Norplant was first approved by the FDA in 1990 (Watkins, 2010, p. 88). By 1992, 13 state legislatures were considering 20 bills that related to Norplant. Some of these bills proposed linking financial aid to families with dependent children to Norplant requirements for the mothers of these families. Some of the bills would have given poor women financial incentive to use Norplant or made the implant a requirement for women in prison or on probation. Others still proposed requiring women who had children with fetal alcohol syndrome or drug addiction to receive the implant (p. 93). Ultimately, none of these such bills passed, but they give a sense of the excitement Norplant generated and the ways in which society saw the implant's potential to regulate women's bodies. Legal scholar Dorothy Roberts comments on this phenomenon, saying that it was not eugenically motivated, but rather driven by the idea "that social problems can be cured by keeping certain people from having babies and that certain groups therefore do not deserve to procreate." Roberts goes on to say, "Why have government programs that distribute

Norplant been promoted so heavily in the Black community? Why is Norplant dispensed at Black inner-city high schools and not white suburban ones? The coercive nature of the device itself, as well as the incentives used to promote it, treats Black women's bodies as objects of social supervision" (p. 95).

In June of 1994, a class action suit was filed against Wyeth-Ayerst, the manufacturer of Norplant, for insufficient warnings about Norplant side effects. Watkins summarizes the allegations against Wyeth-Ayerst below:

The most common complaints against Norplant fell into two main categories. The first involved changes in menstrual bleeding patterns, including irregular bleeding, prolonged bleeding, bleeding between periods, bleeding more frequently, heavier bleeding, lighter bleeding, and amenorrhea. The second involved problems at the insertion site, such as infections and the formation of scar tissue, and problems associated with removal of the implant, which sometimes required long operations under general anesthesia. There were several other side effects associated with Norplant use, such as weight changes, headaches, acne, mood changes, as well as more serious charges levied against the implant, including stroke, blindness, and rheumatoid arthritis (p. 99).

Between 1991 and 1993, 38 reports were received by the FDA regarding women who were hospitalized due to device-related infections or difficulty removing the device. This number is believed to be a significant underrepresentation given that the reporting of such events was voluntary (p. 100). However, frequent reports were made regarding women's difficulty in finding a physician who would remove the device. This was especially true of women who lost their jobs and their health insurance benefits, or women who moved off of Medicaid. Sometimes, the challenge was physicians pressuring women into keeping the implant despite its uncomfortable side effects.

By 1996, 50,000 women had joined cases against Wyeth-Ayerst - five percent of the total number of women who received Norplant in the U.S. (p. 102). According to Watkins, "Wyeth-Ayerst maintained its innocence to the end, claiming that the side effects were clearly

represented in the product labeling. Its president characterized the settlement as ‘purely a business decision’” (p. 103). The product was removed from the market in 2000.

Similar to Essure and the Dalkon Shield, narratives from women whose lives were dramatically affected by Norplant are abundant. In 1994, the CBS prime time news program, “Eye to Eye with Connie Chung,” had a segment featuring two women’s experiences with the Norplant device. One of the women opted to have the device removed on account of weight gain and constant bleeding. The removal procedure took over two hours, despite being advertised to take between 15 and 30 minutes. This woman described the removal procedure as “excruciating . . . I’d liken [it] to labor, and labor was easier” (pp. 100-101). The other woman featured on the program ended up in the emergency room with a severe infection in her arm that developed after a nurse took two and a half hours to remove only one of the six capsules. The program concluded with saying that Wyeth-Ayerst planned to update Norplant’s labeling to better inform women of the chance of “pain, numbness, and scarring” upon removal and that physicians were developing better removal techniques. The first woman maintained, “Who would want to have something implanted in their arm that’s like a time bomb? I don’t think anyone would opt for that choice” (p. 101).

Another woman, referred to as SW to maintain anonymity, explains that she first heard about Norplant in the early 90s when researching different birth control methods. The implant appealed to her because she did not want to worry about missing a pill and ending up with another child; she was content with her two daughters. SW explains her experience shortly after receiving the device: “I suffered from dizziness, headaches, mental issues and weight gain. I was 5-10, and I was always small. But after I had the Norplant implanted, I just started ballooning and had all kinds of issues” (Llamas, 2019). In an attempt to resolve these issues, SW had her

Norplant removed and opted for tubal ligation surgery instead. Shortly after this procedure, she was diagnosed with a benign tumor on her carotid artery. “The tumor had damaged my left facial muscles and my sinus cavity. The problems progressed after the surgery, and that was when I had to cut my tour in England short and go back to the U.S.,” she said. SW was told she suffered from a rare nerve condition called Horner’s syndrome - an incurable disease caused by a stroke, spinal cord injury or tumor. “It’s just been a roller coaster,” SW said. “The vision in my left eye is damaged. Some people would think I was on drugs because of the irregular pupil in my left eye or would comment on the drooping eyelid. I have headaches, irritability, hearing problems, vertigo, phantom pains and memory issues.” These medical issues ultimately caused her to leave her career with the NSA. The persistent medical issues, stress, and financial hardship then caused her to lose her home. SW explains the link to her Norplant implant, “I don’t think it’s a coincidence that I had the Norplant in my left arm, and the tumor was on the carotid artery on the left side of my face. It coincided with the time I had the Norplant, and a specialist said the tumor was rare and not hereditary.” When she tried to file a lawsuit against Wyeth-Ayerst, she was told it was too late because the statute of limitations had passed.

Another woman, Tina Ayotte, mother of two, opted for Norplant after her youngest son was born in 1993. She had the device removed just 5 months later due to hair loss, acne, and heavy menstrual bleeding. Ayotte’s device removal, like many, took far longer than advertised. One of the capsules had moved inside her arm and the doctor had to make a second incision to remove it for a total procedure time of over an hour. “If I’d known before, I’d have never done it,” said Ayotte. “The risk is great and it puts your family through hell” (White, 1995). According to Ralph Pittle, a Seattle attorney with Medical Legal Consultants of Washington, “Scar tissue surrounds the implant and doctors can’t retrieve it as easily as the company led them to believe.”

Lisa Ann Owens shared a similar story. She claims she was never told of the risks prior to receiving the implant. When she decided to have it removed, the doctor “continuously poked, pushed, pulled and yanked” on her arm. Owens filed a lawsuit against her doctors.

Diana Earle received Norplant at just 24 years old. She proceeded to suffer severe headaches, pelvic pain, and mood swings. “I’m dizzy like every day, it seems like,” she said. “Ever since I’ve had this thing put in, everything’s just gone downhill.” Unfortunately, Earle couldn’t even get the device removed because she couldn’t afford the \$200 removal fee.

Clearly, health issues related to birth control devices are not a phenomenon unique to Essure, but rather a trend we see repeatedly, with Essure being the most recent example.

Conclusion:

Throughout the literature and upon contextualization within the history of female contraceptive devices, it becomes clear that Essure is unfortunately not the only problematic device of its kind. Like the Dalkon Shield and Norplant, the widespread harm Essure has caused and surely continues to cause strongly suggests the device’s clinical trials were insufficient. Not only was Essure’s path to market approval lacking sufficient longitudinal data, but testimony from trial participants suggest the data the investigators did have was severely lacking integrity. One of the most challenging outcomes to reconcile is that Essure’s harm could not be entirely undone by its removal from the market in 2019, only mitigated. Women like Angie Firmilino, Ana Fuentes, and Gabby Avina’s lives were permanently damaged. Even those women who seek device removal may not experience a full resolve to their symptoms, not to mention the consequences posed by removal itself - device breakage, hysterectomy, salpingectomy to name a few.

Another frustrating conclusion in the Essure story is that the device is ultimately a less effective sterilization method than laparoscopic surgery. In other words, it intended to solve a problem for which a relatively safe solution already existed. This is not to say that the scientific community should not strive for safer, less invasive, and more effective contraceptive methods. Rather this is to underscore that many women who suffered as a result of this “new and improved” device, whether through physical symptoms, unplanned pregnancy, or adverse professional and personal consequences, would not have faced these negative outcomes had laparoscopic sterilization been the only method available to them. Further, despite appearing more cost efficient, the downstream effects of unwanted pregnancy, follow up surgeries, and adverse effect treatments make the economic consequences of Essure more significant than those of laparoscopic sterilization.

This paper sought to examine the inadequacies of the 2002 approval process for the female sterilization device Essure. As a result of many women experiencing adverse responses to the device often resulting in hysterectomy, salpingectomy, and unplanned pregnancy, it can be concluded that the initial clinical trials were insufficient due to their exclusively short term evaluations of a device intended to be permanent. The case of Essure underscores larger issues in the FDA’s approval process for medical devices in general, namely lack of comparator group requirements for medical devices, vested financial interests between the FDA and industry, and lack of accountability for unethical pressure on trial participants.

These findings lead to me to believe that despite the significant strides that have been made in women’s healthcare and equality in general, women’s bodies are still not their own. There is clearly a persistent stigma against women’s sexuality which allows harmful female contraceptive devices to continue to bring in enormous profits. It is nearly impossible to imagine

a similar device for men existing at all, not to mention remaining on the market for 17 years as evidence continued to mount against it. The story of the Essure device is not new. In fact, it is frighteningly similar to the stories of the Dalkon Shield and Norplant, both of which preceded Essure. U.S. District Judge Miles Lord's comments in regards to the Dalkon Shield ring just as true today in regards to Essure. He says, "I dread to think what would have been the consequences if your victims had been men rather than women, women who seem by some strange quirk of our society's mores to be expected to suffer pain, shame, and humiliation" (Perry & Dawson, 1985, p. x).

Taken together, it is clear that there is an ongoing need to be vigilant and skeptical regarding new female contraceptive devices and that there is a need for major reform to address the corruption that takes place across our government, medical device companies, and the FDA. So long as the current systems remain in place, women remain exceptionally vulnerable to future harmful devices approved on insufficient evidence with profit, rather than safety being the primary concern.

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