Unequal Harm:

The Disproportionate Damage to Women from Dangerous Drugs and Medical Devices

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AMERICAN ASSOCIATION for JUSTICE
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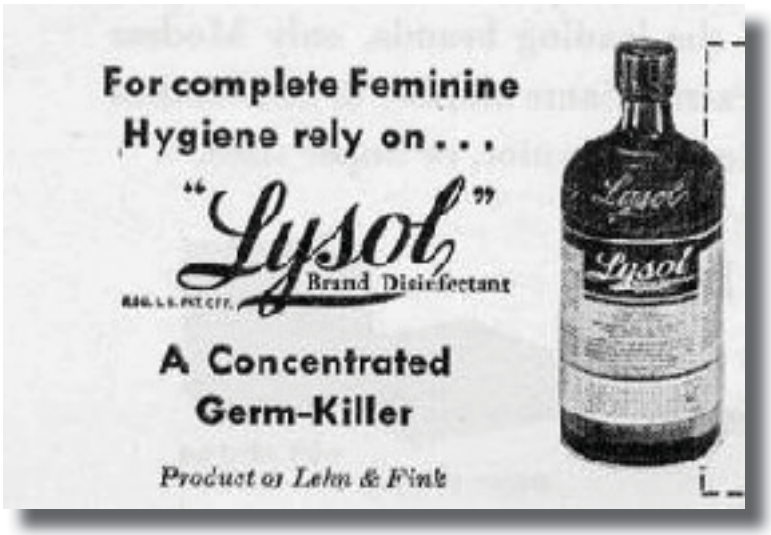
Introduction

Dangerous Products and the Disproportionate Impact on Women

Throughout modern history, women have suffered disproportionately from the effects of dangerous and defective drugs and medical devices. Women take more medications than men, respond differently to them, and are more likely to suffer adverse drug events. Because of the recent *Riegel v. Medtronic* (2008) and *PLIVA, Inc. v. Mensing* (2011) rulings by the U.S. Supreme Court, women injured or killed by dangerous drugs and medical devices may not be able to hold these manufacturers accountable.

Women were historically excluded from Phase 1 clinical trials, rendering many gender-specific risks unknown. Though this policy was changed in 1993, women remain consistently underrepresented in drug and medical device evaluations. Reckless corporations have long taken advantage of this situation. Drugs and medical devices marketed specifically for women have long skirted the edge of responsible medicine.



In the 1800s, the early iterations of today's pharmaceutical giants were marketing extracts of cow ovaries and other substances of shadowy origin. In the 1920s, estrogen treatments were introduced as a "cure for menopause," and grew in popularity for decades, even after the cancer-causing dangers of such hormone-use became widely known. Premarin – an estrogen supplement made from pregnant mares – was selling 30 million prescriptions a year as late as 1975. In the early part of the 20th Century chemical douching – with what was essentially bleach – was heavily marketed to women. "Douche" agents such as Lysol were being pushed as late as the 1970s, not only for hygienic purposes but as subtly veiled contraceptive options.

In fact, birth control has long been both a multi-billion dollar industry and a litany of incidences of corporate neglect and serious health risks. For years, manufacturers have put thoughts of health concerns to one side as they marketed their products. Corporations have consistently rushed products to market with little study, or worse, concealed known issues for the sake of profits. Even when dangers become public knowledge, companies frequently continue to market them and play down

the dangers, anticipating that any repercussions down the road will be more than justified by a continuing stream of profits.

The Failure of Regulation

From the very beginning of the modern pharmaceutical era, regulators have struggled to keep women and other consumers safe. In 1906, partly in response to worthless, impure and outright dangerous medicines such as opium and morphine-based "tonics" to calm women's nerves, the U.S. Food and Drug Administration was created by the Food and Drugs Act of 1906. Under the authority of the new agency drugs had to be labeled and could be seized if illegal. However, the legislation had a number of holes, including giving practically no recourse for false claims of efficacy.

In 1933, First Lady Eleanor Roosevelt presented the "America's Chamber of Horrors" exhibit, which featured among other products, a weight-loss drug that caused death, lotions and creams that caused mercury poisoning, hair dyes that caused lead poisoning, and a mascara that blinded women – all of which were legal under the 1906 Act. In 1938, after 107 people died, many of them children, from Elixir sulfanilamide – an anti-infection drug that added raspberry flavoring to poison, and was marketed with no testing at all – Congress enacted the Federal, Food, Drug and Cosmetic Act.

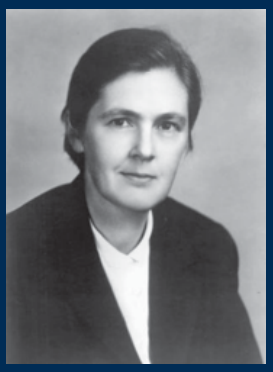
Even then, the makers of deadly medical devices, such as the Dalkon Shield, did not have to be concerned with pre-market approval, simply because approval was not necessary. It was not until 1976 when the law was changed, and FDA approval was needed before a medical device could be sold.

The vast majority of medical devices are never actually approved by the FDA, rather they are "cleared" on the basis of the manufacturers' own assertion that the device is similar to other devices already on the market. This can lead to a next generation of devices cleared based on a previous generations defect. For example, vaginal mesh was a product approved based on a previous generation's defect that continued the cycle of dangerous products.

In fact, drug and device manufacturers have learned to hide behind regulations, arguing that they were immune from accountability for their dangerous products because FDA approval preempted any later attempts to hold them responsible.

Time and again, companies have manipulated and withheld evidence of their product's dangers.

Frances Oldham Kelsey



Born in 1914, Frances Oldham Kelsey was pharmacologist who would have a profound impact on the safety of American consumers.

Her graduate work at the University of Chicago helped identify the toxic agent in the sulfanilamide scandal that killed 107 people. After earning her Ph.D. in pharmacology and an M.D., Kelsey joined the FDA in 1960 as one of only seven drug reviewers. Her first assignment was to review an application for a new sedative for morning sickness, manufactured by Merrell, called Kevadon – the brand name for thalidomide.

At the time, FDA reviewers had only 60 days to review an application, after which a company was free to market the drug. However, Kelsey questioned the manufacturer's claims and denied approval. Merrell applied again, and this time applied political pressure to push through approval. Kelsey continued to remain steadfast in her objections.

Soon, the effects of thalidomide became widely known. The drug had been released in Europe, where it caused thousands of babies to be born with severe birth defects.

Thalidomide woke people to the dangers of modern medicine. Kelsey was celebrated for her steadfastness, and President Kennedy awarded her the President's Distinguished Federal Civilian Service in 1962.

This report examines some of the most notorious examples of corporate misconduct's impact on women's health. Many of the drugs and medical devices profiled here were approved by regulators and marketed on a massive basis, despite manufacturer knowledge of serious health risks. In almost every case, women were put at risk for years, while corporations squeezed every last drop of profit from their products.

Hormone Replacement Therapy – 1930's-Present (still on the market)

The pharmaceutical industry has been making money off "menopause treatments" for 150 years. In the 1800s, the treatments consisted of the likes of cannabis, opium or pulverized cow ovaries. In 1933, Ayerst Laboratories introduced Emminen, an estrogen supplement, extracted from the urine of pregnant women, making it the first modern version of hormore replacement therapy, or HRT.

In 1942, Ayerst Laboratories began marketing Premarin, an estrogen supplement made from pregnant mares, which was selling 30 million prescriptions a year as late as 1975. HRT proved a huge moneymaker for the pharmaceutical industry. But science began to catch up. In 1975, the *New England Journal of Medicine* reported on strong links between estrogen therapy and cancer of the uterus. In 1989, HRT was linked to breast cancer.

However, such scientific findings did nothing to slow marketing and sales of HRT, as pharamceutical manufacturers invested millions in assuaging concerns and pushing supposed benefits. In 1996, Wyeth Pharmaceuticals introduced Prempro, which combined estrogen with progestin. The drug was accompanied by a blitz of advertising in which doctors and celebrities implied it would not only help with traditional menopause symptoms, such as hot flashes and night sweats, but also heart disease, Alzheimer's disease and even cancer. Behind the scenes, Wyeth also invested in DesignWrite, a New Jersey company that created at least 60 positive articles for publication in medical journals. These efforts were extremely profitable, as Wyeth made $2 billion from its HRT drugs in 2001 alone.

In 2002, the federally-funded Women's Health Initiative – the largest clinical trial of HRT ever – was halted after researchers found combined hormones significantly increased the risk of breast cancer, heart attacks, and blood clots in the lungs. HRT sales dropped precipitously.

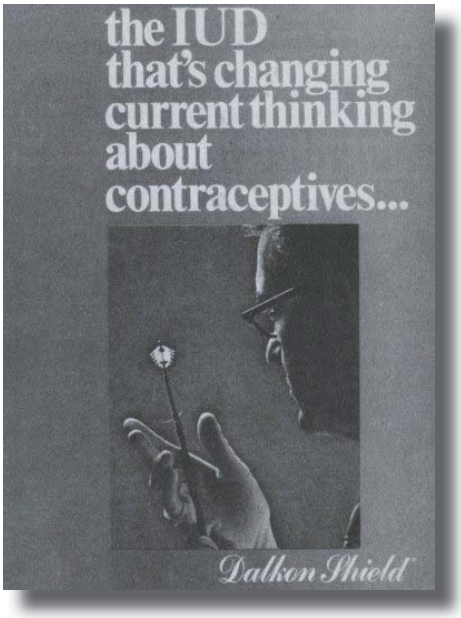
But not forever. Over the next several years, the pharmaceutical industry aggressively attempted to reinvigorate the HRT market. Despite recommendations from groups such as the U.S. Preventive Services Task Force (USPSTF) – a panel of independent experts convened by Congress – HRT has found a resurgence. Industry

analysts expect the global HRT market to pass $3 billion in 2017.

In 2012, Pfizer – the new owners of Wyeth – announced in a securities filing that it had been forced to pay $896 million to settle claims Prempro and other HRT drugs had caused cancer in the women taking them. At that time, the company faced another 4,000 cases.

Dalkon Shield – 1971-1980

In 1978, 34-year-old nurse Margaret Worsham was hospitalized for a pelvic infection. Over the next several days her condition worsened until she was forced to undergo a complete hysterectomy. Worsham had suffered a tubo-ovarian abcess, caused by a contraceptive intrauterine device (IUD) – the Dalkon Shield.



A.H. Robins introduced the Dalkon Shield in 1971 despite knowing the device had fatal flaws. To keep the IUD from being expelled, its creator, Hugh Davis, had designed it with claw-like prongs. These prongs did indeed keep the shield in, so much so that doctors found it would embed itself in and perforate the walls of the uterus. Pulling it out also required an extra strong string, but the multifilament string the device used turned out to be a terrible flaw – a fact that A.H. Robins knew. Instead of being sealed, the string was left open at both ends, a fact that confounded the company staff charged with manufacturing the device. The string's multifilament nature and opens ends made it awfully efficient at wicking bacteria into the uterus.

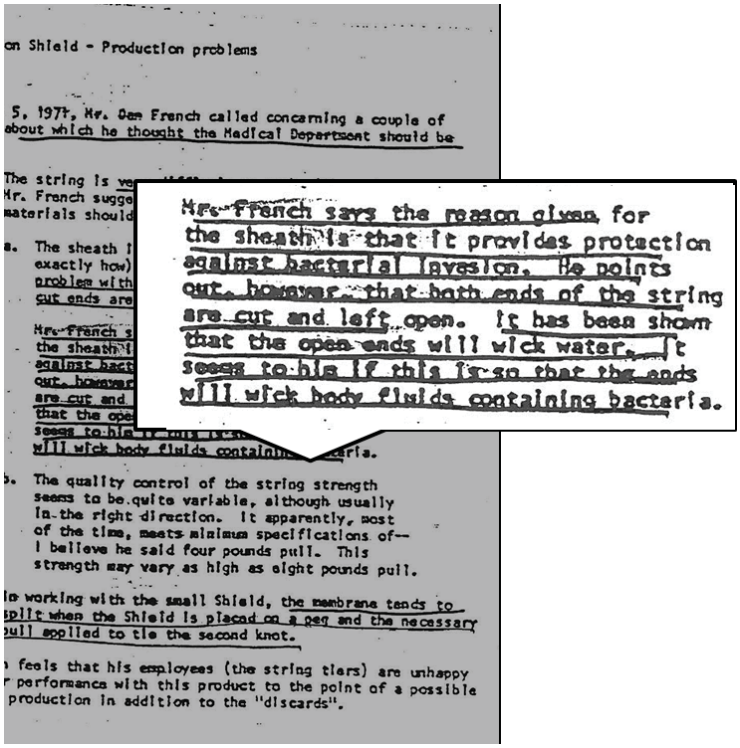
A litany of internal documents uncovered through litigation show a variety of company staff pointed out the problem, but were ignored or told to shut up. One of the company's quality control managers, Wayne Crowder, suggested a fix to the design flaw, but it was rejected by executives who were loath to slow down production. When Crowder complained he could not in good conscience continue to cover up the infection problem, an A.H. Robins executive told him his conscience did not pay his salary, and wrote, "[I]f this product is taken off the market it will be a 'confession of liability.'"

At the time, medical devices like the Shield were not vetted by the FDA, so A.H. Robins chose to introduce the device and market it heavily to women across the country. In its first three years on the market, more than three million Dalkon Shields were sold – more than all other IUD brands combined. More than 230,000

women suffered pelvic infections, miscarriages, stillbirths, infertility, and even death.

A.H. Robins, however, continued to heavily promote the product for several more years. In fact, the company's executives did not just turn a blind eye to problems, they made things worse. They ignored information that leaving the Dalkon Shield in place during a pregnancy was causing septic abortions because they did not want to contradict their marketing materials. Even after learning the device was prone to deterioration and had to be replaced every two years, they changed their replacement recommendation to five years in order to make it more competitive.

Subsequent litigation revealed that, not only had executives known about the dangers of the device, it was not even very effective as a contraceptive. The shield's designer, Hugh Davis, had manipulated data in the only pre-release study ever done. Davis claimed the device produced an annual pregnancy rate of 1.1 percent. However, Davis had told the women in the trial to use the shield in conjunction with spermicidal foam, and ignored pregnancies that were reported after the study period, even when they had occurred during the study. The true pregnancy rate was over five percent. Davis's study was also tainted by a conflict of interest. A.H. Robins had paid him $750,000 for the device and an ongoing share of the profits – something he would deny until forced to admit it during litigation.



In 1974, A.H. Robins was no longer able to control the tide of bad publicity surrounding the shield, and, under pressure from the FDA, halted sales. Even then, the company continued to market the device overseas. By 1975, the FDA reported it knew of at least 15 fatal and 245 nonfatal septic abortions, among a host of other problems.

It was not until 1980, after a string of lawsuits revealed a multitude of problems with the device, that the company finally agreed to issue a letter to doctors recommending the removal of the device. In 1985, facing lawsuits from at least 300,000 women and billions of dollars in liability, A.H. Robins declared bankruptcy. Ironically, this caused its stock to quadruple, and it was bought by American Home Products.

Riegel and the End of Accountability

In 1976, following the disaster of the Dalkon Shield, Congress passed the Medical Device Amendments, which introduced new, stricter safety standards for medical device approval. This process is called pre-market approval, or PMA. In the following years, the U.S. Supreme Court ruled that FDA approval of a medical device did not preclude a patient injured by a dangerous or defective device from using state common and consumer protection laws to hold a corporation accountable.

In 2008, the U.S. Supreme Court changed its position when it ruled that if a device was approved through the PMA process, its manufacturer would be immune from any liability for harm its product caused. This decision drastically lowered a manufacturer's incentive to keep dangerous products off the market. As long as these corporations can hide any potential side effects from the FDA in the PMA process, they can sell dangerous and defective devices without ever having to worry about being brought before a jury.

Reigel in Action - Essure

Essure is a permanent contraceptive device consisting of two coils that is inserted into a woman's fallopian tubes. Essure is controversial, in part because it works by deliberately damaging the body. The device is made of a nickel-titanium alloy and polyethylene terephthalate (PET) resin. Manufacturers of PET explicitly warn against its use "in medical applications involving permanent implantation in the human body" because of the damage it can cause. It is this very damage that Essure's manufacturer, Conceptus, relies on to produce scar tissue to seal off the fallopian tube. Meanwhile, nickel is a known cancer-causing carcinogen, to which approximately 10 percent of all adults are allergic, particularly women. Though aware of the dangers of nickel, Conceptus not only continued its use, but lobbied the FDA to remove the restriction against marketing to women who are allergic or hypersensitive to nickel.

Since Essure's introduction in 2002, more than 730,000 women have had the device implanted. In the decade since, researchers have found that many women have suffered potentially fatal ectopic pregnancies, perforated uteri and small intestines, severe pain, or have been forced to undergo complete hysterectomies.

Due to the *Riegel* decision, the true magnitude of Essure's dangers, and the extent to which the company knew about them, will likely never be known. Essure's PMA approval is essentially a get-out-of-jail card for Conceptus. Now, Conceptus, which was recently purchased by Bayer, is developing a new version of Essure, which, like its predecessor, will be subject to the same loophole if it wins PMA approval.

G.D. Searle Copper-7 IUD – 1974-1986

In 1974, ironically the same year the Dalkon Shield was suspended by the FDA, G.D. Searle began marketing the Copper-7 IUD. Like the Dalkon Shield, the Copper-7 was sold to millions of American women despite the company's internal doubts about its safety. In public, Searle dismissed all claims against it, even though its own information showed over 30 different side effects.

In fact, company executives knew that the Copper-7 had an infection problem and was causing ectopic pregnancies and infertility. Internal memos showed the company asking the original testing lab to "soften" the negative results. Meanwhile, the FDA had castigated Searle as early as 1975, pointing to "serious deficiencies in Searle's operations and practices which undermine the basis for reliance on Searle's integrity." Yet the agency took no action to stop the Copper-7 from being sold.

Not only did Searle continue to sell the device, the company marketed it specifically to young women. A document obtained during litigation showed that the company directed their marketing efforts toward young women who had never been pregnant, even though their own research showed that this population was at particular risk.

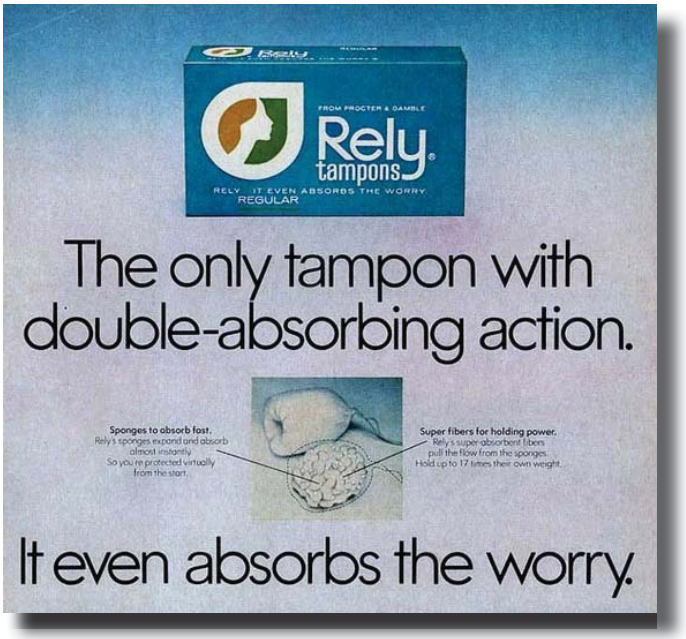
> "The group considered highest risk for infection and subsequent loss of fertility is that consisting of nulligravida, under 26, with multiple sex partners. It seems to be that the identification of such a group by the Food and Drug Administration, mishandled by the lay press, might have an impact on our marketing strategy."
>
> - - G.D. Searle internal document

Searle had been aggressively, and successfully, defending itself against what would become more than 700 lawsuits. But when the internal documents were revealed, a jury awarded plaintiff Esther Kociemba $8.75 million. Searle began settling claims shortly after.

Tampons and Toxic Shock – 1975-1985

In 1980, 38 women died from toxic shock syndrome associated with Procter & Gamble's Rely tampon. Though tampons had been in use for half a century, this new version, introduced in 1975, was substantially different than anything that had been sold before. Rely, which was marketed as the most absorbent tampon ever, was designed with synthetic materials instead of the traditional

cotton that made it far more absorbent than previous tampons.



Procter & Gamble mailed 60 million free samples of Rely tampons to women across the country. At its peak, Rely had cornered half of the market – and women were dying.

In the late 1970s, the U.S. Centers for Disease Control (CDC) began investigating the previously rare toxic shock syndrome – a potentially life-threatening bacterial infection. By 1979, the agency knew of 55 deaths and over 1,000 nonfatal cases, but at first did not realize the deaths were related to tampons.

Procter & Gamble, however, did. The company was receiving as many 177 complaints a month, but had instructed salespeople to deny any link between tampons and toxic shock. It was not until September 1980, as media coverage hit a frenzy, that the company recalled the Rely brand.

Not put off by its competitors' experience, Playtex began marketing its own super-absorbent tampons in the 1980s. The tampons were made with polyacrylate fibers, which increased the chances of the introduction of a staph infection. The company disregarded studies linking their product to toxic shock, and sought to market the product's extra absorbency when other manufacturers were reducing absorbency in reaction to medical information.

Only after a court awarded $10 million in punitive damages to the family of a woman who died from an infection did Playtex remove the super absorbent tampons from the market. Reviewing the case of Betty O'Gilvie, who died from a vaginal infection caused by a Playtex tampon, the 10th Circuit Court of Appeals noted that the company:

> "[D]isregard[ed] studies and medical reports linking high-absorbency tampon fibers with increased risk of toxic shock at a time when other tampon manufacturers were responding to this information by modifying or withdrawing their high-absorbency products [and] deliberately sought to profit from this situation by advertising the effectiveness of its high absorbency tampons when it knew other manufacturers were reducing the absorbency of their products due to the evidence of a causal connection between high absorbency and toxic shock. This occurred in the face of

Playtex' awareness that its product was far more absorbent than necessary for its intended effectiveness."

At least 2,000 women suffered toxic shock syndrome and approximately 100 died as a result.

Parlodel – 1980-1994

Introduced in 1980, Parlodel was Sandoz Pharmaceuticals' trade name for bromocriptine mesylate, a drug that was used to treat Parkinson's disease, cocaine withdrawal, and to suppress lactation in women who had recently had babies but did not want to – or could not – breastfeed. This latter use raised alarm bells when it became clear the drug was killing and disabling women.

In 1989, the FDA expressed its concerns about the drug's use as a lactation suppressant. All of Sandoz's competitors took their version of the drug off the market. Sandoz refused. The FDA threatened to force Sandoz to follow suit, but the company persuaded the FDA to let it continue to sell the drug to as many as 600,000 every year.

In 1989, after nearly a decade of complaints, the FDA asked Sandoz once again to stop selling Parlodel. Sandoz refused once again. Five years later, in 1994, after at least 32 women died from strokes, heart attacks and seizures, Public Citizen sued the FDA to force the agency to take real action. Two days later, Sandoz announced it would halt sales of Parlodel as a lactation suppressant. The FDA later came to the conclusion that Parlodel had not even been very effective for that use in the first place.

Accutane – 1982-2009

In the 1960s, Hoffman-LaRoche's cancer treatment division began studying the chemical compound isotretinoin as a skin cancer treatment. During tests, Dr. Werner Bollag discovered that isotretinoin was effective against acne, but abandoned tests because the drug could cause severe birth defects. Bollag explained, "At that time [the 1970s], in the psychological climate engendered by the thalidomide tragedy, it would be inconceivable to develop an agent with teratogenic properties for the treatment of such a common

complaint as acne."

Hoffman-LaRoche, however, did not give up on isotreinoin. Reborn as Accutane, the company pushed its acne-curing capabilities. The company excluded women from most of its pre-market testing and required negative pregnancy tests and contraceptive use for those that were included. As a result, Hoffman-LaRoche was able to release Accutane with a label that claimed there had been no evidence of birth defects in children. In reality, 40 percent of pregnancies exposed to Accutane resulted in spontaneous miscarriage, and a quarter of babies carried to full term suffered major congenital deformities. In clinical studies, the majority of women who became pregnant while using the drug chose to abort upon just learning of the risk.

Accutane was approved in 1982 amidst much fanfare and within six months had been prescribed more than 200,000 times. At the same time, Hoffman-LaRoche's own researchers, Dr. Frank Yoder, began expressing concern over the "potential tragedy" and saying that "the potential toxicity of this drug has been seriously under-emphasized." Hoffman-LaRoche executives admonished Yoder and other researchers who raised red flags.

Within a year, the FDA announced it knew of at least 12 cases of "adverse pregnancy outcomes" attributed to Accutane. Hoffman-La Roche agreed to change its labeling and sent Dear Doctor letters warning against the possibility of birth defects. Yet the company resisted all suggestions of recalling the drug.

In 1988, an internal FDA memorandum was leaked suggesting as many as 1,300 Accutane babies had been born. Dr. Yoder, no longer held back by Hoffman-LaRoche, called the company "negligent and wrong" and pointed out the difference between the company's exclusion of women during testing to marketing to women after release. "It is incredible to require that in a study but not in a mass market situation," Yoder told *The Washington Post*. "This was very, very wrong."

Hoffman-LaRoche fought to keep Accutane on the shelves for the next two decades, settling confidentially with victims to keep documents out of the public eye. The company pursued many different "campaigns" to ensure pregnant women did not take the drug, but they had little effect, and for 23 years Accutane continued to rake in as much as $700 million a year. In 2009, amidst claims that Accutane was linked to inflammatory bowel diseases and suicide, as well as birth defects, Hoffman-LaRoche finally pulled the drug from the market. Accutane is still available in generic form.

Vaginal Mesh – 1996-Present (still on the market)

Perhaps more than any other product in history, vaginal mesh implants demonstrate the real harm that can occur when corporate greed and lax regulatory oversight combine. The early iterations of this device date back to the "womb supporters" of the 1800s and were known for the pain they caused and the difficulty doctors had in removing them. They were even featured in First Lady Eleanor Roosevelt's 1933 exhibit "America's Chamber of Horrors."

Like their predeccessors, the modern versions of these devices, which are implanted through incisions in the vagina, were designed to help treat pelvic organ prolapse and stress urinary incontinence. The implants underwent a boom in popularity as they became available in kit form in the early 2000s. However, the devices often cause pain, bleeding and infection, and can erode or harden. Making matters worse, they are extremely difficult to remove, despite manufacturers' claims otherwise.

Surgical experts today liken the task of removing such dangerous mesh implants to removing rebar from concrete. Many also believe the entire category of products violates longstanding principles of surgery, because mesh implants in the pelvic region are inherently prone to contamination.

More than a decade after their popularity with doctors soared, their lack of efficacy and true risks are only just being understood. In most cases, versions of vaginal mesh implants were never widely studied or examined by the FDA prior to their introduction. Instead, problematic products like American Medical Systems' Sparc Sling System, Johnson & Johnson's Tension Free Vaginal Tape System and its later ObTape, relied on approval based on the principle that they were "reasonably similar" to a previous product.

This in and of itself is not unusual. The vast majority of medical devices gain FDA clearance through their claimed similarity to prior devices. However, in the case of vaginal mesh, the maze of prior approvals originates with Boston Scientific's ProtoGen sling, a product that should never have been on the market itself, let alone serve as the basis of other products' approval. Despite concealing more than 400 complaints from the FDA, Boston Scientific could not stop the ProtoGen sling from being recalled in 1999 because of high rates of erosion, extrusion and related infection and pain. ProtoGen itself was not even properly evaluated, but instead was cleared for use based on a previous mesh product used for entirely different cardiovascular operations. According to surgeons writing in the *American Journal of Obstetrics & Gynecology*, the ProtoGen sling was

"rushed to market for financial reasons without adequate premarket clinical trials." In the process, it unwittingly ushered in a generation of dangerous products.

One such product was the Gynecare Prolift mesh implant. Johnson & Johnson introduced the device in 2005, but, again, it was never approved by the FDA. In this particular case, the FDA did not even know the device existed, because the giant health care products company decided on its own that it was reasonably similar to Gynemesh, which had previously been approved. The FDA only became aware of Prolift when Johnson & Johnson mentioned it in an application for a different device in 2007. The FDA immediately ordered Johnson & Johnson to halt sales, citing the "potential high risk for organ perforation," in part because of hundreds of complaints about Gynemesh, Prolift's predecessor. However, Johnson & Johnson continued selling the device, in violation of the Federal Food, Drug and Cosmetic Act. Nine months later, in May 2008, the FDA agreed to approve the implant without any sanctions for its continued sale.

As many as 70,000 women have vaginal mesh devices implanted each year. In 2009, the FDA announced that it knew of at least 1,000 adverse events associated with the implants, and warned doctors of the danger. Within two years, the agency reported at least 2,874 new adverse events and warned doctors that complications were "not rare" and that in many cases the mesh did not improve post-surgical outcomes anyway.

In 2013, a jury ordered Johnson & Johnson to pay $11 million in compensatory and punitive damages to Linda Gross, a South Dakota nurse who underwent 18 operations, 400 visits to doctors and physical therapists, and was left in constant pain after she was implanted with the Prolift mesh. The jury found that Johnson & Johnson had failed to warn her surgeon of the risks tied to the implant and had fraudulently misled Gross.

Facing 4,000 lawsuits from injured patients, Johnson & Johnson stopped selling Prolift in 2012. Other mesh implants, however, are still heavily marketed and surgically implanted.

DePuy Hips – 2005-2010

DePuy Orthopaedics – a division of Johnson & Johnson – began receiving complaints about its ASR XL Acetabular hip replacement system immediately after its 2005 introduction. Doctors reported the device shed large quantities of metallic debris and frequently caused infection, fractures, dislocations, necrosis and nerve damage. Women were particularly at risk. A study published in the *Journal*

of the American Medical Association found that women had a 29 percent higher risk of implant failure than men.

DePuy, however, did not recall the device nor warn doctors of the problem. Executives discussed the need to fix the device's flaw, but eventually chose not to do so. The device failed internal tests in 2007, and internal company documents showed that DePuy expected about 40 percent of the devices to fail within five years of implantation. Surgeons attached to the company stopped using the product, but executives buried their complaints. Still the company sold the product. It was not until 2010 that DePuy stopped selling the device, and even then, the company attributed the decision to poor sales, not medical problems.

Injured patients were soon looking to hold the company accountable. The first of thousands of cases involving the device revolved around the experiences of three women – Annelise Rundle, 74; Martha Bender, 69; and Katherine Guy, 60 – each of whom suffered problems from the replacement hip and had to have them removed and replaced. The three women's cases were to be tried together in Nevada state court, until DePuy settled them for $200,000 each. In 2013, the first case to be heard before a jury resulted in an $8.3 million verdict. Over 10,000 more lawsuits are still pending.

Nuva Ring – 2002-Present (still on the market)

In 2007, 32-year-old Jackie Bozicev collapsed and went into a seizure in front of her husband and two-year-old son. Bozicev had suffered a blood clot that had traveled from her pelvis to her lungs. She was dead before an ambulance could get her to hospital.

In 2009, 26-year-old Christen Childs went to an ER thinking she had pulled a muscle in her leg. She was diagnosed with a blood clot, which migrated to her lungs, nearly killing her. Childs would spend the next six days in intensive care, receiving injections of blood thinners in her stomach four times a day.

Both Bozicev and Childs were healthy, did not smoke, and had no history of blood clots. What they did have in common was that they both were using NuvaRing contraceptives.

NuvaRing is a contraceptive vaginal ring about two inches in diameter that is inserted into the vagina and remains there for three weeks of each month. The ring releases low doses of hormones. Merck introduced NuvaRing to Europe in 2001 and to the United States in 2002, touting the freedom from daily birth control it offered women. It has been prescribed more than five million times worldwide.

NuvaRing uses ingredients from the progestin hormone family. These so-called third and fourth generation hormones were supposed to reduce the side effects of earlier generations of contraceptives, such as acne and facial hair. In fact, the FDA found the hormones were neither effective at reducing side effects nor more effective as birth control. They were, however, linked to increased risk of blood clots, heart attacks and stroke.

What makes NuvaRing potentially more dangerous than other contraceptive pills that also use third and fourth generation hormones is its method of delivery. While up to half the hormones in oral contraceptives are absorbed in the digestive tract, NuvaRing's hormones are absorbed directly into the blood. NuvaRing's manufacturer claims not to know how much more dangerous this makes it, and the FDA approved the device based on studies involving oral contraceptives. Yet a Danish study published in the *New England Journal of Medicine* found that women using NuvaRing were 2.5 times more likely to suffer blood clots and twice as likely to suffer a heart attack as women taking oral contraceptives.

The FDA has received more than 1,000 reports of blood clots, including as many as 40 incidences of women dying, yet Merck has chosen to keep NuvaRing on the shelves and denied there is any problem.

Ortho Evra – 2002-Present (still on the market)

Kathleen Thoren, 25-year-old mother of three from Texas. Sasha Webber, a 25-year-old mother of two from Baychester, N.Y. Stephanie Rosfeld, a 25-year-old assistant volleyball coach at the University of Cincinnati. Monica Johnson was a 41-year-old mother of two from Willingboro, New Jersey. Zakiya Kennedy, an 18-year-old college student from New York. Lakesha Smith, 26-year-old from New Jersey. Adrianna Duffy, a 17-year-old freshman at Boston's Trinity College. Zakiya Kennedy, an 18-year-old Manhattan fashion student.

These women, and at least 30 more, died from heart attacks, blood clots in the

brain, strokes, and pulmonary embolisms after using the Ortho Evra contraceptive patch.

When Johnson & Johnson introduced Ortho Evra – the first-of-its-kind birth control patch – in 2002, it was lauded by *Time* magazine as one of the year's "coolest inventions." Eight years later, Ortho Evra was in *Time* once again, this time because of accusations the company had known the patch was far more dangerous than other contraceptive options even before it was released, as claims came to light that the patch caused blood clots.

Ortho Evra's hormone dose turned out to be far higher than was safe, doubling the risk of blood clots that could lead to heart attacks and strokes. Johnson & Johnson had known about and concealed the dangers from the very beginning. In its own pre-release clinical trials, Johnson & Johnson employees arbitrarily changed the record of how much estrogen was being released into women's bodies, leading doctors and the FDA to believe the patch released half the amount it actually did.

Even though the FDA was initially misled about the amount of hormones the patch was releasing, the blood clot problem was known to both the company and regulators early on. As early as August 2002, the FDA knew of multiple deaths and serious injuries involving patch users. Leaked patient reports showed that when compared to the pill, patch users were 12 times more likely to suffer stroke and 18 times more likely to have blood clots. The company refused to study the patch in comparison to contraceptive pills because executives were worried that the patch would compare unfavorably. At least one Johnson & Johnson executive quit in protest at the company's refusal to reveal the danger, and another sued the company after allegedly being wrongfully terminated for trying to blow the whistle.

Johnson & Johnson quietly settled as many as 4,000 lawsuits to keep the problem from bubbling over in the news, while continuing to sell the patch. Six years after its first suspicions of blood clot problems and amidst a wave of incidents, the FDA ordered a black box warning be added to Ortho Evra packaging. It remains on the market.

Yasmin/Yaz – 2001-Present (still on the market)

Yasmin, introduced in 2001, and its successor Yaz, introduced in 2006, were part of a wave of problematic contraceptive drugs and devices, such as NuvaRing, that made use of a new generation of hormones, including drospirenone. These third and fourth generation pills were highly touted by their makers and by scientific studies – often paid for by the manufacturers. In the case of Yaz, the drug was said to not only provide contraception, but contribute to weight loss, prevent acne, reduce PMS, and cure ovarian cancer. Unfortunately, it also came with a significant risk of sometimes fatal blood clots. Bayer, the maker of Yasmin and Yaz, aggressively pushed the drug's miracle cure nature, even when scolded by the FDA for pushing misleading claims and making light of risks.

The FDA reported that at least 50 women had been killed by taking the drug, and Bayer itself admitted to knowing about at least 6,000 more claims of blood clots. Yet Bayer was able to arrange for two studies that, not surprisingly, came to the conclusion Yasmin and Yaz were no more risky than other birth control pills.

Five other studies – not funded by Bayer – found Yasmin/Yaz increased the risk of blood clots by as much as 75 percent. In December 2011, amidst claims that Bayer was deliberately withholding data, the FDA called together a panel to evaluate the benefits and risks of the drospirenone contraceptives. The panel voted 15-11 in favor of keeping the drugs on the market. After the meeting, external investigations found that four members of the panel had links to Bayer. All four had voted in favor of keeping the pills on the market.

Even as controversy raged around the drug, Bayer made approximately $1 billion a year from sales. In April 2012, the FDA ordered Bayer to change Yasmin's warning label to give warning that the drug tripled the risk of blood clots.

In 2012, as thousands of legal cases began to reach court, Bayer was forced to begin settling the claims. By 2013, over 100 women had died, and over 13,000 more had suffered injuries. Bayer planned to put aside $1 billion to pay claims – about two percent of the company's annual revenue.

Though the potentially fatal side effects of these drugs have been known for years, the true effects on women are about to get worse. An April 2013 court ruling allowed companies to resume selling a generic version of Yaz, while generic Yasmin has been available for years. Because of the U.S. Supreme Court's ruling in *PLIVA v. Mensing*, women who are injured or killed by the generic

versions of the drugs will be unable to hold manufacturers accountable for the harm they have caused.

Mensing - One Rule for Brand-Names, Another for Generics

In a 2009 decision, the U.S. Supreme Court ruled that if a patient is injured or killed by a brand name prescription drug, he or she can hold the drug's manufacturer accountable for failure to warn of potential side effects. This decision upheld decades of consumer protection law and was widely considered a stern response to pharmaceutical manufacturers' attempts to push the limits of the law to evade accountability.

So it was a surprise when, in 2011, the Court decided that people injured or killed by generic drugs would not have the same rights as people who took the brand name version of the same drug.

This did not make sense to several members of the Court. In her dissent, Justice Sotomayor wrote, "As a result of today's decision, whether a consumer harmed by inadequate warnings can obtain relief turns solely on the happenstance of whether her pharmacist filled her prescription with a brand-name or generic drug. The Court gets one thing right: This outcome 'makes little sense.'"

Conclusion

The products outlined here are just the tip of the iceberg. There are countless other prescription drugs and medical devices being sold today that are harming women and families. Past experience suggests that it will take years for us to find out if a product like Mirena - the popular contemporary IUD currently spiking concern of mass injuries - will turn out to be the next Dalkon Shield. Time and again, the allure of bigger profits has kept such products on the shelves, even when corporate executives knew that the result was the death of consumers.

Our current laws provide little incentive for the manufacturers of many of these products to keep them out of medicine cabinets and out of women's bodies. History has shown that corporations will take risks if they are financially

acceptable even if the results are devastating to their consumers. History has also shown that the federal regulators alone cannot hope to keep dangerous products off the market. Former FDA Chief Counsel Margaret Porter described the relationship between regulation and the civil justice system as "each providing a significant, yet distinct, layer of consumer protection." Without the courts, regulators are too often left to play catchup, as corporations manipulate and conceal concerns. In many cases, years pass before regulators are ready to take action, and even then they are left negotiating with a company to issue a voluntary recall.

The threat of product liability lawsuits promotes patient safety by encouraging manufacturers to take greater responsibility in providing clear warnings about known adverse effects of their products. The civil justice system has played an invaluable role in keeping corporate misconduct in check when corporations and regulators have proven unwilling or unable to protect the health of women. In almost every case profiled here, the reports of death and serious injury have not forced manufacturers to take their dangerous products off the market; the civil justice system has. It is critical to the health of all Americans – not just women – that the ability to hold pharmaceutical and medical device manufacturers accountable when their products cause harm be restored.

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Conclusion

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