
# FROM ACCUTANE TO ZONITE: A HISTORY OF DANGEROUS DRUGS & DEVICES MARKETED TO WOMEN

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# FROM ACCUTANE TO ZONITE: A HISTORY OF DANGEROUS DRUGS & DEVICES MARKETED TO WOMEN

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# EXECUTIVE SUMMARY

Throughout modern history, women have suffered more than men from the effects of dangerous and defective drugs and medical devices. In the late 1800s, women were frequently given morphine for hysteria and methamphetamines for depression. In the early 20th century, women were encouraged to use Lysol as a douche and unofficial contraceptive aid. In the 1950s and 1960s, women were the victims of some of the worst disasters of modern health care with the thalidomide and DES scandals.

Even after consumer advocacy efforts drove changes in regulation, women continued to suffer disproportionately. From snake oil "hormone treatments" to deadly contraceptive devices, the last 150 years have been littered with dangerous drugs and devices that disproportionately affect women.

Many of these "treatments" spawned from the belief that women were physiologically inferior to men, and "enslaved and tortured" by the twin problems of menstruation and menopause.[1]

In many ways, women are fundamentally more at risk from the potential dangers posed by drugs and medical devices, but not because of such archaic beliefs about their inferiority. Women take more medications than men, respond differently to them, and are more likely to suffer adverse drug events. Yet it was not until 1993 that legislation was enacted requiring women to be included in human subject research.[2] Even today, women are consistently underrepresented in studies, or outright excluded. Nor does the FDA require trials to compare dose efficacy between men and women, though women metabolize drugs differently.[3]

To make matters worse, 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 frequently leads to a domino effect, where a defective device leads to generation after generation of further dangerous products.

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


**BALDWIN'S NERVOUS PILLS (1883):** Patent medicines such as Baldwin's Nervous Pills might contain morphine, cocaine, cannabis, alcohol, laxatives, and good old fashioned snake oil.

## 1880s-Present

# THE CURE FOR HYSTERICAL WOMEN? MORPHINE, COCAINE, BARBITURATES, TRANQUILIZERS, AND PROZAC

In the late 19th century and early 20th century, women with alleged nerve conditions were frequently treated with morphine, cocaine, and even heroin. Many supposedly suffered from "hysteria," or "neurasthenia" – nervous exhaustion thought to be caused by the hectic pace of the modern world.[4]

BY THE 1950S, MORPHINE AND COCAINE HAD BEEN REPLACED BY BARBITURATES AND TRANQUILIZERS LIKE PENTOBARBITAL – A DRUG SO POWERFUL THAT TODAY IT IS RESERVED FOR USE ONLY IN EXECUTIONS.

Women were particularly vulnerable because they were thought to be constitutionally weaker than men, and burdened by their reproductive systems. Conditions that would today be recognized as fibromyalgia and postpartum depression were considered indications of nerve disorders. By the early part of the 20th century, as many as 75 percent of people with opium use disorders were women, who were prescribed the drug for pain (opium treatments for teething babies also sold in the millions).[5]

By the 1950s, morphine and cocaine had been replaced by barbiturates and tranquilizers like pentobarbital – a drug so powerful that today it is reserved for use only in executions. In 1955, the tranquilizer Milltown — known as "Mother's Little Helper" — became the first blockbuster psychotropic drug, with 36 million prescriptions filled in just two years, accounting for a third of all prescription medications in the U.S.[6]

Milltown's popularity dropped in the 1960s when it was found to be significantly addictive, but its place was taken by tranquilizers like Librium and Valium, which were heavily marketed as wonder drugs that could treat everything from anxiety and tension to menopause and marital problems.[7]

In 1980, the marketing of anxiety was transformed by the addition of "major depressive disorder" to the third edition of the Diagnostic and Statistical Manual (DSM-III). The morphine tonics of the 1800s and the barbiturates and tranquilizers of the 1950s and 1960s, were replaced by selective serotonin-reuptake inhibitors, or SSRIs.[8] Just like their predecessors, SSRIs

targeted women in ads that emphasized how drugs could restore them fully to their roles as wives and mothers. In 1988, Eli Lilly introduced Prozac, a drug its scientists had been studying without success since 1971 as a potential treatment for high blood pressure, obesity, and depression.[9] Marketed as a kinder, gentler antidepressant, Prozac was a massive hit, making the company $21 billion until it went off-patent in 2001.[10]

In 2007, GlaxoSmithKline settled a $64 million class action over claims that it had misrepresented the dangers of its blockbuster SSRI Paxil, amid allegations that the company deliberately understated the drug's suicide risk.[11]

**Today**: More than a quarter of all American women are being prescribed at least one mental health medications, twice as many as men.[12] In 2012, GlaxoSmithKline, maker of blockbuster SSRI Paxil, agreed to pay $3 billion, the most ever paid by a pharmaceutical company, over claims it illegally promoted antidepressants for unapproved uses.[13] The company has since found itself in court multiple times over charges it deliberately understated the risk of suicide associated with the drug.[14]


**A CENTURY OF ANXIETY MEDICATION: Miles' Nervine, aka sodium bromide (NaBr), potassium bromide (KBr), and ammonium bromide (NH4Br) (1890); Mebaral, aka Methylphenobarbital, a barbituate (1935); Serpasil, aka Reserpine, an antipsychotic associated with increased suicide risk (1954); Equanil, aka Meprobamate (1956); Mornidine, aka pipamazine, a supposed antipsychotic eventually linked to liver injury (1959); Dexedrine, aka Dextroamphetamine, an amphetamine intended for ADHD and narcolepsy, but frequently prescribed off-label for depression and obesity (1937); Pacatal, aka Mepazine, a tranquilizer strong enough to be used as a surgical anesthetic; Milltown, another brand of Meprobamate, a tranquilizer that became one of the first blockbuster drugs (1955); Butisol, aka butabarbital sodium (1956); Serax, aka oxazepam, a short-term psychoactive benzodiazepine (1967); Mellaril, aka thioridazine, an antipsychotic withdrawn in 2005 because it caused severe cardiac arrhythmias (1983); Abilify, aka aripiprazole, an antipsychotic, the #1 drug in the United States with an estimated revenue of $7 billion a year.**

# 1900s-Present (still on the market)

# TALC AND OVARIAN CANCER

Johnson & Johnson's (J&J) talc-based powder was a mainstay of women's lives from the early 1900s. Though ostensibly for babies, J&J soon realized that the bulk of its powders were used by adults, and the company soon began marketing the product with taglines like, "Best for Baby, Best for You."[15]

J&J's supply of talc comes from Guangxi province, China, and does not have to be approved by the FDA under the 1938 Food, Drug, and Cosmetic Act because it is considered a cosmetic.[16] The company knew for decades that its talc-based powders could increase the risk of ovarian cancer, but failed to warn consumers.[17] Since 1971, more than 20 studies had concluded the talc-based powders posed a risk, including a 1982 study that found a 92 percent increase in cancer-risk.[18] The United States National Toxicology Program classified talc as a carcinogen in 1993.[19]


**"BEST FOR BABY, BEST FOR YOU:" Johnson & Johnson's talc-based powder has long been associated with ovarian cancer.**

Despite the overwhelming evidence, J&J consistently maintained there was nothing to fear, and continued to sell the talc-based powders. Internally, the company worried about the possibility of talc being labeled a carcinogen, and discussed how to influence regulatory agencies and conceal the truth about talc from the public. A September 1997 internal memo from a J&J toxicology consultant suggested that, ""Anybody who denies [the published research] risks that the talc industry will be perceived by the public like it perceives the cigarette industry: denying the obvious in the face of all evidence to the contrary."[20]

**Today**: In February 2016, a St. Louis jury awarded the family of Jacqueline Fox $72 million, including $62 million in punitive damages, in the first of more than a thousand lawsuits alleging a link between J&J's talc-based powders and an increased risk of ovarian cancer. Fox had used J&J's powders for over four decades. She passed away in 2015, three years after being diagnosed with ovarian cancer.[21] In May and October of 2016, two more juries found that J&J had not adequately warned consumers about its talc-based products cancer risks, and awarded the two victims a combined $125 million.[22] In May 2017, a Missouri jury handed the company its largest trial loss yet, when it awarded Lois Stemp $110 million after she developed ovarian cancer associated with J&J's baby powder.[23]

# Another Love-match *Shipwrecked...*

...on the dangerous reef of half-truths about feminine hygiene. "Lysol" has prevented many such tragedies.

# 1920s-1970s

# BLEACH AS A DOUCHE (AND SECRET CONTRACEPTIVE)

In the early part of the 20th century chemical douching – with what was essentially bleach – was heavily marketed to women as a path to a happy marriage. Ads pushed "douche" agents such as Lysol – the leading feminine hygiene product from the 1930s through the 1960s – and Zonite for personal hygiene, often featuring fake doctors warning of a husband's frigidity in the face of a wife's "neglect."[24]

Though on the surface the ads concerned personal hygiene, they were also marketed as subtly veiled contraceptive options. Contraceptives had been rendered illegal by their definition as "obscene" items by the Comstock Act of 1873, and would not become legal again until 1965 (and then only for married women – single women had to wait until 1972).[25]


**Chemical douches like Lysol and Zonite were the leading feminine hygiene products right up to the 1960s. Ads frequently depicted husband's spurning women for their "neglect." The douches were also widely used as contraceptives, despite the fact they were not very effective for this purpose.**

Contraceptives — including intrauterine devices, vaginal pessaries, male caps, and even Vaseline – were still sold post-1873, but their intended use was camouflaged.[26] By 1940, and through to the 1960s, the commercial douche had become the leading contraceptive method for women.[27] Ad campaigns were deliberately targeted at married women, often with language that implied Lysol would stop unwanted pregnancies, including such taglines as, "She was guilty of one neglect," and "troubled with uncertainty."[28]

Nor was it even effective as a contraceptive. Women commonly believed that such antiseptic would kill sperm, yet one 1933 study found that nearly half of those using Lysol as a douche became pregnant.[29] Despite this, commercial douches remained the leading form of contraception until the advent of oral contraceptives in the 1960s.[30]

Not only was bleach an ineffective contraceptive, it was an unsurprisingly terrible personal hygiene product, capable of causing severe inflammation, burning, and even death.[31] Lehn & Fink, the makers of Lysol, targeted women in advertising blitzes from 1890 on, despite scores of injuries and a warning by the American Medical Association (AMA).[32] By 1911, there had been 193 Lysol poisonings and 5 deaths from uterine irrigation, yet when confronted by reports of douche-related injuries and deaths, as well as their ineffectiveness as contraception, neither the manufacturer, the medical profession, or regulators did anything.[33] Lehn & Fink, and other manufacturers, hid behind the wording of their ads, claiming that they were not being sold as contraception, even as they admitted that "personal hygiene" had become code for "contraception."[34] In court cases they claimed that reported burns must have resulted from allergies, and that their products were in full compliance with FDA requirements. After decades of complaints, Lehn & Fink told one claimant in 1961 that the report of a blistered and bleeding vagina was "the first of its kind on record."[35]

**Today**: An estimated 20 to 40 percent of women between ages 15 and 44 use vaginal douches today, despite medical consensus that it is ineffective, and can actually increase the risk of infection and pregnancy complication.[36]


**Despite medical consensus that chemical douching is ineffective, unnecessary, and potentially dangerous, the pharmaceutical industry continues to push douche products.**

## 1930s-Present (still on the market)

# HORMONE REPLACEMENT THERAPY AND THE BUSINESS OF MENOPAUSE

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.[37] 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 an estrogen supplement made from pregnant mares – Premarin (for *pre*gnant *mar*es ur*ine*) – which became one of the most profitable drugs in history.[38]

A WOMAN WHO DIDN'T TAKE HORMONES WOULD BECOME, "A DULL-MINDED BUT SHARP TONGUED CARICATURE OF HERSELF." WHILE A WOMAN WHO DID, "WILL BE MUCH MORE PLEASANT TO LIVE WITH AND WILL NOT BECOME DULL AND UNATTRACTIVE."

Premarin ads tended to feature depressed, often witch-like women depicted terrorizing their own families, with taglines like, "When women outlive their ovaries."[39] These drugs, and the marketing surrounding them, pushed the idea of menopause as an illness that needed to be treated. A 1966 book, "Feminine Forever," funded by Wyeth-Ayerst, made the case for such treatments by saying a woman who didn't take them would become, "a dull-minded but sharp tongued caricature of herself," while a woman who did take the treatments, "will be much more pleasant to live with and will not become dull and unattractive."[40]

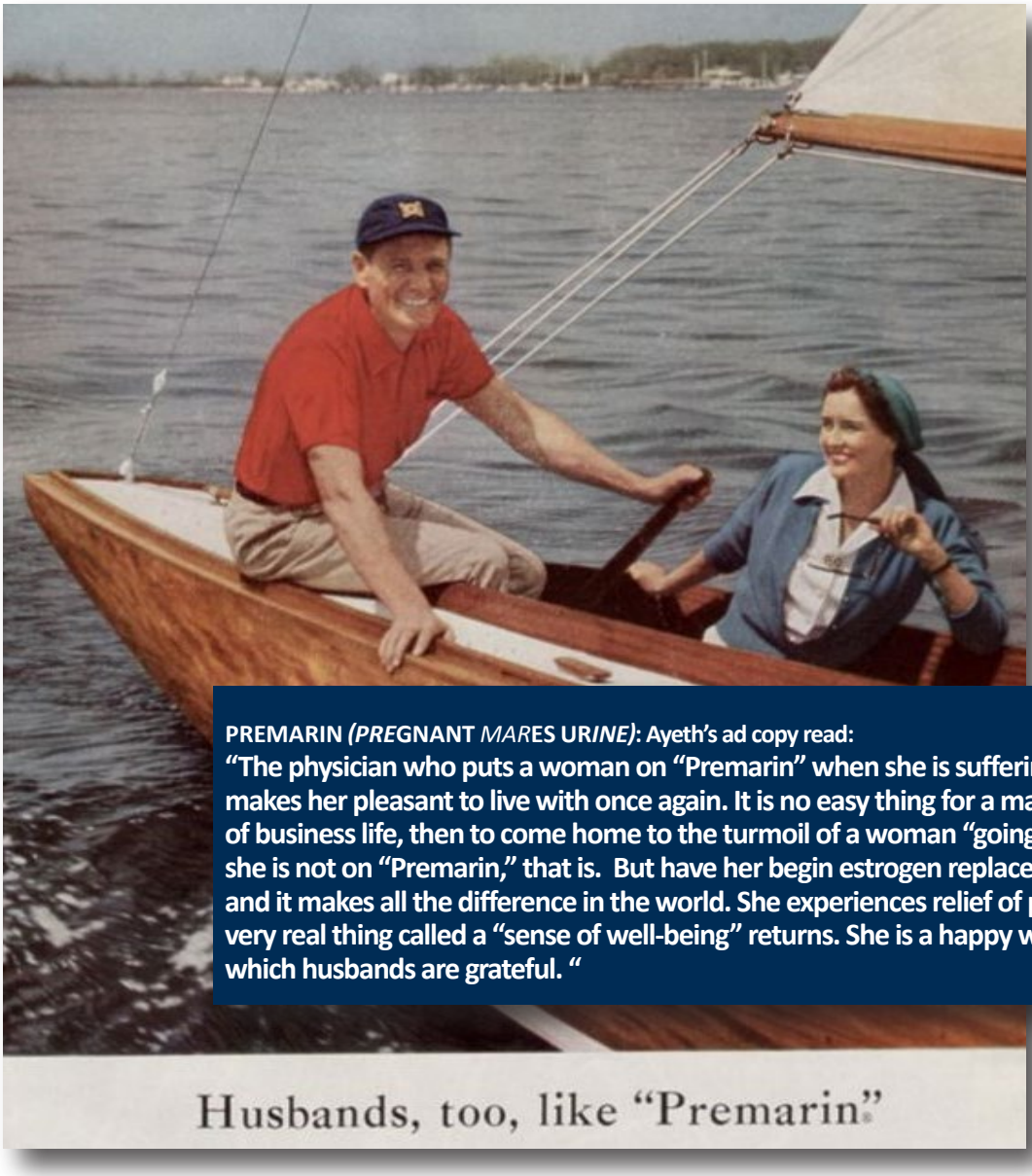
HRT proved a huge moneymaker for the pharmaceutical industry, but science began to catch up. In 1975, the *New England Journal of Medicine* reported on strong links between estrogen therapy and cancer of the uterus.[41] Still, pharmaceutical companies didn't stop investing millions to push menopause as an illness. In 1996, Wyeth Pharmaceuticals introduced Prempro, which combined estrogen with progestin, along with an advertising blitz in which doctors and celebrities implied it would not only help with traditional menopause symptoms, but also heart disease, Alzheimer's disease, and a host of other maladies.[42]

In 2002, the federally-funded Women's Health Initiative – the largest clinical trial of HRT ever – was halted after

researchers found that combined hormones significantly increased the risk of breast cancer, heart attacks, and blood clots in the lungs.[43] HRT sales dropped precipitously.[44]

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 began staging a comeback.[45]

**Today**: In 2012, Pfizer – the new owners of Wyeth – reported in a securities filing that it had paid, or set aside to pay, $1.2 billion to settle approximately 10,000 claims that Prempro and other HRT drugs had caused cancer in the women taking them.[46] But pharmaceutical marketing has made HRT profitable again. Premarin is still worth a billion dollars a year to the company, and industry analysts report the global HRT market was worth $15 billion in 2014, and is anticipated to reach $28 billion by 2022.[47]

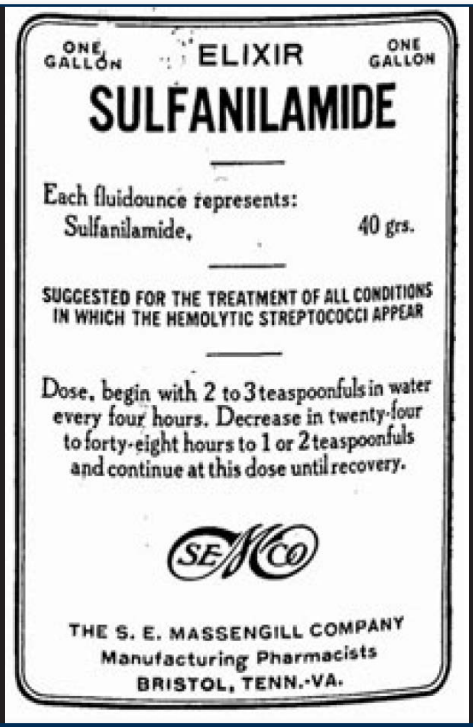



**PREMARIN *(PRE*GNANT *MAR*ES UR*INE)*: Ayeth's ad copy read:**
**"The physician who puts a woman on "Premarin" when she is suffering in the menopause usually makes her pleasant to live with once again. It is no easy thing for a man to take the stings and barbs of business life, then to come home to the turmoil of a woman "going through the change of life." If she is not on "Premarin," that is. But have her begin estrogen replacement therapy with "Premarin" and it makes all the difference in the world. She experiences relief of physical distress and also that very real thing called a "sense of well-being" returns. She is a happy woman again – something for which husbands are grateful. "**

# 1938

# ELIXIR SULFANILAMIDE (aka RASPBERRY ANTI-FREEZE), AND THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

In 1937, 107 people died, many of them children, from Elixir Sulfanilamide – an anti-infection drug made by adding raspberry flavoring to anti-freeze. The pharmaceutical company behind it, S.E. Massengill, tested the concotion for appearance, fragrance, and taste, but not for safety.[48]




**ELIXIR SULFANILAMIDE: The concotion made of raspberry-flavored anti-freeze was never tested for safety, and killed at least 107 people.**

Within two months of its introduction authorities became aware of a rash of deaths and quickly connected them to Elixir Sulfanilamide. The FDA sent inspectors to S.E. Massengill plants, and found that the company was aware its product was killing people, but had only sent telegrams to salesmen, physicians, and pharmacists asking that the product be returned, with no mention of its deadly effects.[49]

Almost every available FDA inspector and chemist was assigned to the taks of tracking down the Elixir and the consumers who had used it. Of the 240 gallons manufactured, all but 234 were recovered. Nevertheless, more than 100 people died in less than two months.[50]

The manufacturer was unrepentant. S.E. Massengill's owner, Dr. Samual Evans Massengill, said, "My chemists and I deeply regret the fatal results, but there was no error in the manufacture of the product. We have been supplying a legitimate professional demand and not once could have foreseen the unlooked-for results. I do not feel that there was any responsibility on our part."[51] The firm's chemist, Harold Watkins, disagreed, and committed suicide after learning of the devastating impact his concoction had wrought.[52]

In the aftermath of Elixir Sulfanilamide, Congress enacted the Federal, Food, Drug and Cosmetic Act, requiring for the first time that manufacturers prove a drug to be safe before it could be marketed.[53]

# 1947-1971

# DES SOWS CANCER FOR A GENERATION

In 1947, the FDA approved Diethylstilbestrol, better known as DES, first as a hormone replacement therapy for menopause and later to reduce the risk of miscarriages, despite concerns from scientists that it was potentially carcinogenic.[54]

The scientist who discovered DES, Edward Charles Dodds, from the Courtauld Institute of Biochemistry in London, began warning doctors and fellow scientists about the drug almost immediately after he first synthesized it. Dodds noticed that the male scientists on his staff who handled DES were growing breasts, which suggested a potential cancer link. He objected to its use for menopause, and wrote personally to doctors using it to prevent miscarriages, explaining that, if anything, DES was likely to cause miscarriages.[55]

These warnings went largely unheeded. From 1947 to 1971, millions of women took the drug, even after research confirmed it did not prevent miscarriages or premature births.[56]

In 1971, researchers at Harvard University noted a cluster of young daughters of mothers who had taken DES were developing rare vaginal tumors.[57] This seminal study prompted the FDA advised doctors to stop prescribing the drug. By this point, an estimated 5-10 million people had been exposed to DES.[58]

Holding the pharmaceutical companies accountable was problematic because DES had been manufactured by hundreds of companies and distributed generically, making it difficult to prove exactly which manufacturer was at fault. In 1979, Joyce Bichler, a 25-year-old cancer survivor, became the first woman to successfully sue over DES injuries, when a court agreed that the named defendant, Eli Lilly, could be held responsible because manufacturers were collectively liable. A jury found that Eli Lilly had coordinated with other pharmaceutical companies to avoid proper testing, and awarded Bichler $500,000.[59]

**Today**: The full consequences of DES are still being played out today. Of the estimated five million children exposed to DES prenatally, 95 percent have experienced some form of reproductive tract problem, from infertility to cancer.[60] In 2011, a study published in the *New England Journal of Medicine* found that infertility was twice as common and the risk of breast cancer nearly doubled in women whose mothers took DES.[61] In 2012, a federal judge in Boston ordered 14 drug companies to enter mediation with 53 women who claimed their breast cancer was connected to DES.[62]

"Really?"

Yes . . .

**desPLEX®**

to prevent ABORTION, MISCARRIAGE and PREMATURE LABOR

*recommended for routine prophylaxis in ALL pregnancies . .*

96 per cent live delivery with desPLEX
in one series of 1200 patients[4]—
— bigger and stronger babies, too.[cf. 1]

No gastric or other side effects with desPLEX
— in either high or low dosage[3,4,5]

# 1950

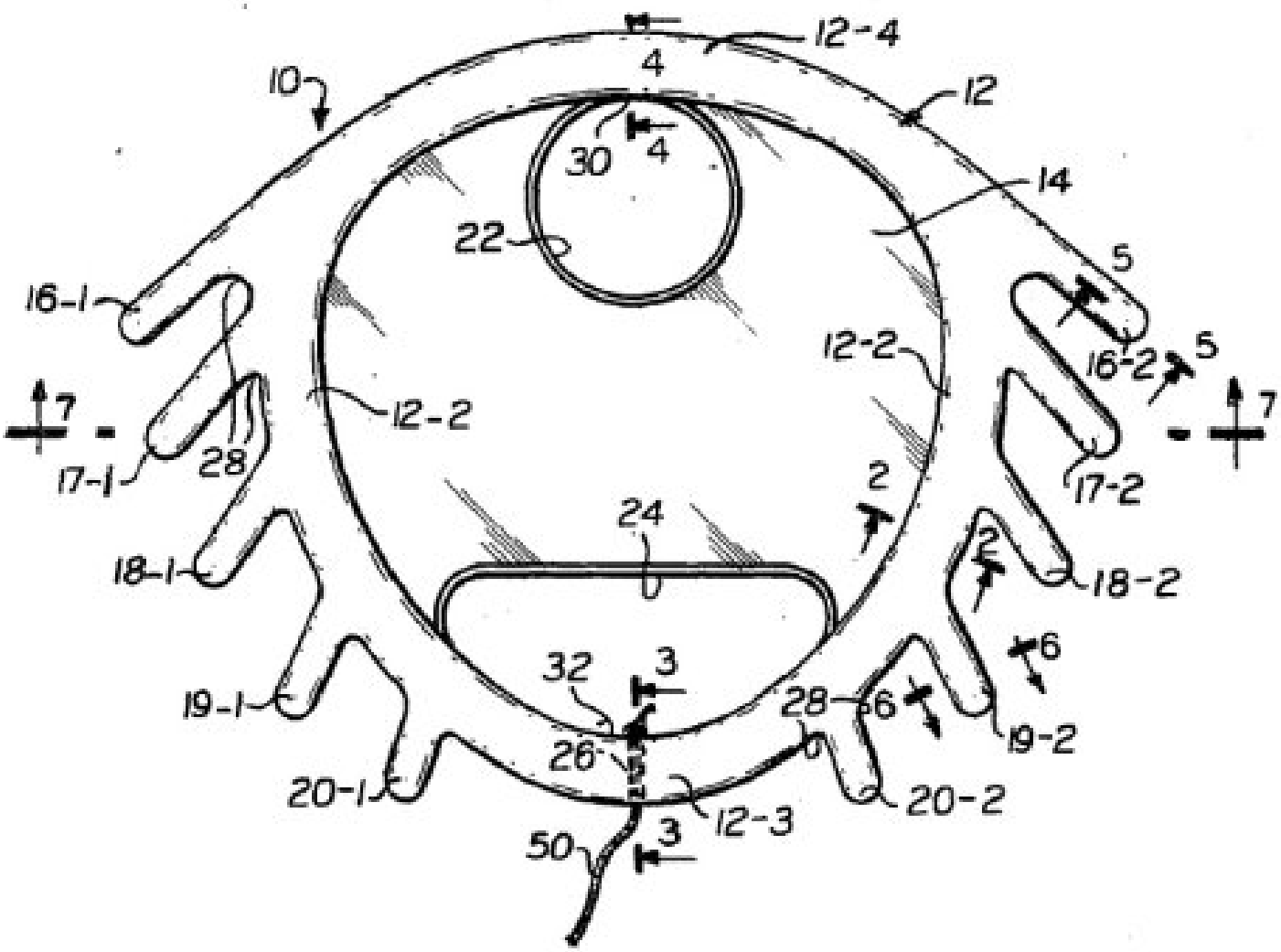
# THE GLOBAL THALIDOMIDE CRISIS

Developed in the 1950s, thalidomide was supposed to treat sleeplessness and morning sickness in pregnant women. Despite intense pressure from the company, the FDA's reviewer, Dr. Frances Kelsey, refused to approve the drug.[63] Nevertheless, the U.S. distributor, Richardson-Merrell (now part of Sanofi), decided to conduct its own large scale human trial to aid its application for official FDA approval. More than 2.5 million doses were sent to approximately 20,000 patients, who did not realize they were unwittingly taking an experimental drug.[64] Soon after, the harmful side effects of thalidomide became clear. More than 10,000 children in 46 countries were born with thalidomide-caused deformities, such as shortened or absent limbs.[65]

In 1970, the original German manufacturer, Chemie-Grunenthal, faced a criminal trial in Germany. The trial would turn out to be highly questionable. In the middle of proceedings, one of Grunenthal's many defense lawyers, Dr. Joseph Neuberger, was appointed the regional minister of justice, and was thus able to control the prosecution. Without recusing himself from the case, Neuberger pressured the prosecution to drop the case. The criminal charges were dropped. The company agreed to pay $28 million into a compensation fund — an amount equal to about 10 percent of the existing claims — and remarkably received permanent legal immunity in return.[66]

**Today**: By 2011, the number of surviving Thalidomide babies had dwindled to an estimated 3,000. Grunenthal is now known to have had strong ties to former Nazi doctors convicted of war crimes for their wartime medical experiments, suggesting that Thalidomide may have its origins in Nazi experiments.[67] New evidence has shown that the company knew Thalidomide was causing nerve damage as soon as it entered the market, but buried the evidence.[68] In 2013, a class action by Australian and New Zealand victims reached an A$89 million settlement with Diageo, the company that now owns the original Australian distributor of Thalidomide. Other class actions around the world are ongoing. Grunenthal continues to fight all claims.[69] Thalidomide is still prescribed for the treatment of leprosy and some cancers.


**THALIDOMIDE: An advert for Distaval, the trade name for Thalidomide.**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# 1971-1980

# THE DALKON SHIELD DISASTER

A.H. Robins introduced the Dalkon Shield in 1971 despite knowing the device had fatal flaws. To keep the IUD from being expelled, it was designed with claw-like prongs that would embed themselves in the walls of the uterus. Pulling it out required an extra strong string, but because the string was left open at both ends, the device wicked bacteria into the uterus.[70] Just 17 days after buying the device from its inventor, and A.H. Robins manager wrote to 39 executives, warning, "The string or 'tail' situation needs a careful review since the present 'tail' is reported to have a wicking tendency."[71] The executives took no action.

*AN A.H. ROBINS EXECUTIVE TOLD CROWDER THAT HIS CONCERNS AMOUNTED TO "INSUBORDINATION," AND THAT HIS CONSCIENCE DID NOT PAY HIS SALARY.*

The device was also a relatively poor contraceptive. The Shield's designer Hugh Davis had claimed a pregnancy rate of 1.1 percent in his initial trials, but before the device had even made it to market A.H. Robins had determined that Davis had played fast and loose with the truth, and the true pregnancy rate was five times higher (an estimated 5.3 percent).[72]

Animal studies for the Dalkon Shield were a failure. In one study, one of eight baboon test subjects died and three more suffered a perforated uterus. The results were never revealed.[73] Proposals from universities and other outside sources to do safety testing were turned down, with one internal memo explaining, "We obviously were not interested in paying premium prices for unfavorable data."[74] Internal documents uncovered through litigation show that a variety of company staff pointed out the problems, but were ignored or told to shut up. Executives were more concerned with the possibility that the stiff string would prove uncomfortable for men during sex.[75]

One of the company's quality control managers, Wayne Crowder, suggested a fix to the design flaw, but was rejected by executives who were loath to slow down production. An A.H. Robins executive told Crowder that his concerns amounted to "insubordination," and that his conscience did not pay his salary.[76]

Another employee, Daniel French, the president of A.H. Robins' Chap Stick division, also voiced concern, and tried to persuade the company's medical department that the device's potential to wick bacteria would be a problem. But

when French's concerns were disregarded, he agreed to manufacture the device as specified, writing that he would not "attempt any unauthorized improvements," and that, "my only interest in the Dalkon Shield is to produce it at the lowest possible price, and … increase Robins' gross profit level."[77]

None of these concerns reached the FDA, which had limited authority to regulate the device anyway. Drug manufacturers had to demonstrate a new drug's safety and efficacy before it could be marketed, but medical devices operated under different rules. The agency could only go after a device after it was released, and then only if it could prove it was sold, "under false and misleading claims," was "adulterated," or was, "unsafe for its intended use." Thus, the Dalkon Shield was introduced in the spring of 1971. A.H. Robins even eliminated the designers' recommendation that women be given a painkiller before insertion, believing it might scare women and physicians, and dampen sales.[78]

In its first three years on the market, more than two million Dalkon Shields were sold, capturing 60 percent of the IUD market.[79] By mid-1972, A.H. Robins had begun receiving warnings from physicians — including physicians acting as paid consultants for the company — that the Dalkon Shield was associated with an unusually high frequency of adverse events. But the company deliberately did not investigate many such warnings, and consistently understated the number of cases it was aware of.[80] More than 200,000 women suffered pelvic infections, miscarriages, stillbirths, and infertility. At least 17 died.[81] Meanwhile, for every million dollars of profit the device created for A.H. Robins, an estimated $20 million was spent on health care for side effects the device caused.[82]

A.H. Robins, however, continued to heavily promote the product for several more years. A.H. Robins lawyer Roger Tuttle recommended not withdrawing the product from the market, and wrote, "[I]f this product is taken off the market it will be a 'confession of liability.'"[83]

MY ONLY INTEREST IN THE DALKON SHIELD IS TO PRODUCE IT AT THE LOWEST POSSIBLE PRICE, AND … INCREASE ROBINS' GROSS PROFIT LEVEL."

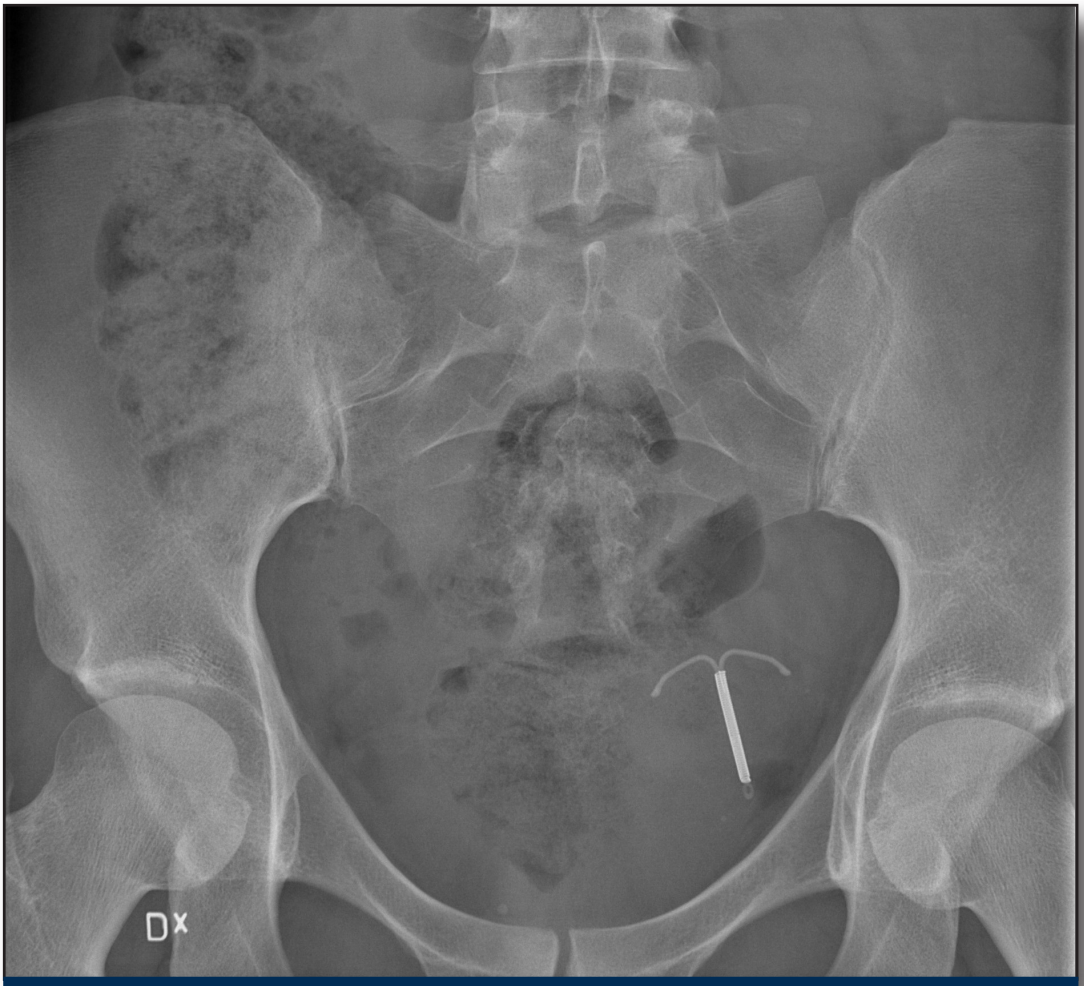
In 1974, A.H. Robins was no longer able to control the tide of bad publicity surrounding the shield, and, under pressure from the FDA, halted sales. Even then, the company continued to market the device overseas. By 1975, the FDA reported it knew of at least 15 fatal and 245 nonfatal septic abortions, among a host of other problems.[84]

Lawsuits piled up against A.H. Robins, but the company fought them aggressively. Thousands of documents were destroyed under suspicious circumstances.[85] The defense lawyers blamed women's high-risk sexual behaviors for the problems. Women were forced to answer intimate questions about hygiene, sexual practices, and relationships, in some cases ruining reputations, careers, and lives.[86]

It was not until 1984, 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. That same year, Roger Tuttle, the former A.H. Robins lawyer who had recommended not taking the device off the market, confirmed there had been an organized cover-up at the company, which had included destruction of documents.[87] In 1985, facing lawsuits from at least 300,000 women and billions of dollars in liability, A.H. Robins declared bankruptcy.[88] Ironically, this caused its stock to quadruple, and it was bought by American Home Products.[89]

**Today**: Use of IUDs fell dramatically in the wake of the Dalkon Shield. Four decades later, IUD use is making a comeback. The two primary choices, Mirena and Paragard have both come under fire because of the dangers they pose, particularly their likelihood of perforating the uterus.[90] Approximately 70,000 women have reported problems with Mirena to the FDA, while the agency has recorded 11,000 adverse events in connection with Paragard.[91]




**WANDERING IUD: An x-ray showing a modern Mirena IUD that has perforated the uterus.**

# 1974-1986

# THE COPPER-7 — IUD AND NECKLACE

In 1974, 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 own doubts about its safety. In public, Searle dismissed all claims against it, even though its own information showed more than 30 different side effects.[92] When Searle pulled the IUD in 1986, it blamed "unwarranted product litigation," and the lack of available liability insurance, but recommended women who already had the device keep it.[93]

In fact, company executives knew that the Copper-7 created 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.[94] Two years after the device's withdrawal, internal documents unsealed at a Minnesota trial revealed that Searle had debated revealing the "three-to-fivefold increased risk of pelvic inflammatory disease," (PID), on a warning label, but decided not to.[95]

Not only did Searle continue to sell the device, the company marketed it specifically to young women, even though their own research showed that this population was at particular risk of infertility. The company went so far as to advertise a Copper-7 necklace to young women who wanted to display their sexual availability.[96] At the same time, an internal report warned of the dangers to this same demographic, stating, "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 FDA, mishandled by the lay press, might have an impact on our marketing strategy."[97]

Searle had aggressively defended itself up to that point. But when the internal documents were revealed, a jury awarded plaintiff Esther Kociemba $8.75 million, and Searle began settling several hundred claims shortly after.[98]

**Today**: Two years after the Copper-7 was pulled from the market, GynoPharma began marketing a similar copper IUD, Paragard.[99]

**IUDS, PAST AND PRESENT: From right to left: the Dalkon Shield, the Copper-7, Paragard, and Mirena.**

# 1976

# THE MEDICAL DEVICE AMENDMENTS ACT

Following the Dalkon Shield disaster, Congress passed the Medical Device Amendments, which sought to impose new, stricter safety standards for medical device approval. Class III devices were now to be approved either through the premarket approval (PMA) process, or the premarket notification [510(k)] process. PMA approval required a manufacturer to submit significant supporting information to the FDA. The 510(k) process, however, required only that a manufacturer show that the device was substantially equivalent to a previously approved medical device.[100]

The lack of analysis in the 510(k) process would become a particular concern in many women's products, for instance vaginal mesh and power morcellators, when devices that had proved safe when used on other parts of the body became introduced to the gynecological setting.

# 1980

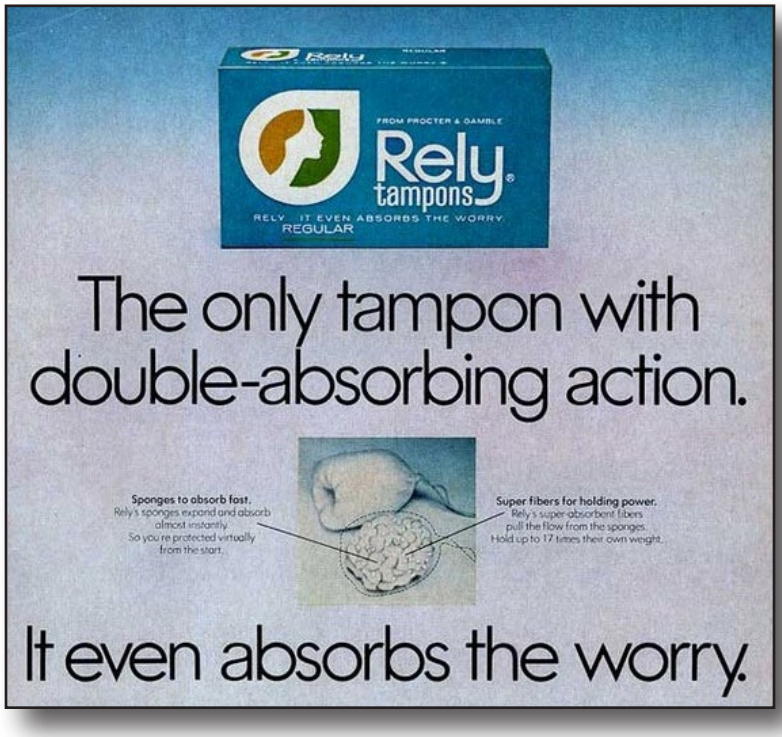
# TAMPONS AND TOXIC SHOCK SYNDROME

In 1980, 38 women died from toxic shock syndrome associated with Procter & Gamble's Rely tampon.[101] 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, which made it far more absorbent than previous tampons. Those superabsorbent synthetics turned Rely into what one medical expert called, a "toxin factory."[102]

The company was able to avoid the beefed-up testing protocols required by the 1976 Medical Device Amendments Act because its test-marketing predated the new rules.[103] But as early as 1975, Procter & Gamble was receiving 100 complaints per month, and internal memos indicated the company was aware Rely was made with cancer-causing agents, and that it could affect the natural microorganisms and bacteria of the vagina.[104] In 1980, Procter & Gamble began national distribution, and sent 45 million free samples to women across the country.

Almost immediately, Rely had cornered a quarter of the market, while the number of complaints grew to 177 per month.[105] The company instructed salespeople to deny any link between tampons and toxic shock.[106] By May 1980, the CDC had tracked 55 cases of toxic shock syndrome, and seven deaths, but did not realize the deaths were related to tampons.[107] Procter & Gamble, meanwhile, went ahead with a plan to market a deodorant version of Rely, even though its own scientists believed it unnecessary.[108]

In July 1980, news reports began linking the tampons to toxic shock syndrome fatalities.



Procter & Gamble executives debated placing a warning label on the product, or sponsoring a PSA on the dangers of toxic shock syndrome. Yet in the end, the executives decided to do neither, with one writing, "We should continue our planned activity to support this brand and build its share to leadership status."[109] Instead, the company distributed two million free samples, and planned a promotion to high school students that year.[110]

By September 1980, the CDC had linked the deaths to Rely tampons. Media coverage hit a frenzy, and after a standoff with the FDA, the company recalled the Rely brand. By the end of that year, 42 women were dead.[111]

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 its product to toxic shock, and sought to market the product's extra absorbency when other manufacturers were reducing absorbency in reaction to medical information.[112]


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 Tenth Circuit noted that the company:

*"[D]isregarded 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."*[113]

Between 1979 and 1986, at least 3,200 women suffered toxic shock syndrome, and 172 died as a result.[114]

**Today**: After the toxic shock fiasco, tampon manufacturers tried to shift responsibility to women, telling them to change tampons more frequently.[115] Though they were once classified as "cosmetics," tampons are today classified as "medical devices." Ironically, this means that a bottle of shampoo must list its ingredients, whereas tampons do not.[116]

# 1980-1994

# PARLODEL, THE DEADLY LACTATION SUPPRESSANT

In 1980, Sandoz Pharmaceuticals introduced Parlodel, 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.[117]

In 1989, the FDA declared lactation suppressant drugs were dangerous, and every manufacturer but Sandoz took its drugs off the market. Sandoz refused.[118] 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 women every year.[119]


**DRUG COMPANY "FREEBIE": A mug promoting Parlodel.**

In 1989, after nearly a decade of complaints, the FDA again asked Sandoz to stop selling Parlodel. Sandoz refused once again.[120] 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.[121] Two days later, Sandoz announced it would halt sales of Parlodel as a lactation suppressant.[122] The FDA later came to the conclusion that lactation suppressant drugs like Parlodel unnecessarily exposed women to potential side effects.[123]

# 1980-PRESENT

# DIRECT-TO-CONSUMER MARKETING EXPLODES

The United States is one of only two Western countries (the other is New Zealand) to allow marketing of pharmaceuticals directly to consumers (DTC). Leading up to the 1980s, such marketing was generally confined to print, because of rules requiring the full list of risks, benefits, and side effects.

In the 1980s, the pharmaceutical industry began using "reminder ads" and "help-seeking ads," which got around the rules by never actually mentioning the drug being marketed. In 1997, the FDA changed the rules so pharmaceutical companies only had to name the most significant potential side effects, paving the way for a tsunami of ads on TV and radio. DTC spending went from $12 million in 1980 to $47 million in 1990, and then $340 million by 1995 – an increase of 2,700 percent over 15 years.[124]

**Today**: The pharmaceutical industry spends more than $5 billion a year on advertising.[125]


**$5 BILLION AD BLITZ: The pharmaceutical industry spends $5 billion a year on ads that frequently resemble their counterparts from a century ago.**

# 1982-2009 (generic still on the market)

# ACCUTANE, BIRTH DEFECTS, AND SUICIDE

Hoffman-LaRoche's cancer treatment unit began studying isotretinoin – the chemical compound that would eventually be marketed as Accutane – in the 1960s for use as a skin cancer treatment, but abandoned the drug after establishing it could cause severe birth defects.[126]

Hoffman-LaRoche, however, did not give up on isotreinoin, and eventually relaunched it as the acne treatment Accutane. The company excluded women from most of its pre-market testing and required negative pregnancy tests and contraceptive use for those that were included, allowing it to

release Accutane with a label that claimed there had been no evidence of birth defects in children.[127] The company recommended the drug be given a pregnancy risk rating of C, the middle of five grades, indicating the drug could be used if the possible benefit outweighed the potential risk to the fetus.[128] The FDA would later require Hoffman-LaRoche change the risk rating to X, the maximum risk rating.[129]

THE U.S. EXPERIENCE "HORRIFIED" THE FDA'S EUROPEAN COUNTERPARTS, WHO GROUPED ACCUTANE WITH THALIDOMIDE AND OTHER VERY DANGEROUS CHEMOTHERAPY DRUGS SUBJECT TO STRINGENT CONTROLS.

Accutane was approved in 1982 amid much fanfare and within a year had been prescribed more than 200,000 times.[130] Forty percent of pregnancies exposed to Accutane resulted in spontaneous miscarriage, and a quarter of babies carried to full term suffered major congenital deformities.[131] The majority of women who became pregnant while using the drug chose to abort upon just learning of the risk.[132] Hoffman-LaRoche's own researchers expressed alarm over the "potential tragedy," but company executives admonished anyone who raised red flags.[133]

Within a year, the FDA announced it knew of at least 12 cases of "adverse pregnancy outcomes" attributed to Accutane.

The U.S. experience "horrified" the FDA's European counterparts, who grouped Accutane with Thalidomide and other very dangerous chemotherapy drugs subject to stringent controls.[134] In the U.S., however, the drug stayed on the market. Hoffman-La Roche agreed to change its labeling and sent Dear Doctor letters warning against the possibility of birth defects, yet resisted all suggestions of recalling the drug.[135]

In 1988, an internal FDA memorandum was leaked suggesting as many as 23,000 pregnant women had been exposed to the drug, and an estimated 1,300 Accutane babies had been born.[136] 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.[137]

**Today**: In 2009, amidst claims that Accutane was linked not only to birth defects but also inflammatory bowel diseases and suicide, Hoffman-LaRoche finally pulled the drug from the market.[138] Accutane is still available in generic form.

# 1991

# MORCELLATORS, AND SEEDING CANCER

In 1991, the FDA approved the first laprascopic power morcellators for use in gynecological surgery.[139] These electric bladed tools are used in minimally-invasive hysterectomies, and in the removal of uterine fibroids. Nearly 20 years after their introduction, the FDA issued a safety advisory, stating that morcellators were responsible for the spread of potentially deadly and aggressive forms of cancer in thousands of women.[140]

Morcellators had originally been approved through the FDA's 510(k) process, which assumed the devices were substantially similar to previous devices. However, in the gynecological context, morcellators were also frequently seeding cancerous tissue throughout the pelvis, abdomen, and other organs.

In November 2013, the FDA received its first notification that a power morcellator might have spread previously-unsuspected uterine cancer.[141] A year later, the FDA recommended morcellators no longer be used.[142]

**Today**: The FDA issued warning letters citing reporting violations to three manufacturers of power morcellators in the five years leading up to its investigation.[143] In 2015, the Federal Bureau of Investigation (FBI) reportedly began looking into whether J&J, the largest manufacturer of the device, had been aware of the issues.[144]

# 1996-Present

# VAGINAL MESH (aka CONCRETE REBAR)

The early iterations of vaginal mesh 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. The devices 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. The devices often cause pain, bleeding, and infection, and can erode or harden. Making matters worse, removing them is extremely difficult, a task surgical experts liken to removing rebar from concrete. Many also believe the devices violate longstanding principles of surgery, because they are inherently prone to contamination.[145]

**CONCRETE REBAR: Vaginal mesh can become embedded in the body. Extraction and repairs have been likened to removing rebar from concrete.**

In most cases, versions of vaginal mesh implants were never widely studied or examined by the FDA before their introduction. Instead, problematic products like American Medical Systems' Sparc Sling System, and J&J'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.[146] This is not unusual. The vast majority of medical devices gain FDA clearance because the manufacturer claims they are similar to prior devices. However, in the case of vaginal mesh, the maze of prior approvals originated with devices that were themselves problematic.

One such device was Boston Scientific's ProtoGen sling, which was recalled in 1999

because of high rates of erosion, extrusion and infection, and which the FDA at the time described as "adulterated and misbranded."[147] The ProtoGen itself had not been properly evaluated, but instead was cleared for use based on a previous mesh product used for entirely different cardiovascular operations, and then, "rushed to market for financial reasons without adequate premarket clinical trials."[148] In the process, it unwittingly ushered in a generation of dangerous products.

"RUSHED TO MARKET FOR FINANCIAL REASONS WITHOUT ADEQUATE PREMARKET CLINICAL TRIALS."

Johnson & Johnson's Gynecare Prolift mesh implant, introduced in 2005, was one such example. Not only was this device not approved by the FDA, but the agency did not initially know it even existed, because the giant health care products company decided on its own that it was reasonably similar to the previously-approved Gynemesh.[149] The FDA only became aware of Prolift when J&J mentioned it in an application for a different device in 2007, at which point the FDA immediately ordered the company to halt sales, citing the "potential high risk for organ perforation," in part because of hundreds of complaints about Gynemesh, Prolift's predecessor.[150] Undeterred, J&J continued selling the device, in violation of the Federal Food, Drug and Cosmetic Act.[151] Nine months later, in May 2008, the FDA agreed to approve the implant without any sanctions for its continued sale.[152]

As many as 70,000 women have vaginal mesh devices implanted each year.[153] 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.[154]

In April 2014, the FDA declared vaginal inserts should be considered high-risk devices. A day later, device maker Endo Solutions Inc. announced it would pay $830 million to settle about 20,000 complaints over its vaginal inserts.[155]

In 2013, a jury ordered J&J 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 J&J had failed to warn her surgeon of the risks tied to the implant and had fraudulently misled Gross.[156]

**Today**: Facing 4,000 lawsuits from injured patients, J&J stopped selling Prolift in 2012. Other mesh implants, however, are still heavily marketed and surgically implanted. In January 2016, the FDA reclassified vaginal mesh from a Class II device to a Class III high-risk device, and ordered manufacturers to submit designs for premarket approval.[157]

# 2000-2013

# TOXIC HIP IMPLANTS

In the 2000s, DePuy Orthopaedics, a division of J&J, began marketing hip replacement systems using metal-on-metal designs that were supposed to last longer than previous devices, despite the fact that its own engineers believed such designs were problematic.[158] Internal memos from as early as 2005 show the company was aware that metal-on-metal hip implants could affect immune function, and could result in debris that would be carcinogenic, causing an increased risk of cancer.[159]

Almost immediately after the introduction of DePuy's ASR hip implant in 2005, the company began receiving complaints from doctors, reporting the device shed large quantities of metallic debris and frequently caused infection, fractures, dislocations, necrosis and nerve damage.[160] In 2007, the device failed internal tests, and the company projected they expected about 40 percent of the devices to fail within five years. Executives discussed fixing the defect, but they never did so.[161]

Women were particularly at risk from the device, facing a 29 percent higher risk of implant failure than men.[162] In 2013, the first case to be heard before a jury resulted in an $8.3 million verdict.[163] J&J and DePuy eventually paid $2.5 billion to settle ASR claims.[164]

In 2010, with thousands of lawsuits pending, DePuy stopped selling the device. However, the company continued selling its Pinnacle hip replacement system, an earlier device on which the ASR had been based.[165] Pinnacle was also causing similar problems because of its metal-on-metal design.

**Today**: In December 2016, in the third of a series of bellweather cases against J&J and DePuy, a federal jury in Dallas ordered J&J and its subsidiaries to pay $1 billion for "despicable and vile conduct" for selling medical devices they knew were seriously defective.[166] About 755,000 Americans have had metal-on-metal hip replacements implanted.[167]

# 2001 - Present (still on the market)

# YAZMIN/YAZ AND MORE BLOOD CLOTS

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 its maker, Bayer, 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, and reduce PMS, suggestions that Bayer paid women's magazines to perpetuate.[168] Unfortunately, it also came with a significant risk of sometimes fatal blood clots.[169] 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.[170]

In December 2011, documents uncovered through litigation revealed that Bayer had deliberately withheld data. The company had developed an internal report that concluded, "When considering only serious AEs (adverse events), the reporting rate for Yasmin was 10 fold higher than with the other products."[171] The report data were never given to the FDA.

In response to such revelations, 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.[172]

By 2015, 190 women had died, over 13,000 more had suffered injuries, and Bayer had spent $1.8 billion to settle claims.[173] As thousands of legal cases began to reach court, Bayer was forced to begin settling the claims. Bayer planned to put aside $1 billion to pay approximately 4,800 claims – about four percent of the company's annual revenue.[174]

**Today**: Yasmin and its successor drug Yaz are both available in both original and generic form. In addition to contraception, Yaz has been approved for acne treatments in those 14 years and older.


**ALL ABOUT THAT YAZ: In 2009, Bayer settled with the FDA over allegations it overstated the drug's ability to improve moods and clear up acne.**

# 2002

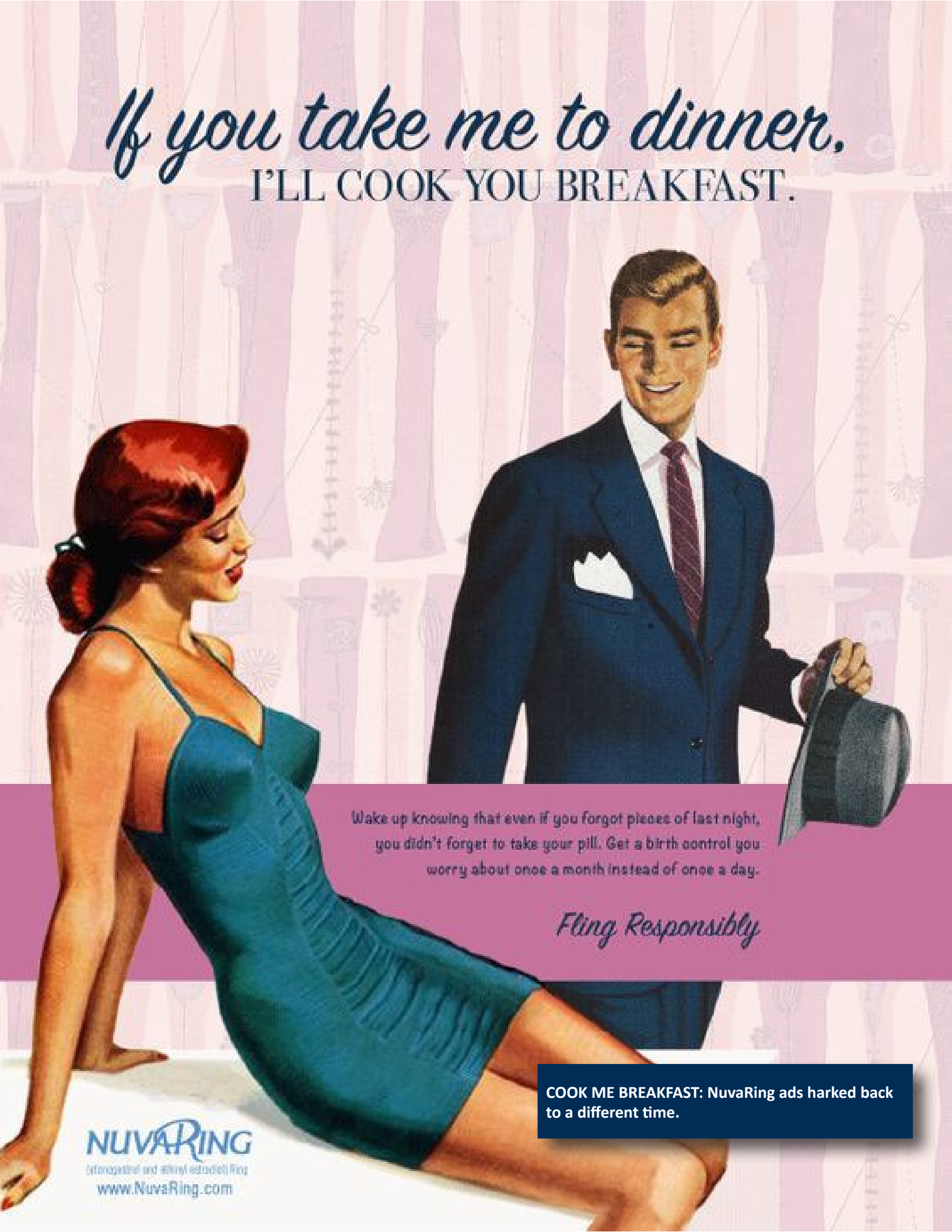
# THE ESSURE LEGACY — INADEQUATE RESEARCH AND PERFORATED UTERI

Essure is a permanent contraceptive device consisting of two coils that are 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. Nickel is a known cancer-causing carcinogen, to which approximately 10 percent of all adults are allergic, particularly women. 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.[175] It is this very damage that Essure's original manufacturer, Conceptus, relied on to produce scar tissue to seal off the fallopian tube.. 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.[176]

Since Essure's introduction in 2002, more than 900,000 women have had the device implanted.[177] Since then, researchers have found that many women have suffered potentially fatal ectopic pregnancies, perforated uteri and small intestines, severe pain, or were forced to undergo complete hysterectomies.[178] Meanwhile, the postmarket clinical trials that were supposed to track patients with Essure have been "inadequately rigorous," often incomplete, and sometimes delayed for years or abandoned altogether.[179]

In 2013, the FDA became aware of a "significant increase in the number of adverse event reports related to Essure," including pain, cramping, nausea, and perforations.[180] Between the device's approval in 2002 and the end of 2016, there were 14,919 reports of complications.[181] In August 2015, a *British Medical Journal* study found that women who used Essure were 10 times more likely to undergo reoperation than women who had tubal ligation.[182] Moreover, a 2014 study found that Essure wasn't even very effective as a contraceptive device, with a 5.7 percent annual risk of pregnancy.[183]

**Today**: In February 2016, an FDA advisory committee ordered Bayer to conduct a postmarket surveillance study to determine its risks.[184] The agency also required a black-box warning, as well as a Patient Decision Checklist—a document highlighting the implant's use, safety, and effectiveness—to ensure women were aware of and understood the risks. Multiple lawsuits have been filed against Bayer, but all face hurdles because of the U.S. Supreme Court's 2008 *Riegel v. Medtronic, Inc.* decision, which allows Bayer to claim that its original FDA approval renders it immune from any liability for harm its product caused, whether or not it knew of the potential harm.[185]




**COOK ME BREAKFAST: NuvaRing ads harked back to a different time.**

# 2002-Present (still on the market)

# NUVARING, AND A NEW GENERATION OF BLOOD-CLOTTING HORMONES

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 a hospital.[186] 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. She then spent the next six days in intensive care, receiving injections of blood thinners in her stomach four times a day.[187] In 2011, Erika Langhart, an athletic 24-year-old about to start law school, died from a pulmonary embolism a few days before visiting her family for Thanksgiving.[188] In 2012, one of Erika's college friends, 25-year-old Megan Henry, was hospitalized in Utah while training for the 2014 Olympic Games. A CT scan showed dozens of blood clots in her lungs. She was hospitalized for a week and told her athletic career was over.[189]

All the women were healthy, did not smoke, and had no history of blood clots. They were also all using NuvaRing, a contraceptive vaginal ring about two inches in diameter that is inserted into the vagina. The ring releases low doses of hormones. NuvaRing was brought to market in the United States in 2002, initially by Organon, which was taken over by Schering-Plough five years later, which was then bought by Merck in 2009. Marketing touting freedom from daily birth control focused heavily on social media, targeting college-aged girls and millenials.[190] It has been prescribed more than 44 million times for women in the United States.[191]

NuvaRing uses ingredients from the progestin hormone family, which were supposed to reduce the side effects of earlier generations of contraceptives. 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.

Making NuvaRing potentially more dangerous than other contraceptive pills was also its method of delivery. While up to half of the hormones in oral contraceptives are absorbed in the digestive tract, NuvaRing's hormones are absorbed directly into the blood.[192] NuvaRing's manufacturer claimed to not know how much more dangerous this made it, while the FDA approved the device based on studies involving oral contraceptives. Yet there have been a multitude of studies suggesting that the third-generation progestins used by

NuvaRing are far more likely to cause blood clots than earlier forms of the hormone.[193] A *New England Journal of Medicine* study 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.[194] A 2012 *British Medical Journal* study found NuvaRing posed a 90 percent greater chance of suffering a blood clot. The FDA itself put the increased risk at 56 percent. But NuvaRing's labeling said simply the risk "may be greater."[195]

Even this warning was more than Organon executives wanted to admit. When first bringing NuvaRing to market, Organon executives had resisted the FDA's request to warn about the higher risk of blood clots. "We should really try to get it out of the text," one wrote in an email in the fall of 2000.[196] By December of that year, executives negotiating with the FDA had managed to water down the agency's label recommendation to note merely that it was "unknown" if NuvaRing posed an increased risk of blood clots. "The label change looks much better," wrote David Stern, Organon's director of U.S. reproductive marketing, in an internal email. Then he added, "What are the chances that this section can be removed altogether?"[197]

Executives at Schering-Plough, the company that bought Organon, were also very aware of NuvaRing's blood clot problem, and devised a campaign to instruct drug reps how to nullify doctors' concerns.[198]

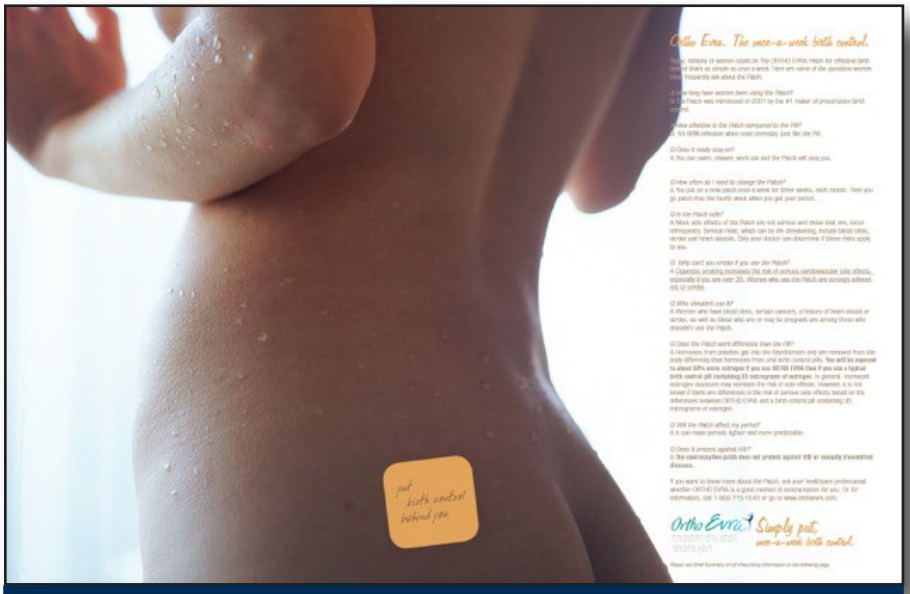
**Today**: In 2014, Merck settled a class action by NuvaRing victims for $100 million.[199] Several generic versions of NuvaRing are set to hit the market once Merck's patent expires in 2018.[200]

# 2002-Present (still on the market)

# ORTHO-EVRA—CELEBRATED INVENTION, THEN STROKES AND BLOOD CLOTS

When J&J introduced Ortho Evra – the first-of-its-kind birth control patch – in 2002, it was lauded as one of the year's best inventions by *Time* magazine.[201] Eight years later, Ortho Evra was highlighted in *Time* once again, this time because of revelations the company had covered up its deadly side effects.[202]

Ortho Evra's hormone dose turned out to be far higher than was safe. 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.[203] J&J had done everything they could to conceal the dangers, manipulating records and refusing to allow comparisons to contraceptive pills, because there was "too high a chance that study may not produce a positive result for Evra."[204] A 2005 internal letter from J&J Vice President Dr. Patrick Caubel warned that, "The estrogenic exposure [of the patch] was unusually high, as was the rate of fatalities." Based on the company's decision to ignore this "compelling evidence," Caubel resigned.[205]




**ORTHO EVRA PATCH: Ads for J&J's Ortho Evra Patch featured labels on the patch with slogans such as "put birth control behind you."**

As early as August 2002, the FDA knew of multiple deaths and serious injuries involving patch users. At least one J&J 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.[206]

**Today**: J&J quietly settled as many as 4,000 lawsuits to keep the problem from bubbling over in the news, while continuing to sell the patch.[207] Six years after the 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.[208] Ortho Evra was discontinued in 2014, however, the generic version, Xulane, remains on the market.

# 2008 & 2011

# *RIEGEL, MENSING,* 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. 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.

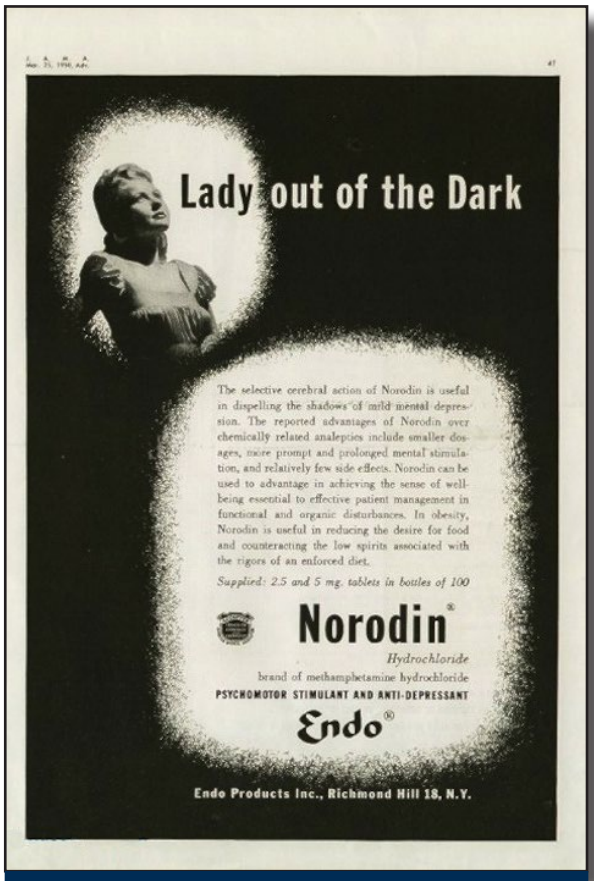
In 2008, the Court changed its longstanding position that FDA approval of a medical device did not preclude a patient injured by a dangerous or defective device from using state common and consumer protection laws to hold a corporation accountable. In *Riegel v. Medtronic, Inc.*, Charles Riegel and his wife brought a lawsuit after a Medtronic catheter ruptured in his coronary artery during heart surgery. The Riegels alleged the catheter was negligently designed and manufactured, but the court ruled that if a device was approved through the PMA process, its manufacturer would be immune from any liability for harm its product caused.[209] Critics pointed out that the device in question was approved based on its similarity to previous devices, and had received little scrutiny from the FDA. Giving its manufacturer immunity without regulatory oversight amounted to a loophole in the law.[210]

In 2011, the Court struck another blow against consumers, holding in *Pliva, Inc. v. Mensing* that state law failure-to-warn claims against generic pharmaceutical manufacturers were pre-empted by federal law. The ruling involved the consolidated cases of two women who had developed tardive dyskinesia, an often irreversible movement disorder, from taking metoclopramide, the generic version of Reglan, a drug treatment for digestive track problems. The plaintiffs argued the manufacturers were liable because the drug's warning label did not mention that prolonged use could cause tardive dyskinesia. However, the court sided with the manufacturers' argument that they could not change or strengthen drug labels without prior FDA approval.[211]

**Today**: The two decisions drastically lowered a manufacturer's incentive to keep dangerous drugs and devices off the market, and left consumers potentially without any recourse when injured or killed by those products.

# CONCLUSION

In December 2016, the United States Congress passed the 21st Century Cures Act, a bill that greatly weakened patient safety, under the guise of funding boosts for medical research. The legislation rolled back regulations requiring pharmaceutical companies prove drugs and medical devices were safe and effective through randomized clinical trials, allowing them instead to obtain FDA approval on the basis of little more than their own claims. The legislation also opened the door for pharmaceutical companies to promote off-label uses of their drugs to insurance companies.[212]




**Norodin, one of a variety of brand names for methamphetamines in the 1950s, was prescribed for nerves and diet management. Half a century later, SSRIs fulfilled much the same function, and were prescribed to a quarter of all women.**

Proponents hailed the Act as a solution to a supposed approval bottleneck at the FDA. In reality, the FDA approves as much as 89 percent of all applications, and does so quicker than its counterparts in Europe and Canada.[213] Not only is there no bottleneck, the drugs and devices highlighted in this report highlight just a few examples of how inadequate the regulatory approval process already is. Allowing pharmaceutical companies to market their drugs and devices for any use they can dream up, and without any scientific proof that they are safe, will inevitably result in future drugs and devices that are less safe for the American people.

Time and again, the allure of bigger profits has tempted corporations into keeping dangerous products on the shelves, even when company executives knew that to do so would likely result in death or injury to 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. 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 upheld.

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