Center for Justice & Democracy
90 Broad Street, Suite 401
New York, NY 10004
Tel: 212.267.2801
centerjd@centerjd.org
http://centerjd.org

# THE BITTEREST PILL – How Drug Companies Fail To Protect Women And How Lawsuits Save Their Lives

**By Amanda Melpolder, Amy Widman and Joanne Doroshow**

## Executive Summary

Women across the country have suffered tremendously as a result of defective and dangerous drugs and medical devices. History shows that many FDA-approved drugs and devices that have caused some of the most serious injuries and death have been marketed specifically for women. This is largely due to the number of products routinely prescribed to otherwise healthy women to control some aspect of their reproductive system. In addition, some drugs have had a disproportionate impact on pregnant women and their children.

Many drugs and devices were made safer only after women and their families filed lawsuits against those responsible. Sometimes, companies that have been hit with large verdicts or settlements act immediately to change their unsafe product or practice. Lawsuits also have had a tremendously beneficial role spurring medical research and alerting the public – and ultimately pressuring regulators – to act on larger health risks and problems. As a result, the lives of countless other women have been saved.

In addition, unlike the regulatory scheme, which provides no direct benefit to victims, civil cases hold companies directly accountable to those whom they have hurt, and provide their victims with compensation to help rebuild their lives. Drug company immunity would remove the most significant and effective financial consequence to a company for choosing to keep a dangerous drug or device on the market.

The following are some examples that illustrate these points:

### Hazardous Birth Control:

- Ortho-Evra Patch. This weekly birth control patch, approved by the FDA in 2002 and marketed to young women with sexy television commercials and fashion runway shows, caused blood clots, heart attacks and strokes. Both the company and FDA knew of major problems with the patch but kept the information quiet until documents, including those produced in litigation, forced the information out.

- Dalkon Shield IUD. This IUD caused at least 17 American deaths and over 200,000 injuries including pelvic inflammatory disease, perforated uteruses, and infertility. The FDA suspended distribution of the IUD after three years but did not recall existing stock or require the company to tell doctors to remove them. For the next 10 years, the

company continued to promote the device. It took several lawsuits and the threat of larger punitive damages awards for the company finally to urge women to have the Dalkon Shield removed and offered to finance the removal.

- Copper-7 IUD. Like the Dalkon Shield, this IUD led to deaths and injuries. It was pulled from the market after numerous lawsuits, coupled with the company's inability to obtain products liability insurance. Actual injuries and deaths of women, which came years before the devices were withdrawn, never had that effect.

- Ortho-Novum 1/80 Birth Control Pill. This pill contained extremely high and dangerous levels of estrogen leading to blood clots and blood disorders. One woman suffered life-threatening injuries after taking this pill. As a result of this case, the manufacturer lowered estrogen levels in the pill.

**Lethal Hormones:**

- DES was a synthetic estrogen approved by the FDA to prevent miscarriages. DES did not work but instead caused cancer, infertility and other serious physical problems for the women who took it, and the children they carried. For almost two decades after the drug was proven ineffective, manufacturers continued to push the drug and expose hundreds of thousands of women and their offspring to risk. Until women started bringing lawsuits, many DES exposed women did not know about the risks they faced.

- Estrogen replacement therapy (ERT) or hormone replacement therapy (HRT). Hormones were approved by the FDA and heavily promoted by the pharmaceutical industry beginning in the 1960s to women experiencing menopause. Yet evidence had existed since the 1930s and 1940s that estrogen therapy caused cancer. After years of struggle by consumer groups and women's health organizations to bring attention to the cancer and other risks, in 2002 NIH researchers finally confirmed a significant increase in the risk of breast cancer, heart attacks, blood clots and strokes. By then, an untold number of women had been harmed or killed from being over-prescribed HRT.

**Other Harmful Drugs and Devices:**

- High-absorbency tampons. These tampons cause "toxic shock syndrome" resulting in many deaths. A woman died from toxic shock syndrome after using super-absorbent tampons, and her family sued. The company stopped making these tampons only after the jury's punitive damage award.

- Parlodel. The FDA approved this drug in 1980 to suppress lactation after birth. It caused heart attacks and strokes. The FDA requested the drug's five manufacturers to voluntarily take it off the market. One company refused and for the next five years, continued to promote the drug and persuaded hospitals to prescribe it. Only after a large jury award and petitions by consumer groups to force the FDA to act, did the company withdraw the drug from the market.

- Accutane. Accutane is an acne drug to which the FDA gave fast track approval despite knowing it caused severe birth defects as serious as Thalidomide if taken by pregnant women. As a result of the company's continuously failed policies to prevent women who were or could become pregnant to take the drug, hundreds of severely deformed babies have been born. Juries have now started to hold the company accountable in these cases.