

March 12, 2009

**VIA FACSIMILE AND HAND DELIVERY**

The Honorable Senator Edward M. Kennedy, Chairman  
Senate Committee on Health, Education, Labor, and Pensions  
Dirksen Senate Office Building, United States Senate  
Washington, DC 20510

The Honorable Congressman Henry Waxman, Chairman  
House of Representatives Energy and Commerce Committee  
2125 Rayburn House Office Building  
Washington, D.C. 20515

***Re: Medical Device Safety Act of 2009***

Dear Chairman Kennedy, Ranking Member Enzi, and Members of the Committee on Health, Education, Labor, and Pensions; and Chairman Waxman, Ranking Member Barton, and members of the Energy and Commerce Committee:

**The undersigned organizations committed to women's health and safety, ask you to prioritize passage of S. 540 and H.R. 1346, the *Medical Device Safety Act of 2009*.** This important legislation corrects the U.S. Supreme Court's recent decision in *Riegel v. Medtronic*, 128 S. Ct. 999 (2008), by reflecting Congressional intent to allow patients harmed by negligent medical device manufacturers to access the court system in order to obtain compensation and hold companies accountable. Immunity should not be given to device manufacturers that fail to adequately warn about or prevent device risks; especially when the manufacturer knows, or should know, that the device could cause serious injuries or death.

For 30 years, the federal medical device law and state tort law have coexisted without problem, and with the support of many FDA officials. In fact, in the important case *Wyeth v. Levine*, decided on March 4, 2009, the U.S. Supreme Court acknowledged the "longstanding coexistence of state and federal law and FDA's traditional recognition of state-law remedies." It also noted that "the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." The Court recognized that lawsuits are especially important since "the FDA has limited resources to monitor the 11,000 drugs on the market and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge."

The same reasoning should apply to the risky medical devices considered in *Riegel*. Unfortunately, due to the Supreme Court's confusion regarding whether Congress intended to preempt claims for medical devices, in *Riegel*, manufacturers of Class III FDA-approved medical devices were given complete immunity from liability for product-related deaths and injuries. *This immunity protection even extends to manufacturers who fail to warn the FDA and consumers about device problems that arise after obtaining FDA approval.* By eradicating manufacturer accountability, thousands of patients injured by defective devices now have no remedy for their injuries.

As advocates for women's rights and women's health, we have a heightened interest in restoring Congressional intent to allow for state tort suits by injured women and their families, and believe that all persons unfairly harmed by faulty medical devices should have their day in court. Medical devices marketed primarily to women, many of which relate to women's reproductive health, have a record of safety problems. The FDA's handling of these devices, as well as manufacturers' development and marketing of the product, can be prone to inappropriate corporate pressure and interference.

As with other drugs and devices, those devices marketed to women have caused significant harm, even after FDA approval. A recent report by the Center for Justice & Democracy (CJ&D) chronicles the harm that FDA-approved drugs and devices have caused women. The CJ&D report, entitled *The Bitterest Pill: How Drug Companies Fail to Protect Women and How Lawsuits Save Their Lives* (issued October 2008), details the harm caused by drugs and devices marketed only to women, such as the Ortho-Evra birth control patch, the Dalkon Shield IUDs and high-absorbency tampons. The damage has been severe in many instances (including heart attacks, blood clots, and death). Moreover, this report shows that it is often damages awarded by juries rendering verdicts in favor of patients harmed by these devices that have led to manufacturers withdrawing unsafe products, or altering the marketing of these devices.

The *Medical Device Safety Act* will restore women's ability to be compensated, and hold device manufacturers accountable. This serves three crucial functions: it allows women to mitigate their injuries; it helps to deter misleading and careless marketing of devices to women; and it provides an extremely important incentive (in addition to the FDA's regulatory authority) to manufacturers to strive to monitor and improve the safety of their products. The *Medical Device Safety Act* also takes the vital step of making its clarification of Congressional intent retroactive to the date when Congress enacted the *Medical Devices Amendment of 1976* (the statute the Supreme Court wrongly interpreted to accord immunity to manufacturers) to protect consumers whose claims will otherwise be barred by *Riegel*.

In the three decades leading up to the 2008 *Riegel* decision, women were able to count both on FDA regulation and state tort law to ensure the safety of devices. As supporters of women, we urge you to quickly enact the *Medical Device Safety Act of 2009*.

We look forward to working with you and your staff to pass this very important legislation.

Sincerely,

Alliance for Justice  
American Medical Women's Association (AMWA)  
Center for Justice & Democracy  
Center for Medical Consumers  
Center for Science in the Public Interest  
Clearinghouse on Women's Issues  
Dalkon Shield Information Network  
DES Action USA  
Government Accountability Project (GAP)  
InjuryBoard.com  
National Asian Pacific American Women's Forum  
National Capital Area Union Retirees  
National Congress of Black Women  
National Consumers League  
National Council of Women's Organizations  
National Organization for Women (NOW)  
National Women's Health Network (NWHN)  
Northwest Women's Law Center  
Ovarian Cancer National Alliance  
OWL - The Voice of Midlife and Older Women  
US PIRG  
Women's International Public Health Network  
Women's Research and Education Network

Encl.: Executive Summary: Center for Justice & Democracy report, *The Bitterest Pill: How Drug Companies Fail to Protect Women and How Lawsuits Save Their Lives*. Full report at [http://www.centerjd.org/archives/studies/BitterestPill\(f\).pdf](http://www.centerjd.org/archives/studies/BitterestPill(f).pdf)

cc: U.S. Senate and U.S. House of Representatives (w/Encl.)



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## **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.