



Corporate License to “Hit and Run”
*President Obama and Congress Must Stop Big Corporations from
Overturning a Hundred Years of Consumer Protection*

The **Medical Device Safety Act (H.R. 1346)**, introduced in Congress on March 5, gives President Obama and all Senate and House members the opportunity to stop an effort by major drug and medical manufacturers to overturn consumer protection rights every American has had for more than a hundred years.

The attack on consumer protection was supported by the Bush administration as part of an overall strategy during its final days to lock into place special interest protections for big corporations at the public’s expense.

Historically, Americans harmed by prescription drugs and medical devices have had the right to sue and be heard by a jury in state court. Since the Food and Drug Administration (FDA) was created nearly 80 years ago, it has considered state tort claims by individuals as one vital tool for ensuring consumer product safety.

But in a case decided in February, 2008, the U.S. Supreme Court ruled that Americans can’t sue corporations that manufacture medical devices such as defibrillators, heart pumps, and artificial heart valves, hips, and knees if the U.S. Food and Drug Administration (FDA) gave permission for the product to be marketed.

Allowing individuals who have suffered injuries to hold corporations accountable...

- Provides big corporations with an incentive to make sure a medication, car seat, crib, toy, or other consumer product is safe, and to recall a product or issue proper hazard warnings if new risks are discovered after the product is released on the market.
- Ensures that individuals whose health or livelihoods are harmed can seek compensation for damages.

The Court’s more recent decision on March 4 in the *Wyeth v Levine* case, interpreting a different law, upheld patients’ rights to sue drug companies whose products were approved by the FDA but later found unsafe.

But the Court indicated in the *Wyeth* decision that if the Bush administration had followed better procedures in trying to shield corporations from consumer lawsuits, their decision may have been different.

It’s now up to Congress to protect Americans’ health and safety for the long term by passing legislation that clearly establishes that federal approval to market a product does not prevent someone harmed by that product from holding the manufacturer accountable for the damage.

As part of its “anything goes” approach to corporate interests, the Bush administration inserted provisions designed to give corporations total immunity from lawsuits into more than 60 regulations to stop Americans from filing unsafe product lawsuits against manufacturers of many products, encompassing everything from cars to mattresses that could be flammable.

These new “hit and run” rights for big corporations...

- Have never been adopted by Congress.
- Were developed by the White House and President Bush’s political appointees at federal agencies over the objection of the agencies’ own safety experts.

Turning the FDA’s permission to market into a hit-and-run license with no legal accountability ignores a number of obvious facts:

- **Permission to market is based only on the limited evidence available at the time the FDA grants its approval.** Much or all of that evidence is provided by manufacturers themselves. A 2003 memo from Dr. John Jenkins, director of the Office of New Drugs, and Jane Axelrad, associate director for drug policy at the FDA’s Center for Drug Evaluation and Research, said the new policy is “based on a false assumption that the FDA-approved labeling is fully accurate and up-to-date in a real-time basis. We know that such an assumption is false.”
- **Many drugs and medical devices that were marketed with federal permission later caused serious health damage,** including Vioxx, Zolof, Fen-Phen, Avandia, and Celebrex.
- **Accountability through legal liability is the only effective incentive for companies to recall unsafe products or issue new warnings when consumers have been harmed.**
- **Lawsuits have often been the only way to expose deliberate cover-ups by big corporations** that knew their product was unsafe and hid that fact from the public. Examples include cases involving tobacco, asbestos, defective medical drugs, environmental toxins, and other products.
- **The corporations’ new hit-and-run theory goes against common sense.**

Saying that a permit to market a drug or other product means a corporation can’t be held accountable for damages it may later cause makes as little sense as saying that as long as someone is issued a driver’s license he or she shouldn’t be held accountable for causing a serious accident. Or that as long as an oil company got a permit to build a chemical plant, it is not responsible if it fails to protect its workers and surrounding communities from serious illness. Or that as long as a big construction company got a building permit it can’t be held accountable if the skyscraper or bridge it builds collapses.

- KEY SPECIFIC CASES -

Riegel v. Medtronic, Inc. On February 20, 2008, the U.S. Supreme Court sided with Medtronic, the manufacturer of a faulty medical device. Charles and Donna Riegel sued Medtronic for injuries Charles sustained when the Medtronic Evergreen Balloon Catheter used by his physician burst during an angioplasty procedure, requiring advanced life support and an emergency coronary bypass procedure.

The Court upheld the position of the company and the Bush Administration that Riegel could not sue in state court because the Medical Device Amendments of 1976 explicitly preempted “different” state “requirements.”

Wyeth v. Levine. On November 3, 2008, the U.S. Supreme Court heard oral argument in a case involving a professional musician, Diana Levine. Levine went to the emergency room for a migraine. She was given an intravenous push injection of the Wyeth Pharmaceutical drug, Phenergan. Complications with at least 20 previous patients had shown that such an injection could lead to gangrene if the drug invaded an artery. Yet, Wyeth had not changed its warning label to tell doctors of this increased risk of gangrene

Levine lost her arm, depriving her of her livelihood as well as her quality of life.

A Vermont jury and the state’s Supreme Court ruled that Wyeth should be held accountable for its failure to warn doctors about the gangrene risk. But Wyeth appealed to the U.S. Supreme Court with support from the Bush administration. They argued that while the laws under which the FDA operates do not explicitly address preemption of a right to sue in state court, that preemption is implied by FDA permission to market a drug.

On March 4, 2009, the Court ruled in favor of Diana Levine.