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## Issue: Should We Be Prohibited From Filing Product Liability Lawsuits Against Medical Device Manufacturers And Pharmaceutical Companies?

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POSTED: Thursday, March 13, 2008

FROM BLOG: [Drug Injury Watch](#) - Prescription Drug Side Effects News and Information from Attorney Tom Lamb

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### Opinion: Patient Lawsuits Are A Significant Incentive For These Manufacturers And Companies To Ensure That Their Products Are Safe For Use By American Patients

(Posted by Tom Lamb at [DrugInjuryWatch.com](#))

First of all, I presume most of you believe – because as Americans we have always looked to our court system to vindicate our rights – that we are allowed to file these lawsuits today.

With regard to most cases against medical device companies, however, as of February 2008 you are wrong; and, soon, injured patients may not be allowed to get any legal compensation from a pharmaceutical company for serious side effects caused by their prescription drug.

On February 20, in the *Riegel v. Medtronic* case, the U.S. Supreme Court granted legal immunity to manufacturers of medical devices which had been approved by the FDA. This means that in the future, for most instances, the medical device manufacturers will have no financial accountability for their mistakes if and when their products harm a patient.

To reach this decision, the Supreme Court used the legal doctrine of “federal preemption”. Ironically, this doctrine comes from our Founding Fathers’ Constitution, but in recent years it has been used by the current Bush Administration to abolish a person’s right to sue when injured by a company’s product.

As a start, let us focus on the FDA-approval part of the Supreme Court’s *Riegel* decision.

During this past year, the Institute of Medicine, the Government Accountability Office, and the FDA’s own science board have all issued reports that essentially reach the same conclusion: The FDA is largely incapable of protecting the public from unsafe medical devices and drugs.

Moreover, the FDA does not do its own testing; rather, the FDA is almost totally

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dependent on the companies that it is suppose to oversee to provide the agency with data concerning the safety and effectiveness of new prescription drugs and medical devices.

Further, the vast majority of FDA approvals occur without there being any representation of patients' interests; and, safety decisions after the drug or device is approved rarely include input from patient advocacy groups.

Meanwhile, the medical device manufacturers and the pharmaceutical companies clearly have an inherent conflict of interest when addressing safety issues concerning their products, which are intended to make them a profit.

In addition, these business corporations have stronger legal obligations to their stockholders than they do to the patients who use their products.

Let's return to the question at hand: Should patients have access to our court systems in oder to file lawsuits for injuries caused by unsafe drugs and medical devices?

In October of this year, 2008, the Supreme Court will hear oral arguments in the *Wyeth v. Levine* case. The primary issue in that case is whether people who suffered a drug injury should be able to get any legal compensation from the pharmaceutical company responsible for that drug.

You will probably be surprised to learn that, at this hearing, the drug company's lawyers will be assisted by the Bush Administration's Solicitor General in making their argument that an injured patient should not have any legal right to compensation.

In more detail, the drug company Wyeth and the Bush Administration will be arguing in this *Levine* case that the Food, Drug and Cosmetic Act of 1938 -- under which the FDA regulates prescription drugs -- has "implied preemption" due to the structure of this statute, *i.e.*, the law's actual text does not include any preemption clause.

The *Levine* case involves a Vermont woman who lost a hand and forearm to gangrene after being improperly injected with the drug Phenergan. At the trial of this lawsuit, Wyeth argued that its drug had met FDA's federal labeling requirements and, therefore, the drug company should not have any legal liability under state law for this patient's injury.

The trial court judge disagreed with Wyeth on this issue, and the jury in that case went on to award \$6.8 million in legal compensation to Mrs. Levine for her injury.

The Vermont Supreme Court ultimately upheld the judge's ruling and the jury verdict; but the U.S. Supreme Court later accepted this case for review -- upon the request of the drug company and the Bush Administration.

As stated above, oral arguments regarding the federal preemption issue will be made to the nine Supreme Court Justices in the *Levine* case later this year, in October 2008.

Sometime thereafter, and no later than the summer of 2009, our Supreme Court will decide whether the FDA approval of a prescription drug will serve as a prohibition against patients filing their personal injury and wrongful death lawsuits against drug companies.

According to some critics, the prohibition of drug injury lawsuits by operation of the federal preemption doctrine may have some merit in an ideal world where the FDA was performing its drug-safety regulatory functions at 100%. But that has not been the situation in the past, nor is it the case today.

It is my opinion that the U.S. Congress should move quickly to pass legislation that would correct the *Riegel* decision by the Supreme Court, and serve to prevent such a ruling against patients' rights in the *Levine* case.

This legislation is needed because, in my experience, the possibility of becoming involved in product liability litigation is a significant incentive for the medical device manufactures and the pharmaceutical companies to ensure that their products are safe for use by American patients.

I would like to hear what you think about this issue as well as my opinion about use of the federal preemption doctrine in this context. You can do so by submitting a Comment, below.

Also, I encourage you to share this piece with others by email, bookmarking, etc. Of course, I understand that not all people will line-up with me on this issue. I believe, however, that all citizens will agree that this federal preemption issue is too important to remain as low-profile as it has been to this point in time.

(Thanks for reading this issue-and-opinion piece, which is a departure from the usual news and information about prescription drug side effects that is presented here at [Drug Injury Watch](#).)

**P.S.** I have posted this issue on the HeyMonkeyBrain! part of Squidoo:

"What if you were hurt by a drug and couldn't sue?"

That page can be found here: <http://www.squidoo.com/preemption>

Perhaps you can help get this debate started?

Thanks for your effort and time. (3/20/08)

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