The Court Confronts a Grievous Injury

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For years, the Bush administration has worked with industry to try to water down the public's protections by preventing states from enforcing rules and regulations tougher than those required by the federal government.

It has tried to apply this policy of pre-emption to rules issued by a slew of federal agencies and is now asking the Supreme Court to approve its improper ideological stand when it comes to drug safety.

On Monday, the court heard arguments in the case of a Vermont musician who lost her arm after being injected with an anti-nausea drug. There is no doubt that Diana Levine was badly injured by a drug made by Wyeth. The only question is whether the Supreme Court will uphold her right to sue the company over its failure to adequately warn of a drug's dangers. Or will it buy the arguments of the industry and the Bush administration that companies like Wyeth should be protected from such lawsuits in state courts if the products that caused the injury met federal regulatory standards?

The administration wants approval by the Food and Drug Administration to be the final word in these cases, not state laws like Vermont's that often require the manufacturer to meet a higher standard in warning doctors and patients about potential dangers. The court should rule in favor of Ms. Levine.

Ms. Levine went to a clinic seeking relief for a migraine headache. She received Demerol for her headache and Wyeth's Phenergan to combat nausea, both administered by injections into the muscle, which is the preferred route of administration. When the headaches persisted, she returned for more treatment.

This time, the same medicines were administered by an intravenous "push" technique that is known to be risky — using a needle inserted into a vein. A physician's assistant mistakenly hit an artery, with catastrophic results. Ms. Levine quickly developed gangrene; her hand and lower arm had to be amputated. She sued the physician's assistant, the supervising physician and the clinic for malpractice and won an out-of-court settlement, as well she should have.

Then she sued Wyeth for failing to warn the clinicians to use the much safer "IV drip" technique, in which the drug is injected into a stream of liquid

flowing from a hanging bag that already has been safely connected to a vein, making it highly unlikely that the drug will reach an artery. A trial court awarded her $6.7 million, and the Vermont Supreme Court upheld the verdict. Now Wyeth, supported by the Bush administration, has asked the Supreme Court to reverse the verdict on the grounds that Wyeth complied with federal regulatory requirements.

We do not buy Wyeth's argument that it did everything it needed to, or could have done, to warn doctors about the dangers involved in the treatment Ms. Levine received. Wyeth did warn of some dangers of the drug treatment, in words approved by the F.D.A., but the state court was well within its rights to conclude that those warnings were insufficient.

And that is the greater point. When Congress revised the federal law governing the F.D.A. in 2007, drug companies wanted, but did not get, a provision shielding them from this sort of lawsuit. The drug industry and its administration allies now want the court to ignore the absence of express legal language and grant drug companies immunity based on a phony assertion that state lawsuits improperly usurp federal regulatory authority.

For the court to broadly endorse the concept of "implied pre-emption" in this case would show disrespect for the considered decisions of Congress and could foreclose injury suits involving not only drugs, but also motor vehicles, household products and other things. The ultimate effect would be to undermine consumer safety.

Far from usurping the F.D.A.'s power, litigation aimed at holding drug companies liable for problems like those in this case complement the agency's efforts to protect the public. For many years the F.D.A. welcomed state failure-to-warn suits as reinforcing those efforts; two former commissioners, David Kessler and Donald Kennedy, made that point in a brief in the case.

Only under President Bush did the agency overrule its top staff members and try to pre-empt such suits. We hope this business-friendly Supreme Court will preserve the consumer protection that state tort actions often provide. Otherwise, the incoming president and Congress will need to pass corrective legislation.