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POSTED: Tuesday, March 04, 2008

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

The following blog post is from an independent writer and is not connected with Reuters News. The opinions and views expressed herein are those of the author and are not endorsed by Reuters.com.

Our Tort System Provides A Needed Means Of Accountability; Law Professor: "A lot is lost without these lawsuits."

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

On March 3, 2008 the U.S. Supreme Court issued its ruling in the *Warner-Lambert v. Kent* case and, in so doing, declined the invitation of pharmaceutical companies -- and the Bush administration -- to prohibit drug injury lawsuits from being filed by patients who have suffered serious side effects caused by unsafe prescription drugs.

The tie vote by which the Supreme Court arrived at its decision in *Warner-Lambert v. Kent*, however, means that this ruling does not set any precedent on the federal preemption issue that is the increasing focus of products liability lawsuits that involve FDA-approved prescription drugs and medical devices.

From the March 4, 2008 article, "[Court Allows Suit Against Drug Maker](#)", by *New York Times* reporter Linda Greenhouse:

This case, *Warner-Lambert Co. v. Kent*, presented a narrow slice of the broad pre-emption issue that the court will take up in its next term. In that new case, *Wyeth v. Levine*, the question is whether the Food and Drug Administration's approval of a drug's label precludes individual damage suits based on the claim that the label failed to include sufficient information or adequate warnings.

In essence, if the answer is yes, most individual lawsuits for damages caused by approved drugs would be pre-empted. Last month, in *Riegel v. Medtronic Inc.*, the court interpreted a federal law, the Medical Device Amendments, as barring most individual lawsuits against manufacturers of approved medical devices....

The Bush administration, which has embraced a broad theory of federal pre-emption of individual tort suits, entered the case on the manufacturer's behalf. It argued that "permitting lay juries to second-guess" the adequacy of a drug application would interfere with the

agency's "exercise of its expert judgment."

In more detail, the Bush administration will be arguing in *Wyeth v. Levine* (No. 06-1294) 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 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 labeling requirements and, accordingly, the drug company should face no liability under state law. The trial court judge disagreed, and the jury in that case awarded \$6.8 million in legal compensation to Levine for her injury.

According to some critics, federal preemption of drug injury cases 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.

In his March 3, 2008 article, "[Patients' ability to sue at risk](#)", *Los Angeles Times* reporter Daniel Costello presented these facts which tend to show why federal preemption of drug injury cases is a bad idea:

The FDA "doesn't have the ability at this time to oversee in a comprehensive fashion everything it regulates," said David A. Kessler, a former FDA chief and a professor at UC San Francisco.

A trio of recent reports, including one by the FDA's own advisory committee, has raised serious questions about the agency's recent performance.

Last fall a yearlong study by the FDA's advisory committee found "the agency is so underfunded and understaffed that it's putting U.S. consumers at risk in terms of food and drug safety."

In an unusual public departure from the view of the Bush administration, the current FDA commissioner, Andrew C. von Eschenbach, said in an interview last week that the agency needed a systemic overhaul that could take years....

Some legal experts and attorneys are concerned that without such lawsuits, regulators and the public may never hear of evidence that manufacturers knowingly marketed products they knew were unsafe.

In recent years, documents and e-mails uncovered in court cases have shown that some companies kept safety issues involving their products from the FDA.

"Without the tort system, what reasonable assurance do we have we will learn about the bad actors?" asked David Vladek [sic], a law professor at Georgetown University.

"A lot is lost without these lawsuits."

Oral arguments in the *Levine* case are scheduled for October 2008. Sometime thereafter the Supreme Court will decide whether FDA approval of a prescription drug prohibits the filing of personal injury and wrongful death lawsuits against drug companies.

No doubt we will continue to hear a lot about this important policy issue in the months to come.

P.S. Dr. David A. Kessler, Dean and Vice Chancellor for Medical Affairs at the University of California San Francisco and former FDA Commissioner, and David C. Vladeck, Professor of Law at Georgetown University Law Center, explore the legality

and wisdom of this continuing effort by the FDA and the Bush administration to persuade lower courts, including the Supreme Court, to preempt most failure-to-warn claims asserted by patients against drug companies in this recent law review article:

David A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts To Preempt Failure-To-Warn Claims*, 96 GEO. L.J. 461 (2008).

Dean Kessler and Professor Vladeck explain how the FDA's position, if ultimately adopted by the Supreme Court, would effectively eliminate a significant incentive for the drug company to ensure that its drug labels reflect accurate and up-to-date safety information, *i.e.*, the possibility of failure-to-warn product liability litigation. The authors explain, also, why the FDA's view that the agency, alone, is capable of regulating the safety of prescription drugs in the U.S. is unrealistic.

This 35-page scholarly article is compelling and insightful as to why federal preemption of drug injury cases is a bad idea. (3/5/08)

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