Consider Yourself Warned!

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Federal Preemption of State Prescription Drug Claims and Its Potential Impact on Product Liability Claims and Insurance

The issue of the day in the United States pharmaceutical arena is federal preemption and exactly how, or even if, preemption will operate to bar state law claims against drug manufacturers, in particular those actions sounding in failure to warn and design defect.

On November 3, 2008, the United States Supreme Court will hear oral argument on this hotly-debated issue in *Wyeth v. Levine,* which will decide whether a state common law "failure to warn" claim is preempted by the United States Food and Drug Administration's ("FDA") approval of a drug and the drug's warning label. Under the federal Food, Drug and Cosmetic Act ("FDCA"), the FDA is charged with determining both the safety and efficacy of drug products sold and marketed in the United States. Pursuant to its mandate under the FDCA, the FDA must also ensure that drug labeling "adequately informs users of the risks and benefits of the products and is truthful and not misleading." *See* 71 Fed. Reg. 3935. The question in *Levine* is whether state common law can impose requirements on drug companies that go beyond the requirements imposed by the FDA. In other words, does a lay jury sitting in state court have the power to second-guess the FDA's drug approval and labeling decisions?

A Supreme Court ruling in favor of preemption could result in sweeping changes in a nation that between 2000 and 2006 saw over 65,000 lawsuits, many involving multiple plaintiffs, filed against drug manufacturers. In 2006 alone, just over 17,000 products liability lawsuits were filed against drug manufacturers. Depending on the scope of a pro-preemption ruling in *Levine,* many of these lawsuits could vanish and the number of future claims could drop precipitously, impacting not only the pharmaceutical manufacturers who have been the targets of mass tort litigation but, indirectly, the insurers of these companies as well. The stakes are undeniably high — to put things in perspective, Merck's 2007 settlement of the Vioxx litigation came at the staggering price of $4.85 *billion* dollars.

Adding fuel to the preemption fire is the fact that there is an undeniable political aspect to the preemption debate. There are those who argue that the Bush administration is seeking to achieve its goal of tort reform through regulatory agencies such as the FDA, which has spoken out in favor of preemption. The FDA's current position constitutes a 180-degree shift from the position it has traditionally espoused throughout its long history, during which it consistently maintained that its drug approval process and state tort liability claims operated independently, with each providing a significant, yet distinct, level of consumer protection. Indeed, the FDA's current position in favor of preemption did not even emerge until Daniel Troy, a Bush appointee, became chief counsel to the FDA in 2001. It is no wonder that critics of preemption argue that big business, including "big pharma," has insinuated itself into the top levels of government, including those federal agencies charged with protecting consumers. Many are now asking whether business and politics trump science and medicine at the FDA, an agency that has been widely criticized as being underfunded and understaffed.

This paper will explore the potential impact of federal preemption of state common law tort claims against drug manufacturers. Beginning with an overview of the preemption doctrine under United States law, it will then discuss the FDA's changed position on preemption, the deference which courts must give to the agency's position, and how some courts have reacted to the FDA's change in position. Next, this paper will discuss recent and pending United States Supreme Court jurisprudence on preemption, beginning with a significant decision rendered by the high court in early 2008 on the preemption of claims involving FDA-approved medical devices. Finally, this paper will explore the impact that a pro-preemption ruling by the Supreme Court in *Levine* might have and what could be left of state common law tort claims against drug makers if the high court rules in favor of Wyeth.
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