

OPINION

■ DRUG SUIT PRE-EMPTION

No special treatment

By Sol Weiss SPECIAL TO THE NATIONAL LAW JOURNAL

PRE-EMPTION threatens the vitality of state tort law and the historic co-existence of federal prescription drug safety standards and common law remedies for injuries arising from prescription drugs. The recent trend of pharmaceutical companies filing procedural motions seeking immunity from state law tort liability and prevailing raises serious questions about federalism. Why should this industry deserve special treatment?

Courts that grant dismissals do so by ignoring the force of the settled presumption against pre-emption that protects consumers. Furthermore, in the context of prescription drugs, Congress never intended to pre-empt state court litigation. There is a complete absence of any concrete law from Congress that might be frustrated by a state law tort suit.

Congressional intent is the “ultimate touchstone of preemption analysis,” *Cipollone v. Liggett Group Inc.* (1992). In ascertaining that intent, the U.S. Supreme Court’s pre-emption jurisprudence has repeatedly applied a presumption against pre-emption. See, e.g., *Bates v. Dow Agosciences LLC* (2005). The Supreme Court has always held fast to the presumption, especially in implied (conflict) pre-emption cases. *Geier v. Am. Honda Motor Co.* (2000). The rationale for that practice is clear: The presumption against pre-emption—and in favor of the

sovereign state—is at its strongest when Congress has not explicitly trumped that sovereignty. Should mere regulatory action remove all means of judicial recourse for consumers injured by unsafe drugs?

In 2006, the Food and Drug Administration (FDA), without public comment, in a preamble, announced its belief that a tort lawsuit for a failure-to-warn case is pre-empted when the warning urged by the lawsuit has not been required by the FDA. 71 Fed. Reg. 3922, 3936 (Jan. 24, 2006). This preamble follows earlier amicus briefs filed by the FDA arguing the same outcome.

FDA should get little deference

Some courts have given deference to the FDA’s view of pre-emption. However, under the high court cases *Skidmore v. Swift & Co.* (1944) and *U.S. v. Mead Corp.* (2001), the degree of deference should be reduced by the fact that the FDA’s earlier position was different. Under *Mead*, courts should afford a “relatively low level of deference” because the FDA’s position has been inconsistent; the FDA is not an expert on federalism concerns; and there is no evidence of any degree of formality in its position. Some courts that apply implied pre-emption discuss the tension between the FDA regulations and the potential for verdicts caused by unsafe drugs under common law. Both fora seek to balance safety and efficacy. If those results do conflict, Congress could, if it so chooses, step in and pass curative legislation.

Allowing multiple-source inquiries into the strength of warnings on drug labels can have important benefits. State courts provide a check on agency power. Discovery in state tort suits provides a useful venue to raise questions about new and existing drugs. Immunity from litigation eliminates these potentially valuable

information-gathering tools.

The scope and power of regulations against common law lawsuits was addressed by the high court in *Sprietsma v. Mercury Marine* (2002). The plaintiff argued that a motor boat was unreasonably dangerous without protective propeller guards. The Illinois Supreme Court found that the U.S. Coast Guard had explicitly considered and rejected the adoption of a regulation requiring propeller guards under the Federal Boat Safety Act (FBSA). The state court thus concluded that “the Coast Guard’s failure to promulgate a propeller guard requirement equates to a ruling that no such regulation is appropriate.” The Supreme Court reversed, holding that the plaintiff’s claims were neither expressly nor impliedly pre-empted by the FBSA. The court commented that it was “quite wrong” to view the Coast Guard’s rejection of the protective measure in question as “the functional equivalent of a regulation prohibiting all states from adopting such a regulation.” Rather, the recommendation by the Coast Guard “left the law applicable to propeller guards exactly the same as it had been before the subcommittee began its investigation.”

The FDA’s conduct, in post-marketing safety analysis, closely parallels the agency’s conduct underlying the regulatory inaction in *Sprietsma*. *Sprietsma* mandates that an agency’s intentional and careful consideration does not convey an “authoritative message of federal policy against” safety measures that trumps the positive effects from jury verdicts finding products unsafe without proper warnings. Conflict pre-emption infringes on the Seventh Amendment right to a trial by jury. It vests absolute power in an agency that at best is underfunded and that has close associations with drug companies that earn greater profits with fewer warnings. **NLJ**

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