

October 25, 2006

ALM

New Rulings in Drug Cases Highlight Debate Over Pre-emption

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SPECIAL TO LAW.COM

10-25-2006

The U.S. Food and Drug Administration's January 2006 pronouncement favoring pre-emption of state law failure-to-warn claims against prescription drugs, 71 Fed. Reg. 3921, has spawned a number of judicial opinions and given renewed energy to the pre-emption debate.

Although fewer than a dozen cases have been decided since the FDA's pronouncement – formally, the 2006 Preamble to its Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products – the better reasoned decisions bring into sharp focus the reasons for and against pre-emption. It's anyone's bet which of these decisions will reach the U.S. Supreme Court for final resolution.

The FDA has stated that the agency is the ultimate authority for decisions about scientific and public health issues concerning prescription drugs, including decisions about whether indications, risks and benefits are adequately described in warning labels. 71 Fed. Reg. at 3921, 3934-35. The FDA's approval of labeled warnings, whether under the new or older labeling regime, sets not just the minimum standard for risk/benefit information; it sets the only standard. Additional or different warnings may render a drug's label "false or misleading," resulting in unsafe use or a reluctance to use a drug that is indicated, safe and effective. *Id.* at 3935-36.

As a result, principles of conflict pre-emption bar an array of state law failure-to-warn claims. Among these are claims involving the failure to include scientific information that the FDA considered but did not approve, as well as claims critical

of information that the FDA did approve.

Not all courts agree with the FDA's position on pre-emption, as nicely illustrated by recent rulings from opposite ends of the country: *In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation*, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006), and *McNellis v. Pfizer Inc.*, 2006 WL 2819041 (D.N.J. Sept. 29, 2006).

In *Bextra and Celebrex*, the U.S. District Court for the Northern District of California dismissed state law failure-to-warn claims involving a prescription drug because they conflict with the FDA's determination of the proper warning and pose an obstacle to the full accomplishment of the objectives of the Food, Drug and Cosmetic Act. The original label for the drug was approved in 1998, with a revision in 1999 to warn about some cardiovascular risks and a further revision in 2005, as required by the FDA, to include additional cardiovascular warnings.

In dismissing claims that the cardiovascular warnings were not adequate, the court gave deference to the FDA's interpretation of the pre-emptive reach of its labeling regulations. The placement of the FDA's opinion in a preamble was not a contrary factor, the court said, "because agencies normally address problems in a detailed manner and can speak through a variety of means, including regulations, preambles, interpretive statements and responses to comments" (quoting *Hillsborough County v. Automated Medical Labs.*, 471 U.S. 707,



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718 (1984)). Moreover, by delegating responsibility to the FDA for administering the Food, Drug and Cosmetic Act, Congress impliedly delegated the authority to determine which state laws conflict with its regulations. The court discounted the impact of the FDA's "180-degree reversal of its prior position" on pre-emption, recognizing that an agency's view may change over time and especially with a change in administration.

In contrast, the New Jersey federal district court in *McNellis* did not allow the pre-emption defense. Relying on the fact that the text of the relevant FDA regulations had been unchanged for years, the court determined that the regulations do not conflict with New Jersey's failure-to-warn laws. Recognizing the preamble as "an official agency statement" that favors pre-emption of conflicting state law claims, the court declined to give much deference to the FDA's interpretation because the agency's position has not been consistent over time, the regulations allow increased warnings when new risks emerge, and the Food, Drug and Cosmetic Act does not contain an express pre-emption clause.

Following the decision in *McNellis*, a federal court in Pennsylvania reached a similar result and did not grant the manufacturer's pre-emption motion. See *Perry v. Novartis Pharma. Corp.*, No. 05-5350 (E.D. Pa. Oct. 16, 2006). The *Perry* court found that a state law requirement to provide an additional warning would not create a conflict or make it impossible to comply with state and federal law. Key to the *Perry* court's ruling was that the FDA had not made a finding about a link between the product and the alleged adverse event. Framing the court's decision were recent concerns about the effectiveness of the FDA's safety monitoring of recently approved drugs, which makes the availability of state tort suits an "important backstop to the federal regulatory scheme." *Perry*, slip op. at 17.

Earlier this month, the 2nd U.S. Circuit Court of Appeals, in dicta, similarly minimized the impact of the FDA's view on the pre-emptive reach of its drug labeling rules: "[W]hatever deference would be owed to an agency's view ... an agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against

preemption." *Desiano v. Warner-Lambert et al.*, slip op. at 20 n.9 (2d Cir. Oct. 5, 2006). Also noteworthy is the amply reasoned decision in *Colacicco v. Apotex Inc.*, 432 F.Supp.2d 514 (E.D. Pa. 2006) (granting pre-emption; currently on appeal to the 3rd Circuit).

What impact can we expect these and other recent decisions to have on pharmaceutical litigation? Without doubt, the preamble will continue to spawn pre-emption filings, at least in federal court and for some time until the jurisprudence develops clearer parameters. These decisions should make their way quickly to appellate courts and later application for review by the U.S. Supreme Court.

We may also expect an increased focus by pharmaceutical plaintiffs on claims of consumer fraud, which were not pre-empted in *Bextra and Celebrex* and may more easily avoid the reach of the preamble. Plaintiffs may also try to bring tort claims under the rubric of defective manufacture or other design defects, although in most situations it is much more difficult to prove a cause-and-effect relationship between those defects and alleged personal injuries. Finally, there will likely be increased pressure on state court judges not to grant pre-emption motions, especially given their more distant perspective from federal agencies and presumably greater inclination to sustain state tort laws.

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