THE NATIONAL
LAW JOURNAL
DAILY UPDATES AT NLJ.COM THE NEWSPAPER FOR THE LEGAL PROFESSION MONDAY, MAY 21, 2007 ALM

FOOD AND DRUG LAW

Labeling and Pre-emption

By Robert Weiner

IN THE MOVIE *Annie Hall*, a stranger in line behind Alvy Singer (Woody Allen's alter ego) at a movie theater expounds loudly on the recondite, but then-trendy philosophy of Marshall McLuhan. Singer, irked, declares that the know-it-all does not understand McLuhan. The stranger smugly responds that he teaches on the subject and has valuable insights. Singer replies, "I happen to have Marshall McLuhan right here," whereupon McLuhan steps out from behind a sign and obligingly tells the show-off, "You know nothing about my work."

This scene captures the current debate on whether the Food and Drug Administration (FDA)'s regulation of the labeling of prescription drugs pre-empts conflicting state laws. For years, lawyers suing drug companies have argued, and convinced many courts, that FDA regulation of prescription-drug labeling does not pre-empt failure-to-warn claims under state tort law. In January 2006, in the preamble to its new labeling rule, the FDA disagreed. The agency said that state lawsuits seeking different labeling than the FDA had mandated conflicted with federal law and were pre-empted. 71 Fed. Reg. 3922, 3933-3936 (Jan. 24, 2006).

The response shows that life does not always imitate art. Unlike McLuhan, when the FDA said what its regulations mean, lawyers for plaintiffs disagreed and even convinced some courts—so far a minority. Likewise, when the FDA said that tort lawsuits impede its efforts to achieve its regulatory objectives, these same lawyers claimed to know better what gets in the FDA's way. Again, some courts—a minority—have agreed.

The dispute highlights the fault lines in our federal system of government. The supremacy clause of the U.S. Constitution gives Congress authority to override state law, expressly or by implication. That authority extends to the federal agencies created by Congress to achieve its statutory goals. Neither the Food, Drug, and Cosmetic Act (FDCA) nor the FDA regulations implementing it expressly pre-empt state failure-to-warn claims involving prescription drugs. But they can do so by implication when those claims conflict with FDA regulation. Such a conflict can arise in two ways: when compliance with both state and federal law is impossible and when state law stands as an obstacle to achieving the objectives of federal law. *Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 372-73 (2000).

Labeling of antidepressants brought issue to the fore

Before 2000, most courts had held that the FDCA and the FDA's labeling regulations did not impliedly pre-empt such lawsuits. But after 2000, the issue was framed both more frequently and more starkly. Antidepressants were the paradigm. For years, plaintiffs and consumer groups had argued that these drugs increased the risk of suicide, particularly in adolescents, and that the labeling should say so. The FDA repeatedly disagreed, finding the evidence insufficient to support such a warning. Indeed, when one manufacturer unilaterally inserted such a warning, the FDA ordered it removed. Ultimately, in 2004, scientific evidence developed that convinced the agency to require a suicide warning for the entire class of antidepressants. But the FDA still reaffirmed that the evidence had previously been insufficient.

A cascade of tort litigation ensued, alleging that the labeling should have warned earlier of an increased risk of suicide. The FDA filed amicus briefs supporting the defendants in at least four of those cases. In those briefs and others, the FDA argued that state law could not require prescription-drug labeling to say what the FDA had forbidden, or forbid labeling from saying what the FDA had required.

Some courts rejected this conclusion. Thus, the FDA spoke more formally and to a wider audience in January 2006. In December 2000, the FDA had proposed new regulations governing prescription-drug labeling. In issuing the new rules

Robert Weiner *is a partner at Washington-based Arnold & Porter LLP.*

five years later, the agency included a preamble responding to the comments it had received. 71 Fed. Reg. at 3922-3994. Several comments had advocated that the new rules expressly pre-empt failure-to-warn claims. The FDA did not adopt such a provision. Rather, it noted in the preamble that under "existing pre-emption principles," certain claims are pre-empted when they conflict with FDA requirements. Id. at 3933-3934.

Elaborating, the FDA first made clear its disagreement with the recurring argument that its regulations impose only minimum safety standards. The agency, it said, strives for labeling that provides optimal protection to patients. Second, the agency affirmed that its regulations do not permit companies unilaterally to add warnings to the labeling. And, third, it said that when state requirements conflict with FDA directives, they impede its regulatory efforts.

But the FDA went on to explain why its objection in this instance was more than merely reflexive. The labeling of prescription drugs, the agency said, is the centerpiece of its management of the risks of drugs. To that end, the FDA carefully controls the labeling so that it reflects the agency's review of the science and communicates the agency's conclusions about how to use the drug safely and effectively. The FDA worried that state tort suits can disrupt the careful balance it had struck in the interest of public health, substituting the disparate judgments of countless mini-FDAs—judges and juries—focused on individual cases. In the FDA's view, more warnings are not necessarily better. For courts to require warnings the FDA found unsupported, the agency concluded, would both submerge important information and scare doctors and patients away from useful, lifesaving drugs. And it would displace a uniform regulatory scheme in favor of an erratic one.

Though unsurprising, the FDA's conclusions proved controversial. Opponents sought to overrule the FDA's judgments in court, attacked its competence and called for congressional investigations. To displace the FDA's interpretation of its own regulations, it was necessary to overcome the proposition that an author is in the best position to say what his or her work means. That principle is reflected in many Supreme Court decisions requiring deference to agencies' judgments on the meaning and effect of their regulations. E.g., *Auer v. Robbins*, 519 U.S. 452, 461 (1996).

Opponents of pre-emption, however, cited an exception to this rule, affording less weight if the agency's views have been inconsistent. Principally, the opponents focused on the FDA's statement when it proposed its new labeling regulation in 2000 that the proposal did not pre-empt state law. Notice of Proposed Rulemaking, 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000). Because that determination was a complete reversal, the opponents claimed, no deference was due.

But the FDA's statement in 2000 was not so far-reaching. As required by an executive order, the 2000 notice discussed the impact of the proposed rules on federal-state relations, and confirmed that there was no proposal *expressly* to pre-empt state law. But the FDA's statement did not forswear *implied* pre-emption of state laws in conflict with FDA requirements, nor give states blanket authority to countermand the FDA's instructions. The discussion in 2006 thus merely highlighted a point not discussed in 2000, that FDA requirements *impliedly* pre-empt "conflicting or contrary state law." 71 Fed. Reg. at 3934.

When the FDA said what its regulations mean, lawyers for plaintiffs disagreed and even convinced some courts—so far a minority.

The opponents also claimed that the FDA lacks power to pre-empt conflicting state laws. They cited a statement in the 1962 amendments to the FDCA stating that they did not pre-empt state laws absent a direct and positive conflict with federal law. Pub. L. No. 87-781, § 202, 76 Stat. 780, 793 (1962). But all the FDA said in the preamble was that its regulations pre-empt state laws when there is such a conflict. 71 Fed. Reg. at 3934.

Nonetheless, the Supreme Court of Vermont recently found that this statutory language precluded the FDA from overriding state laws even when they obstruct its ability to do its job. *Levine v. Wyeth*, No. 2004-384, 2006 WL 3041078, at ¶29-¶34 (Vt. Oct. 27, 2006). On this theory, Vermont could bar FDA inspectors from entering the state. It would be odd indeed if that was what Congress intended.

Should oversight come from Congress or the courts?

As regards the FDA's competence, the opponents touted studies criticizing its regulation of drug safety. But if there are deficiencies in FDA regulation, it does not necessarily follow that the solution is more lawsuits, and in particular, more lawsuits of the type the FDA has said get in its way. Congress is currently considering funding, oversight and reform of the FDA. Are courts really better situated to make these judgments? Will it really improve FDA regulation to give thousands of lay jurors authority to override the agency's regulatory judgments?

A final argument of the opponents is that pre-empting tort claims against pharmaceutical companies leaves some injured people without compensation. That is true. But the claims pre-empted are those that conflict with requirements imposed by the FDA. In those cases, it is a fair question whether the companies following the FDA's directives are the appropriate source of compensation, and whether litigation is the best way to determine who is. It is also a fair question whether the "warning inflation" such suits engender furthers public health.

The issues are now before the 3d U.S. Circuit Court of Appeals in two cases involving antidepressants. The court will consider whether, as stated in the preamble, FDA regulation of prescription-drug labeling pre-empts conflicting state laws. *Colacicco v. Apotex Inc.*, No. 06-3107, consolidated with *McNellis v. Pfizer Inc.*, No. 06-5148. The result in those cases may influence the effectiveness of federal regulation for many years to come.