

Prescription Drug Preemption Awaits Resolution

Wednesday, May 07, 2008 --- A recent McDermott "On the Subject" discussed the decision of the Supreme Court of the United States this term in *Riegel v. Medtronic Inc.*, 128 S. Ct. 999 (2008), holding that U.S. Food and Drug Administration (FDA) premarket approval of a Class III medical device preempts state tort law under the express preemption provision in the Medical Device Amendments of 1976. (For more information, see "Supreme Court Holds That FDA Premarket Approval of Class III Medical Device Preempts State Tort Law," published Feb. 28, 2008.)

The McDermott article mentioned that there were two other closely watched FDA preemption cases involving the agency's new drug approval process, which lacks an express preemption provision, that were also awaiting decision by the Supreme Court.

Since then, one of these two cases, *Warner-Lambert Co. LLC v. Kent*, 128 S. Ct. 1168 (2008), has been decided. However, because of Chief Justice Roberts' recusal and the resulting 4 to 4 split, the ensuing decision, if it can be characterized as that, was a simple affirmance of the ruling below without opinion under the Supreme Court principle that ties leave the result below undisturbed.

Accordingly, this did not shed any real light on the Supreme Court's thinking about preemption in the prescription drug context.

Hence, interested parties will need to wait until next term, when the Supreme Court finally hears argument in and ultimately decides *Wyeth Inc. v. Levine*, No. 06-1249, cert. granted, 128 S. Ct. 1118 (January 18, 2008) before they can expect any definitive word on the prescription drug preemption controversy from the High Court.

In the meantime, a divided panel of the U.S. Court of Appeals for the Third Circuit last week issued its long-awaited decision in two consolidated cases involving preemption in the context of suicide warnings for antidepressant drugs. (*Colacicco v. Apotex, Inc., et al.*; *McNellis v. Pfizer, Inc.*, ___ F. 3d ___, 2008 U.S. App. LEXIS 7463 (April 8, 2008), available here .

The two judge panel majority found that the state law failure to warn claim was preempted in each of the two cases, largely because of the peculiar — possibly sui generis — facts relating to the history of FDA's regulation of adult suicide warnings in antidepressant drug labeling.

On multiple occasions, including seven times in the case of the Pfizer product Zolof, and both before and after the decedent's death in each case,

the agency required the defendants to market the product with the specific labeling in question while being aware of the broader concerns about suicide and suicidality.

Moreover, at the relevant times before each of the unfortunate deaths, the agency had “clearly and publicly stated its position” rejecting the need for the specific warnings the plaintiff sought to impose under state law. (2008 U.S. App. LEXIS at *50.)

In according preemptive effect to FDA’s actions in the two cases, the panel majority was careful to couch its holding in the narrowest possible terms on the respective records before it, as follows:

“[W]e need not decide whether preemption would be appropriate under different facts — such as where the FDA had not rejected the substance of the warning sought or where the FDA only stated its position after a lawsuit had been initiated — or under the broader theories of preemption argued by the parties.

“Thus, we do not decide whether the FDA’s mere approval of drug labeling is sufficient to preempt state-law claims alleging that the labeling failed to warn of a given danger, [or] whether FDA approval of drug labeling constitutes minimum standards in the absence of the FDA’s express rejection of a specific warning ... Our holding is limited to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires.” (Id. at *50-51) (Citation omitted).”

In dissent, Judge Ambro took a decidedly different view of both the numerous esoteric questions of law at issue in the cases, such as the applicability of the “presumption against preemption,” as well as the policy implications of according preemptive effect to FDA actions even in the limited context of this particular case.

“The FDA toolkit is imperfect and incomplete by design. The FDA relies on the information provided by drug manufacturers (to repeat, it does no independent testing), and will always lack the inside perspective on clinical trials and data analysis stemming from those trials.” (Id. at *87.) (Parenthetical in original.)

For these and other reasons, including the limited deference that he would have accorded to FDA’s views about the preemptive effect of its actions, Judge Ambro would have rejected the defense arguments on preemption.

Inasmuch as one of the two judges in the majority was sitting by designation from the U.S. Court of International Trade, it might be argued that the split among the Third Circuit judges in these consolidated cases was 1 to 1, which suggests a heightened possibility of review of this panel decision by the en banc Third Circuit.

Whether that possibility ensues, or whether the panel decision stands as is,

the fact remains that it does not resolve the fundamental questions about the nature and extent of preemption of state law tort claims in the “garden variety” case that lacks the kind of repeated, intensive and public FDA oversight that took place in the case of the labeling for antidepressant drugs.

Nor does it meaningfully address or answer questions about the effect on preemption of the FDA’s proposed regulations on supplemental applications for labeling changes that were published for comment on Jan. 16, 2008, and that were viewed as an effort to bolster the agency’s position on preemption. (For more information, see McDermott “On the Subject,” “FDA Issues Proposed Regulations on Supplemental Applications for Labeling Changes,” published Jan. 18, 2008.)

It also does not consider the impact on the question of the new authorities over drug safety and drug labeling granted to FDA under the Food and Drug Administration Act Amendments of 2007, Pub. L. No. 110-85, 121 Stat. 823. For the definitive answer to some of these intriguing and perplexing questions, we must wait until next term.

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