

Client Alert

Recent Federal Court Decision Dismissing as Preempted Pharmaceutical Failure-to-Warn Claims

In a ruling of great potential usefulness in the defense of pharmaceutical litigation, a federal district court in Pennsylvania (Baylson, J.) on May 25, 2006 dismissed a lawsuit claiming that alleged inadequate warnings accompanying the anti-depressant prescription medication Paxil and/or its generic equivalent had led to the suicide of plaintiff's wife. The court held that plaintiff's state law failure-to-warn claims were impliedly preempted by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 *et seq.* (hereinafter, the "Act")), and the regulations promulgated under the Act by the United States Food and Drug Administration ("FDA"). (*See Colacicco v. Apotex, Inc.*, No. 05-5500, 2006 WL 1443357 (E.D. Pa. May 25, 2006).)

In *Colacicco*, at the request of the court, the FDA had submitted an *amicus* brief stating its position that FDA regulations impliedly preempted state law failure-to-warn claims. (The FDA had filed similar *amicus* briefs in two earlier Zolofit cases, *Kallas v. Pfizer, Inc.*, No. 2:04-CV-0998 (D. Utah) (*amicus* filed Sept. 15, 2005) and *Motus v. Pfizer, Inc.*, Civ. Nos. 02-CV-55372, 02-CV-55498 (9th Cir.) (*amicus* filed Sept. 10, 2002)—both of which cases were resolved prior to any preemption ruling.) The *Colacicco* court based its preemption decision in large part upon the position expressed by the FDA itself, observing that "[f]undamentally, a series of Supreme Court decisions point this Court in the direction of deference" to the FDA (*see* 2006 WL 1443357, at *1)—even if, as plaintiff argued, the position of the FDA may have changed over time. (*See* 2006 WL 1443357, at *7-15, esp. 11-13.)

The *Colacicco* court found that when Congress passed the Act, it "vested the FDA with authority to regulate the specifics of drug labeling, making important judgments of what is required for safety of the consuming public, what new drugs may appear in the marketplace, and what warnings their instructions and labels must carry." (*See* 2006 WL 1443357, at *1.) The court rejected the plaintiff's argument—an argument previously embraced by various other courts rejecting preemption—that FDA approval of pharmaceutical labeling constituted simply "minimum standards." (*See* 2006 WL 1443357, at *9-10, 16-17.) The court cited to the FDA's position that, contrary to the view expressed in earlier court decisions rejecting preemption, a manufacturer is *not* free to alter its labeling for pharmaceutical products absent prior approval by the FDA. (*See* 2006 WL 1443357, at *9, 10, 17.) The court stated that public policy interests required that warnings be scientifically substantiated; to suggest that a manufacturer should or could adopt a warning other than that approved by the FDA would present a risk of misbranding and pose potential dangers to patients. (*See* 2006 WL 1443357, at *9.)

The decision in *Colacicco* is also one of the first to embrace the position asserted by the FDA in its January 24, 2006 Preamble to the Rule regarding "Requirements on Content & Format of Labeling for Human Prescription Drug & Biologic Products." (*See* 71 Fed. Reg. 3922-3997 (Jan. 24, 2006).) (Prior to *Colacicco*, a state court in New Jersey had also cited and relied upon the FDA's position in the Preamble when holding that state law failure-to-warn claims were preempted. *See Abramowitz v. Cephalon, Inc.*, No. BER-L-617-04, 2006 WL 560639, at * 3-4 (N.J. Super. Mar. 3, 2006).) In its

Preamble to the Rule, the FDA took the position that the Act established “both a floor and a ceiling” with respect to pharmaceutical labeling, and therefore preempted state failure-to-warn claims. (*See* 71 Fed. Reg. 3934-3935.) The *Colacicco* court found the Preamble to be an interpretive rule clarifying the FDA’s longstanding position regarding preemption. (*See* 2006 WL 1443357, at *15.)

It is likely that the *Colacicco* decision will be appealed to the Third Circuit. While the ruling is not binding on any court other than the Eastern District of Pennsylvania, it can be expected that, given the comprehensiveness of the court’s analysis, other federal courts will give careful consideration to *Colacicco* when deciding preemption issues in other pharmaceutical failure-to-warn cases.

Depending upon how other courts in turn view the analysis, *Colacicco* might well prove to be an important turning point in pharmaceutical litigation.

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June 7, 2006

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