Case Note: *Colacicco v. Apotex Inc./McNellis v. Pfizer Inc.*, 521 F.3d 253 (3d Cir. 2008)

Third Circuit Court of Appeals Rules State Law Failure-to-Warn Claims Preempted in Anti-Depressant Cases

by M. Karen Thompson

In a precedential opinion issued April 8, 2008, the Third Circuit Court of Appeals ruled that failure-to-warn claims against manufacturers of selective serotonin reuptake inhibitors (SSRIs) are preempted by actions taken by the Food and Drug Administration (FDA) pursuant to its authority under the Federal Food Drug and Cosmetic Act, and corresponding regulations. In their 2–1 ruling, Judges Dolores Sloviter and Jane Restani[1] dismissed the state law claims of two plaintiffs whose family members committed suicide after taking the anti-depressant drugs. The plaintiffs had claimed that the drugs' labeling failed to warn of an alleged association with an increased risk of suicidality.

Significant to the majority's ruling was the FDA's regular monitoring of the claimed association between suicidality and SSRIs for almost 20 years, coupled with its consistent refusal to require stronger suicide warnings for adult patients on the drugs' labeling, both before and after the suicides in question. This history of active FDA involvement enabled the Third Circuit to sidestep the broader issue of whether the FDA's mere approval of drug labeling would be sufficient to preempt state law claims. Instead, the court determined that the FDA's own actions, taken in accordance with its statutory authority, and its clear and public rejection of the need for the warnings argued by the plaintiffs, preempted each the plaintiff's failure-to-warn claim. The majority also relied on the FDA's continued review of existing scientific studies regarding suicidality to dispose of the plaintiffs' claims that the FDA lacked sufficient information to mandate stricter warnings.

In so ruling, the court essentially adopted the FDA's explanation in its *amicus* brief filed in *Colacicco,* that the basis for federal preemption was the FDA's repeated determinations that there was insufficient scientific evidence of an association between use of SSRIs and suicide or suicidality. The court was careful to limit its ruling to situations in which the FDA had acted to publicly reject the very warnings the plaintiffs argued state law required. Under those circumstances, the court did not address whether the FDA's stance on preemption had been consistent prior to 2006, when the agency released its preamble to a final rule on prescription drug labeling.

The majority also rejected the plaintiffs' arguments that preemption was inappropriate because Congress never expressed any intent to preempt state law tort actions challenging drug labeling. While recognizing the presumption against preemption, the majority noted the tension between such a presumption and implied conflict preemption, which analyzes preemption in the absence of any explicit intent. It concluded that state common law tort actions based on a failure-to-warn present pharmaceutical manufacturers with varying standards and subject them to considerable liability.

The majority also rejected the plaintiffs' contentions that 21 C.F.R. Section 314.70(c), which allows drug manufacturers to strengthen and augment warnings without seeking prior FDA approval, renders FDA labeling requirements mere minimum standards for the information to be included in the drugs' labeling, and that state law failure-to-warn claims requiring a manufacturer to strengthen warnings do not conflict with FDA regulations, but complement them. The plaintiffs also claimed that only the FDA's explicit rejection of a manufacturer's request to seek a stronger suicide warning would suffice to establish conflict preemption. The court rejected the need for such formality.

The decision represented an affirmance of Judge Michael Baylson of the Eastern District of Pennsylvania, who had dismissed the *Colacicco* complaint on the basis of conflict preemption.[2] In *McNellis*, Judge

Continued on Page 7

Case Note

Continued from Page 5

Jerome Simandle had denied Pfizer's motion for summary judgment on preemption grounds, but certified his order for interlocutory appeal.[3] Pfizer's application for interlocutory review was granted, and the case was consolidated with the plaintiff's appeal in *Colacicco*.

Judge Thomas Ambro dissented, and would have applied the presumption against preemption in cases where Congress has not enacted an express preemption provision. He commented that state tort law actually complements the FDA by eliciting more information than the FDA would obtain from manufacturers. Characterizing the FDA's prior positions on preemption as "inconsistent," he concluded the FDA's recent statements in support of preemption, both in its *amicus* brief in *Colacicco* and in its informal statement in the preamble to the final rule on drug labeling, deserved little deference. Because neither drug manufacturer had enhanced the FDA-approved warnings, and had sustained no FDA sanction as a result, in his view no true conflict had occurred.

On May 5, 2008, a majority of the Third Circuit denied the plaintiffs' petition for rehearing and rehearing *en banc*. ■

ENDNOTES

1. Chief judge, United States Court of International Trade, sitting by designation.
2. *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514, 537-39 (E.D. Pa. 2006).
3. *McNellis ex rel. DeAngelis v. Pfizer Inc.,* No. Civ. 05-1286 (JBS), 2006 WL 2819046 (D.N.J. Sept. 29, 2006).

M. Karen Thompson *is a member of the firm of Norris McLaughlin & Marcus, P.A, who regularly practices in the area of products liability and toxic torts. The firm represented Pfizer Inc., along with Wheeler, Trigg & Kennedy, Pfizer's national counsel, in* McNellis.