

PRODUCT LIABILITY

April 2007 ~ No. 10

In this issue...

THE “PREEMPTION PREAMBLE” OF THE FDCA – A YEAR LATER

Patricia E. Lowry and Dori K. Stibolt review the caselaw determining whether to give deference to the January 2006 Food and Drug Administration issued policy proclamation regarding the preemptive effect of FDA approval of prescription drug labeling over state product liability claims against drug manufacturers.

About the authors...

Patricia E. Lowry is a partner with Squire, Sanders & Dempsey L.L.P. in West Palm Beach, Florida, where she specializes in products liability and employment litigation, with a special emphasis on pharmaceutical and medical device defense. She is the leader of the Squire Sanders product liability and mass tort practice group.

Dori K. Stibolt is a senior associate with Squire, Sanders & Dempsey L.L.P. in West Palm Beach, Florida. Ms. Stibolt practices products liability and employment litigation.

International Association of Defense Counsel

The IADC dedicates itself to enhancing the development of skills, professionalism and camaraderie in the practice of law in order to serve and benefit the civil justice system, the legal profession, society and our members.

One North Franklin, Chicago, IL 60606 USA

www.iadclaw.org

Phone: 312.368.1494 Fax: 312.368.1854

E-mail: aomaley@iadclaw.org

In January of 2006 the Food and Drug Administration (FDA) issued a major policy proclamation regarding the preemptive effect of FDA approval of prescription drug labeling over state product liability claims against drug manufacturers. The “preemption preamble” states in part that “under existing preemption principals, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting state law.” 71 Fed. Reg. 3922, at 3934.

Since the FDA’s preemption preamble was published a year ago there have been a number of judicial opinions that have decided whether to give deference to the FDA’s statement. Thus far, the cases have been sharply divided and the issue continues to be debated in courts around the country.

Cases Finding Preemption

Colacicco v. Apotex, Inc.

In *Colacicco*, the plaintiff’s wife was prescribed Paxil, but instead used a generic form of the drug. *Colacicco v. Apotex, Inc., et al.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006). The plaintiff’s wife later committed suicide and the plaintiff sued the manufacturer of the generic drug, Apotex, Inc., and Paxil’s manufacturer, GlaxoSmithKline, based on a failure to warn theory. *Id.* at 519-520.

Apotex and GlaxoSmithKline argued that the plaintiff’s state law failure to warn claims should be dismissed, among other reasons, because such claims were preempted as set forth in the FDA’s preemption preamble. *Id.*

at 524. The FDA filed an *amicus* brief presenting the agency’s position that because it had “repeatedly determined that there was inadequate evidence of an association between adult use of SSRI drugs and suicidality,” the state law failure to warn claims “are preempted because such a warning statement would actually have been ‘false and misleading,’ and thus contrary to federal law.” *Id.* at 524-525. In reaching the conclusion that the plaintiffs’ failure to warn claims were impliedly preempted, the *Colacicco* court considered both the preemption preamble and the FDA’s *amicus* brief, and held that the agency’s position, as expressed in both, was entitled to “significant deference.” *Id.* at 529, 532, 537 - 538.

In re Bextra and Celebrex Mktg. Sales Practices & Prod. Liab. Litig.

In *Bextra and Celebrex*, the putative class brought claims seeking economic damages resulting from their purchases of Celebrex. *In re Bextra and Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, No. 05-1699 CRB, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006). In particular, the plaintiffs alleged that the manufacturer of Celebrex had engaged in a deceptive marketing scheme which failed to disclose an increased cardiovascular risk – a warning not required by the FDA – and that as a result the manufacturer was able to sell more of the drug at a higher price than equally effective and less expensive medications. *Id.* at *1, 4. In addressing the issue of whether plaintiffs’ claims should be dismissed because they conflict with

the FDA's regulation of Celebrex, the court first looked to the FDA's position on preemption as set forth in the preemption preamble, and determined that it must give deference to the FDA's interpretation of the preemptive effect of its regulations. *Id.* *6. The court also found that the FDA had "specifically considered whether Celebrex poses a greater risk of adverse cardiovascular events than other NSAIDs" and determined that the scientific evidence did not establish that Celebrex posed a greater risk than other NSAIDs. *Id.* *10. The court thus found that plaintiffs' failure to warn claims conflicted with the FDA's determination of the proper warning, and held that plaintiffs' claims premised on Pfizer's failure to warn consumers and physicians of cardiovascular risk were preempted. *Id.*

Conte v. Wyeth, Inc., et al.

The plaintiff in *Conte* alleged neurological injuries due to overexposure to the prescription drug metoclopramide. *Conte v. Wyeth, Inc.*, No. CGC-04-437382, slip op. (Super. Ct. S.F. Cty., Cal. Sept. 14, 2006). The plaintiff argued that she was overexposed to metoclopramide due to the defendant Purepac's "dissemination of false, misleading and/or materially incomplete information about the drug's side effects, including information contained in Purepac's 'package inserts.'" *Id.* at p. 1. Purepac responded by arguing that the plaintiff's failure to warn claims were preempted because the claims necessarily conflicted with federal law because compliance with the

standards urged by plaintiff would require Purepac to make labeling statements that differ, or add to, previously approved FDA labeling. *Id.* at p. 2. In addressing the preemption question, the court cited the FDA's interpretation as set forth in the preamble, that the FDCA establishes "both a 'floor' and a 'ceiling,'" and that "state law 'failure to warn' claims are necessarily preempted to the extent they conflict with federal regulatory law by requiring addition labeling, i.e., additional warnings." *Id.* at 6-7. Relying on the decisions in *In re Bextra and Celebrex* and *Colacicco*, both of which the court found "very persuasive," the court granted summary judgment in favor of the defendant on the state law failure to warn claims on the grounds that they were preempted. *Id.* at p. 9.

Abramowitz v. Cephalon, Inc., et al.

In *Abramowitz*, the plaintiff alleged that the defendant, Cephalon, Inc., failed to provide sufficient warnings that the sugar-based ingredients in the prescription drug Actiq caused tooth decay and tooth loss. *Abramowitz v. Cephalon, Inc., et al.*, 2006 WL 560639 (N.J. Super. Ct. Mar. 3, 2006). The court reviewed the manufacturer's warnings and determined as a matter of law that there was insufficient evidence for the plaintiff to pursue a failure to warn claim under New Jersey state law. *Id.* at *3. The court further opined that absent its finding under New Jersey law, pursuant to the preemption preamble, "the FDA's decision to approve the defendant's label for Actiq would preempt a state claim for failure to warn." *Id.*

Citing language contained in the preemption preamble, the court reasoned that while not all state claims are preempted, “it is clear that the FDA has assumed authority over the regulation and approval of pharmaceutical labels in the United States, and therefore, any state claim that would challenge an FDA approved warning is preempted.” *Id.*

Ackermann v. Wyeth Pharmaceuticals

The plaintiff in *Ackermann* brought an action based in part on the manufacturer’s failure to warn of an increased risk of suicide in some patients while taking the antidepressant drug Effexor. *Ackermann v. Wyeth Pharmaceuticals*, No. 4:05CV84, 2006 U.S. Dist. Lexis 64499 (E.D. Tex. Sept. 8, 2006). In his Report and Recommendation, the Magistrate Judge cited the language of the preamble that the FDA “believes that State laws conflict with and stand as an obstacle to achievement of the full objectives and purposes of Federal law when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated.” *Id.* at *18-19. The court held that “absent some evidence that a drug manufacturer misled the FDA or failed to disclose critical information, preemption should apply in a failure to warn case.” *Id.* at *19. “To usurp the FDA’s regulation in this area offers the potential for far more harm than benefit to patients. . . . Patients would possibly be denied the benefits of a useful drug because of contraindications that were

speculative or remote. In the end analysis, uniformity as to warnings promotes confidence in the safety and efficacy of drugs for which Congress has mandated that the FDA is to have exclusive jurisdiction.” *Id.* at *19-20. The opinion was withdrawn as moot in light of an order granting complete summary judgment on other grounds. (E.D. Tex. Dec. 20, 2006).

Cases Rejecting Preemption

McNellis v. Pfizer, Inc. et al.

McNellis involved the prescription drug Zoloft which the plaintiff claimed caused the suicide of the plaintiff’s father. The plaintiff alleged that the manufacturer failed to adequately warn of the suicide risk despite the presence of the warning label which the FDA had authorized. *McNellis v. Pfizer, Inc., et al.*, No. 05-1286 (JBS), 2005 U.S. Dist. LEXIS 37505 (D.N.J. Dec. 29, 2005) (*McNellis I*), *id.* at *3-4. The defendant moved for summary judgment arguing that the plaintiff’s state law failure to warn claim was preempted by federal law because the FDA “would consider any label suggesting that Zoloft ‘can and does cause suicide’ ‘false and misleading,’ and therefore in direct contravention” of the FDCA. *Id.* at *9. Contrasting the express preemption language set forth in the Medical Device Amendments (MDA), the court denied the defendant’s motion, holding that the FDCA labeling requirements are “minimum standards” and that “states can impose stricter requirements regarding labeling and warnings if they so choose by

operation of customary tort law.” *Id.* at 32.

In response to defendant’s motion to vacate based on the preemption preamble, the *McNellis* Court issued a second opinion in September of 2006, *McNellis v. Pfizer, Inc., et al.*, No. 05-1286 (JBS), 2006 U.S. Dist. LEXIS 70844 (D.N.J. Sept. 29, 2006) (*McNellis II*), *interlocutory appeal granted*, No. 06-5148 (3d Cir. 2006), denying the motion. *Id.* at *15. First, the court reasoned, the text it relied on in *McNellis I* – that a drug manufacturer is permitted to unilaterally strengthen the warning on its labels under certain circumstances – was not changed. *Id.* Second, the FDA’s position regarding preemption has been inconsistent and therefore the preemption preamble was not entitled to substantial deference, the regulations allow drug manufacturers to enhance label warnings when new risks emerge, and the Court found unpersuasive cases relying on medical device regulations that contain an express preemption clause. *Id.* at *15-16.

Jackson v. Pfizer, Inc., et al.

Similarly, the *Jackson* court addressed defendants’ motions for summary judgment on claims that Nebraska common law required additional warnings relating to the risk of suicide in connection with use of the prescription drugs Zoloft and Effexor. *Jackson v. Pfizer, Inc., et al.*, 432 F. Supp. 2d 964 (D. Neb. 2006). The *Jackson* court found the preemption preamble “not persuasive,” noting the FDA’s failure to comply with its requirements to communicate with

states prior to a preemption decision, and following the Eighth Circuit’s “minimum standards” analysis when reviewing FDA regulations, as well as recent Eighth Circuit authority holding that “implied preemption is rarely found absent a direct conflict or a frustration of federal purpose.” *Id.* at 968 & n.3.

Perry v. Novartis Pharma. Corp., et al.

The plaintiffs in *Perry*, parents of a child diagnosed with lymphoblastic lymphoma, alleged that their child’s use of the prescription drug Elidel caused his lymphoma. *Perry v. Novartis Pharma. Corp., et al.*, 456 F. Supp. 2d 678, 679 (E.D. Pa. Oct. 16, 2006). The defendants moved to dismiss the failure to warn claims arguing that the FDCA and regulations promulgated thereunder preempted any such claims. *Id.* The *Perry* court rejected preemption under the circumstances in that case, and found that “state law may require a manufacturer to at least seek FDA approval for the addition of a new warning where there has been no determination by the agency whether there is a link between the adverse health effect to be warned against and the use of the drug.” *Id.* at 685. The court held that the preemption preamble was not entitled to any special consideration in its analysis, primarily because the preamble deals chiefly with specific warnings that FDA had specifically considered and rejected as scientifically unsubstantiated. *Id.* at 684. The court noted, however, that where “the FDA has made a conclusive determination, positive or negative, as to the existence of a link

between the drug at issue and some adverse health consequence, state law cannot mandate that a manufacturer include additional warnings beyond those that the FDA has determined to be appropriate to the risk.” *Id.* at 685-86.

Levine v. Wyeth

The *Levine* plaintiff alleged severe injury and the amputation of her arm as a result of being injected with the prescription drug Phenergan. *Levine v. Wyeth*, No. 2004-384, 2006 Vt. LEXIS 306 (Oct. 27, 2006). The plaintiff brought an action for negligence and failure to warn. *Id.* at *2. The lower court rejected Wyeth’s argument that the FDA’s approval of the Phenergan label preempted state common law claims that the label was inadequate. Following a jury verdict in favor of the plaintiff, Wyeth appealed. Wyeth argued that the FDA’s actions made it impossible to comply with both state and federal law “because the FDA prohibited the use of a stronger warning with respect to IV-push administration of Phenergan” and had directed Wyeth to “[r]etain verbiage in current label.” *Id.* at *20-21. Although the preemption preamble was issued after briefing and oral argument in the *Levine* case, the court considered the preemption preamble in reaching its decision. *Id.* at *30-37. A divided court rejected preemption and held that it need not decide the level of deference to give the preemption preamble because it would not affect the outcome of the appeal. The court held that Congress intended the FDCA to preempt only those state laws that would make it impossible

for manufacturers to comply with both federal and state requirements. *Id.* at *26-27, *33-34. According to the majority, “nothing in the FDA’s new statement alters our conclusion that it would be possible for defendant to comply with both its federal obligations and the obligations of state common law. The regulatory framework for prescription drug labeling allows drug manufacturers to add or strengthen a warning to ‘increase the safe use of the drug product’ without prior FDA approval.” *Levine*, 2006 Vt. LEXIS 306 at *34, *citing* 24 C.F.R. § 314.70(c)(6)(iii)(C). “Even if the new rule eliminated or altered this provision, the change in the regulation did not take effect until June 2006.”

Judge Reiber dissented in *Levine* and concluded that the plaintiff’s claims should be preempted because “it would be impossible for defendant Wyeth to comply with the requirements of both state and federal law” because Wyeth would have to eliminate uses of Phenergan approved by the FDA and required to be included in the Phenergan labeling. Judge Reiber also opined that the jury’s verdict posed “an obstacle to federal purposes and objectives” because the jury concluded that the drug’s FDA-approved use and labeling was unreasonably dangerous; thus, the FDA’s and the jury’s conclusions were in direct conflict. *Levine*, 2006 Vt. LEXIS 306 at *46-48 (Reiber, C.J., dissenting).

Conclusion

As demonstrated by the judicial opinions above, questions remain

regarding the effect of the preemption preamble on state failure to warn claims. What degree of deference should courts give the preemption preamble? How narrowly should courts interpret FDCA preemption? Should courts decide preemption on a case-by-case or drug-by-drug basis as determined by the particular labeling history for the drug involved? Eventually, the appellate courts and perhaps the United States Supreme Court will be asked to settle the debate.