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Prescription Drug Litigation Pre-emption

A Status Report from the Defense Perspective

Part Two of a Two-Part Series

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The Food and Drug Administration's ("FDA") pre-emption analysis in the preamble to its Jan. 24, 2006 drug-labeling rule has resulted in a significant shift in judicial recognition of pre-emption in prescription drug litigation. While only a handful of courts had upheld prescription drug pre-emption arguments prior to the FDA preamble, a solid majority of courts informed by the FDA's preamble analysis have found state law claims pre-empted. Part One of this series discussed key battlegrounds upon which future FDA pre-emption arguments will be fought. This second installment reviews recent case law and also discusses two new FDA *amicus* briefs in which the FDA provides further guidance on the proper scope of pre-emption in prescription drug litigation.

Judicial Response to the FDA Preamble

As of press time, there have been seven opinions published in Westlaw or official reporters that have adjudicated pre-emption arguments after consideration of the FDA preamble, with five courts holding plaintiffs' claims pre-empted and two courts rejecting the FDA pre-emption analysis.

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Courts Holding Prescription Drug Claims Pre-empted

1) Abramowitz v. Cephalon, Inc., No. BER-L-617-04, 2006 WL 560639 (N.J. Super. Ct. Law. Div. Mar. 3, 2006). The *Abramowitz* court was the first to address the FDA preamble, and the first to agree with the FDA's pre-emption analysis. *Abramowitz* involved allegations that the prescription drug Actiq® caused tooth decay because it is administered by way of a lollypop type dispenser designed to mask the drug's bitter taste. In finding the plaintiff's failure-to-warn claim pre-empted, *Abramowitz* held that "this court must respect [the FDA's] decision with regard to pre-emption of state claims." *Id.* at *4. The court also agreed with the FDA's conflict pre-emption analysis, explaining that the plaintiff's claim necessarily was premised on the assertion "that an FDA approved label was insufficient, and hence, that the FDA decision to approve the label was inappropriate." *Id.* at *3. The court rejected the plaintiff's argument that the defendant should have provided additional warnings based on post-marketing adverse event reports, finding that there was "no evidence that the defendants attempted to hide or suppress this information." *Id.*

2) In *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006), a federal district court provided the most extensive judicial analysis to date of the FDA preamble, holding that tort claims brought against a prescription drug manufacturer and generic drug manufacturer were pre-empted. *See* Le Gower article *infra* at 3.

3) In re Bextra and Celebrex Marketing Sales Practices and Prod. Liab. Litig., No. M: 05-1699, 2006 WL 2374742 (N.D. Cal. Aug. 16, 2006). *In re Bextra* is a putative class action in which the plaintiffs allege that the defendants violated consumer protection laws by marketing Cox-2 inhibitors without adequate warnings of cardiovascular risks and gastrointestinal side effects. In dismissing the plaintiffs' cardiovascular risk claims, the court explained that the FDA had considered the allegedly necessary warning and found it to be scientifically unsubstantiated. The court noted, however, that the FDA need not expressly determine that a proposed warning would be false or misleading for pre-emption to be required, explaining that the FDA has urged a broader theory of pre-emption: "The FDA is the agency charged with administering the FDCA and striking a somewhat delicate balance among its statutory objectives. The FDA is in a better position than the court to determine whether state laws that encourage manufacturers to propose defensive labels upset the FDA's careful balance of statutory objectives." *Id.* at *9 (internal citation and quotations omitted). The court held that the preamble was entitled to deference regardless of whether the FDA had changed its pre-emption position, and that the FDA's view of the pre-emptive effect of its own regulations could be disregarded only if it were "plainly erroneous or inconsistent with its regulations," which it is not. *Id.* at *8. The court also held that the plaintiffs' allegation that the drug manufacturer withheld cardiovascular risk data from the FDA "does not change the pre-emption analysis," because "[t]he law is well established

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that a claim premised on a drug manufacturer's failure to provide data to the FDA is pre-empted. *Id.* at *10 (citing *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001)). The court denied the defendant's motion to dismiss the plaintiffs' false advertisement claim regarding alleged gastrointestinal side effects, finding that there was no judicially noticeable evidence at the motion to dismiss stage that the FDA had reviewed and approved the advertisements at issue. *Id.* at *11.

4) Ackermann v. Wyeth Pharmaceuticals, No. 4:05CV84, 2006 WL 2591078 (E.D. Tex. Sept. 8, 2006). In *Ackermann*, a magistrate judge recommended that the court dismiss on pre-emption grounds the plaintiff's claim that a Selective Serotonin Reuptake Inhibitor ("SSRI") manufacturer failed to provide adequate suicide warnings. The magistrate judge found that the FDA's pre-emption analysis was entitled to deference and distinguished a pre-preamble ruling in the same court that had rejected pre-emption, explaining that the court had not had the benefit of the FDA's analysis. 2006 WL 2591078, at *7. The magistrate judge also explained the strong public health reasons supporting pre-emption:

> Allowing each state to require different standards for drug labeling promotes confusion not only for the manufacturers but also the consumers. To usurp the FDA's regulation in this area offers the potential for far more harm than benefits to patients. A manufacturer would find itself in a position where every known or possible consequence of ingesting its product would have to be disclosed even in light of a paucity of valid scientific testing to support the disclosure. Patients would possibly be denied the benefits of a useful drug because of contra-indications 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.*

5) Conte v. Wyeth, Inc., No. CGC-04-437382, 2006 WL 2692469 (Cal. App. Dep't Super. Ct. Sept. 14, 2006). In *Conte*, the plaintiff contended that a generic drug manufacturer failed to provide adequate warnings regarding the purported risks from long-term ingestion of metoclopramide. In holding the plaintiff's claims pre-empted, the court explained that the issue of federal pre-emption of state failure-to-warn claims "has been the subject of much disagreement among the courts that was apparently cleared by a recent pronouncement from the FDA interpreting the meaning of the FDCA." *Id.* at *4. The court noted that there is a "settled policy of providing broad deference to an administrative agency's interpretation of the statutory scheme it was empowered to administer," that the FDA had specifically rejected the reasoning of pre-preamble case law that had denied pre-emption arguments, and that the plaintiff's arguments that the FDA had changed its pre-emption position did not alter the deference due to the preamble. *Id.* at *5, *6. The court stated that state law attempts to impose additional warnings "can lead to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use" and that state law actions "threaten the central role of the FDA, an expert agency responsible for evaluating and regulating drugs, because such actions ask judges and/or juries to second-guess the risk/benefit assessments of the drug." *Id.* at *6.

Courts Rejecting the FDA's Pre-emption Analysis

1) Coutu v. Tracy, No. C.A. PC/00-3720, 2006 WL 1314261 (R.I. Super. May 11, 2006). In *Coutu*, the court allowed the plaintiffs to proceed with claims that a drug manufacturer had failed to adequately warn of alleged risks of the drug Propofol in children, holding that the FDA's pre-emption analysis was not entitled to deference. In so ruling, *Coutu* relied heavily on the FDA's statement in the 2000 preamble to the proposed new labeling rule, in which the FDA stated without analysis that the proposed rule would not give rise to pre-emption. *Id.* at *4. *Coutu* stated that it was "not convinced that state laws, encouraging more stringent warning standards, frustrate the purpose of the FDA." *Id.*

2) Jackson v. Pfizer, Inc., 432 F. Supp. 2d 964 (D. Neb. 2006). *Jackson* is another SSRI drug case involving alleged failure-to-warn of suicide risk. In allowing the plaintiff to proceed, the court summarily dismissed the FDA's pre-emption analysis, stating that it was "not persuasive" and finding, without analysis, that the FDA failed to comply with its requirements to communicate with the states prior to issuing the preamble. 432 F. Supp. 2d at 968 & n.3. The court found that there had "been no Congressional directive that the field is pre-empted" and relied heavily on reasoning in pre-preamble case law. *Id.* at 968.

Post-Preamble FDA *Amicus* Briefs

The FDA has filed two *amicus* briefs in recent months in which it has confirmed and elaborated upon the pre-emption analysis set forth in its preamble. These *amicus* briefs provide important further guidance on the FDA's pre-emption position and on the proper scope of pre-emption in prescription drug litigation.

FDA Amicus Brief in Colacicco v. Apotex

On May 10, 2006, the FDA filed an amicus brief in *Colacicco v. Apotex, Inc.*, No. 05-CV-05500 (E.D. Pa.). The FDA explained that the application of conflict pre-emption "is vital to ensure that state tort law does not undermine FDA's authority to protect the public health through enforcement of the prohibition against false or misleading labeling of drug products in the [FDCA]." *Colacicco Amicus Br.* at 6. With regard to SSRI drugs, the FDA recounted the regulatory history in which it had repeatedly reviewed the scientific evidence and determined that increased warnings about an alleged suicide risk were not appropriate. The FDA rejected the plaintiff's suggestion that there could only be a pre-emptive conflict if the FDA had prohibited an increased warning,

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citing the Supreme Court opinion in *Geier* for the proposition that "there is no requirement of a specific, formal agency statement identifying conflict for pre-emption to apply." *Id.* at 15.

***FDA Amicus Brief in* Perry v. Novartis Pharmaceuticals Corp**

Another court requested the FDA's views on pre-emption in a product liability case involving the prescription drug Elidel®, a topical medication used for the treatment of eczema that the plaintiffs allege caused lymphoma. *Perry v. Novartis Pharmaceuticals Corp.,* No. 05-5350 (E.D. Pa) (filed Sept. 21, 2006). The FDA's *amicus* brief, filed on April 21, 2006, represents the first occasion in which the FDA has spoken on the need for pre-emption in the context of a specific prescription drug other than SSRIs. The FDA explained that the "underlying principles of conflict pre-emption that must be applied" to failure-to-warn claims against Elidel® "are the same" as those in SSRI litigation. *Perry Amicus Br.* at 1. The FDA explained that because it "has not occupied the field," determinations of pre-emption "require an analysis of the agency's actions [of the drug at issue] and the actions that are alleged to give rise to liability." *Id.* at 11. The FDA explained that the agency need not have rejected the plaintiff's proposed warning. Rather, "state tort law is pre-empted if it imposes liability for a company's failure to provide a warning that the FDA has rejected, or would reject, as scientifically unsubstantiated." *Id.* at 2. Further, the plaintiffs cannot seek to impose liability for the defendant's use of warning language that had been approved by the FDA: "[W]here FDA has determined that a particular warning is necessary to ensure safe and efficacious use of a drug, it would undermine federal regulatory objectives for a manufacturer to be found liable under state law for providing that warning." *Id.* at 10. The FDA also explained that pre-emption does not rest on a finding that it would be impossible to comply with both FDA regulations and state tort law. "Even if compliance with both state and federal law ... would not be impossible, state tort liability would pose a sufficient threat to federal regulatory objectives to be pre-empted." *Id.*

Turning to the specific case, the FDA explained that because the FDA-approved Elidel® label states that a causal relationship between Elidel® and lymphoma has not been established, "federal pre-emption bars any claim that defendants should have warned of a causal link between Elidel® and lymphoma." *Id.* at 11. The FDA noted that "[e]ven as of January 2006 ... FDA's determination was that available scientific evidence has not established the existence of a causal relationship between Elidel® and the development of malignancies ... Necessarily, therefore, no causal relationship had been established before that time and, had defendants attempted to claim such a relationship in their labeling, the drug would have been deemed misbranded by FDA." *Id.* at 12. The FDA also explained that "any claim premised on defendants' failure to provide additional warnings about Elidel® as of the drug's approval in 2001, premised on scientific information known to and considered by FDA as part of the approval process, would also be pre-empted." *Id.* at 12.

The FDA explained that because of the vagueness in plaintiffs' allegations, it could not say whether the failure to warn claim was pre-empted "in its entirety." *Id.* at 2. The FDA made clear, however, that the plaintiffs would need to make a specific showing that the FDA would have approved a specific alternate warning as of the time of the prescription in order to avoid pre-emption. The plaintiffs need to explain "what an appropriate warning would have said; what causal relationship, if any, should have been asserted for the development of malignancies; and what comparative claims of safety should have been made, and as to what drugs." *Id.* at 11. Further, the plaintiffs must explain "when these warnings should have been given, which is a crucial factor in determining whether state tort liability would conflict with FDA's labeling decisions." *Id.* at 11.

CONCLUSION

Less than a year after the FDA issued its preamble, it has become clear that plaintiffs face a significant legal hurdle in alleging that prescription drug manufacturers should be liable for failing to provide litigation-inspired increased warnings. The FDA — not plaintiffs' attorneys — has been properly charged under federal law to make balanced labeling judgments protective of the public health. Unless they are in demonstrable accord with the FDA's balanced regulatory judgment, plaintiffs' failure-to-warn claims will be pre-empted.

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