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A legal update from Dechert's Mass Torts and Product Liability Group

District Court Dismisses Failure-to-Warn Claims Based on Implied Preemption and Deference to FDA Position

In the first decision of its kind following the issuance of the FDA's Final Rule addressing prescription drug preemption in January 2006, Judge Michael Baylson of the Eastern District of Pennsylvania held in *Colacicco v. Apotex, Inc., et al.*, Civ. No. 05-cv-5500, 2006 WL 1443357 (E.D. Pa. May 26, 2006), that the FDA's preemption pronouncements were entitled to judicial deference and that a failure-to-warn claim involving a prescription drug was impliedly preempted.

This decision promises to be a landmark in the judicial debate over the preemption doctrine, as the court adopted the FDA's position, thus distinguishing it from older cases that found no preemption because drug makers were allegedly free to modify their warnings without prior FDA approval. The holdings in *Colacicco*, if widely adopted, could result in far greater judicial acceptance of preemption in prescription drug product liability litigation than has previously been the case.

Judge Baylson dismissed the claims of a plaintiff who sued SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), the manufacturer of Paxil, and Apotex, Inc., the manufacturer of the generic version (paroxetine hydrochloride), after his wife allegedly ingested the generic and committed suicide. The key holding in Judge Baylson's opinion is that courts must afford deference to the FDA's position that its regulations preempt state tort claims for inadequate warnings, as outlined in various FDA *amicus* briefs and the preamble to the 2006 labeling requirements. Dechert partner Joseph K. Hetrick and associates Joshua G. Schiller and David J. Stanoch represented defendant GSK in *Colacicco*.

Colacicco v. Apotex, Inc.: Background

In *Colacicco*, the plaintiff's wife allegedly was prescribed Paxil and instead took the generic version, paroxetine hydrochloride. Shortly thereafter, she allegedly committed suicide. *See id.* at *2. Plaintiff sued both Apotex, the manufacturer of the drug his wife actually took, and GSK, the manufacturer of Paxil. Plaintiff's primary theory against GSK was that GSK should be held liable because the warnings on generic Paxil were identical to those on the name brand version. *See id.*

Both defendants contended, among other things, that plaintiff's claim was barred because it is impliedly preempted by federal law and that neither owed plaintiff's wife a duty of care.[1] *Id.* at *3. In part, both defendants relied on the FDA Final Rule preamble to the 2006 labeling amendments[2] to show that federal regulations preempt state tort claims for inadequate warnings.

In response to the defendants' motions to dismiss, the court requested that the FDA file an

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1 GSK argued that it did not owe a duty of care because plaintiff did not actually take its drug. Apotex argued that it did not owe a duty of care because it was required under FDA regulations to provide the same warnings as GSK. *Id.* at *3.

2 *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-97 (Jan. 24, 2006) (effective date June 30, 2006).

amicus brief addressing several preemption-related issues. In its brief, the FDA urged three key points:

- Because at the time of the decedent's death, the FDA rejected claims that adult use of Selective Serotonin Reuptake Inhibitors ("SSRIs") was associated with increased suicidality, any such warning would have been considered "false and misleading" and the drug would be considered misbranded.[3] *see id.* at *8-9.
- Allowing state tort law to impose additional burdens would frustrate the purpose of FDA regulations because it could lead to over-warning and chill the use of beneficial drugs. *see id.* at *9.
- The 2006 Preamble reflects a statement of the FDA's longstanding views on preemption and that the Food, Drug, and Cosmetic Act ("FDCA") establishes both a "floor" and a "ceiling" for warnings and state tort law cannot require any further warnings. *see id.* at *10.

Court Holds that FDCA Preempts State Tort Law

The court held that where imposing state tort liability for failure to warn would conflict with FDA-approved labeling, the federal regulations preempt state tort law. *Id.* at *13. The court stated, "The FDA's view is critical to this Court's analysis because Supreme Court precedent dictates that an agency's interpretation of the statute and regulations it administers is entitled to deference." *Id.* at *7 (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 844 (1984)).

Notably, the court considered not only the FDA's *amicus* brief, but also the "Preemption Preamble" to the 2006 Final Rule concerning Labeling Requirement Amendments. *See id.* at *10. The court held that it could properly consider the 2006 Preamble[4] and that the "FDA has acted within its authority, and this Court must respect its expert judgment that an October 2003 warning label other than approved by the FDA would have been in direct, actual conflict with federal law." *Id.* at *11.

Additionally, the court held that any changes in the FDA's preemption position between 2000[5] and 2006 did not require that the court ignore the FDA's current position. *Id.* at *12. Overall, the court found that, since 2000, the FDA has consistently maintained that "the Supremacy Clause bars state tort liability specifically for failure to include a warning on a drug label that is in conflict with or contrary to the warnings approved by the FDA." *Id.* at *13.

Finally, the court considered the position that numerous other courts outside of the Third Circuit have considered the implied preemption issue and rejected it. *See id.* at *16.[6] Regarding those opinions, the court held, "This Court has concluded not that their analysis itself is wrong, but rather that it is improper for a federal district judge to engage in this analysis in the first place." *Id.* The court provided three rationales in support of its preemption decision:

- Previous courts to consider the issue did not have either a clear *amicus* brief on the topic, or "an express statement of policy, formally published in the Federal Register, taking the position that state law failure-to-warn claims are preempted by the FDCA." *Id.* Thus, the court principally held that the 2006 preamble represents the type of unambiguous statement necessary to trigger *Chevron* deference.
- The FDCA and the FDA's preamble represent a political determination regarding the economic determination regarding the allocation of risk. *See id.* at *16-17. Given the FDA's position in the 2006 Preamble, the court found that it was not a proper judicial determination to overrule that political determination. *Id.*
- The FDA's position that a generic manufacturer cannot modify its warnings in any way

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3 *See* 21 U.S.C. §331(a), (b), (k).

4 *See id.* at *13-15 (holding that the 2006 Preamble may be retroactively applied because it merely clarifies existing laws).

5 *See* 65 Fed. Reg. 81082, 81103 (Dec. 22, 2000).

6 The opinion considered a number of other courts' decisions. *See id.* at 16 (*citing Hurley v. Lederle Laboratories Div. of American Cyanamid Co.*, 863 F.2d 1173 (5th Cir.1988); *Laisure-Radke v. Par Pharmaceutical, Inc.*, 2006 WL 901657, *3 (W.D. Wash. Mar. 29, 2006); *McNellis v. Pfizer, Inc.*, 2005 WL 3752269, at *14 (D.N.J. Dec. 29, 2005); *Witczak v. Pfizer*, 377 F. Supp.2d 726, 729 (D. Minn. 2005); *Zikis v. Pfizer, Inc.*, 2005 WL 1126909, at *8 (N.D. Ill. May 9, 2005); *Cartwright v. Pfizer*, 369 F. Supp.2d 876, 887 (E.D. Tex. 2005); and *In re Paxil Litigation*, 2002 WL 31375497, at *1 (C.D. Cal. Oct. 18, 2002)).

without prior approval was entitled to full *Chevron* deference. *Id.* at *17.[7]

Court Holds that GSK Owed No Duty of Care to Plaintiff Who Took Generic Drug

In an important alternative holding, the court held that "a name brand drug manufacturer does not owe a legal duty to consumers of a generic equivalent of its drug." *Id.* at 19. The court held that, under Pennsylvania law, "to impose a duty in this case 'would be to stretch the concept of foreseeability too far,' as GSK cannot reasonably expect that consumers will rely on the information they provide when actually ingesting another company's drug." *Id.* at *21 (quoting *Foster v. American Home Products Corp.,* 29 F.3d 165 (4th Cir. 1994)).

The court also found that "unfair consequences would result if we were to impose a duty upon [the pioneer drug manufacturer], when it obtained no benefit from the sale of [the] generic equivalent." *Id.* In so holding, the court primarily relied on the *Foster* decision from the Fourth Circuit and its progeny.[8] Thus, this decision not only represents the first reading of Pennsylvania law on the issue of liability for generic drugs, but is also consistent with a growing body of case law rejecting any such liability in any context.

Conclusion

The preemption decision in *Colacicco* is one of the first in the nation to consider the 2006 Preamble, and it is unquestionably the most thorough. Prescription drug manufacturers have been asserting preemption as a defense unsuccessfully for decades. The ruling here, that the 2006 FDA Preemption Preamble represents an "express statement of policy" worthy of *Chevron* deference, could well be a watershed that changes the fundamental landscape of prescription drug product liability litigation.

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7 In addition to the preemption ruling, the court made an important ruling under Pennsylvania law that a original "pioneer" manufacturer cannot be held liable for alleged inadequate warnings accompanying a generic manufacturers product, because only a product manufacturer can be liable under any kind of negligent warning theory. *Id*. at *19-21.

8 The court stated that "the *Foster* decision has encountered widespread acceptance." *Id*. at *20. The court also cited to numerous other courts that have considered and either accepted or approved of *Foster*. *See Tarver v. Wyeth, Inc.*, 2005 WL 4052382 (W.D. La. Jun. 6, 2005); *Block v. Wyeth, Inc.*, 2003 WL 203067 (N.D. Tex. Jan. 28, 2003); *DaCosta v. Novartis AG,* 2002 WL 31957424 (D. Or. Mar. 1, 2002); *Christian v. 3M*, 126 F. Supp. 2d 951, 958 (D. Md. 2001); *Miller v. Bristol-Myers Squibb Co.*, 121 F. Supp. 2d 831, 836 (D. Md.2000); *Sharp v. Leichus*, 2004-CA-0643, 2006 WL 515532 (Fla. Cir. Ct. Feb.17, 2006); *Kelly v. Wyeth*, MICV 2003-03314-B, slip. op. (Mass. Super. Ct. May 6, 2005); *Sheeks v. Am. Home Prods. Corp.*, No. 02CV337, slip. op. (Colo. Dist. Ct. Oct. 15, 2004); *Sloan v. Wyeth, Inc.*, No. MRS-L-1183-04, slip. op (N.J. Super. Ct. Oct. 13, 2004); *Beutella v. A.H. Robins*, Civil No. 980502372, slip. op. (Utah Dist. Ct. Nov. 7, 2001).

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