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

Third Circuit Upholds Implied Preemption of State Law Failure-to-Warn Claims Against SSRI Manufacturers

In a critical 2-1 decision in the consolidated appeal docketed as *Colacicco v. Apotex, Inc.*, Nos. 06-5148, 06-3107 (3d Cir. Apr. 8, 2008), the United States Court of Appeals for the Third Circuit suggests a significant shift towards judicial acceptance of implied preemption in pharmaceutical product liability litigation. The ruling adds important new preemption precedent in advance of the U.S. Supreme Court's Fall 2008 hearing of a similar case involving implied preemption and prescription drug warnings, *Wyeth v. Levine*, No. 06-1249 (cert. granted Jan. 18, 2008).

The Third Circuit affirmed dismissal of state law failure-to-warn product liability claims in *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006) (Baylson, J.), and reversed a conflicting order in *McNellis ex rel. DeAngelis v. Pfizer Inc.*, No. Civ. 05-1286 (JBS), 2006 WL 2819046 (D.N.J. Sept. 29, 2006) (Simandle, J.).[1] In so holding, the Third Circuit found the FDA's repeated consideration and rejection of the very warnings urged by the plaintiffs—specifically, an increased risk of suicide in adults—preempts state law claims that a drug manufacturer has a duty to include the warnings that the FDA rejected. Although the Third Circuit limited its ruling to the specific situation in which the FDA clearly and publicly rejected the warnings at issue, the Third Circuit's analysis provides favorable discussion beyond this holding. Importantly, the Third Circuit found FDA regulatory action—that is, the position the FDA took concerning the additional warnings—was entitled to preemptive effect even without the manufacturer submitting a formal supplement to the warnings. Addressing another disputed issue, the Third Circuit found the FDA's view on the preemptive reach of its own regulations was entitled to deference. Finally, the Third Circuit partially or wholly rejected several arguments commonly made by plaintiffs against implied preemption in pharmaceutical product liability cases.

The Third Circuit Holds the FDCA, FDA Regulations, and FDA Action Impliedly Preempt State Tort Law

The Third Circuit held that the FDA's repeated consideration and rejection of the same warnings urged by the plaintiffs—an increased risk of suicide among adults—impliedly preempt state law claims based on a drug manufacturer's failure to include such warnings on its drug's label. *See* Slip Op., at 33, 40-41. The Third Circuit applied implied conflict preemption principles, namely, whether the state tort

[1] *Colacicco* involved claims against SmithKline Beecham Corporation d/b/a GlaxoSmithKline ("GSK"), the manufacturer of Paxil®, and Apotex, Inc., the manufacturer of a generic equivalent, alleging that the decedent committed suicide as a result of taking generic Paxil®. Grant of the defendants' motions to dismiss was affirmed. *McNellis* involved similar suicide allegations against Pfizer Inc. concerning its drug, Zoloft®. Denial of the defendant's summary judgment motion was reversed on an interlocutory appeal. Both Paxil® and Zoloft® are SSRI antidepressants. Dechert partner Joseph K. Hetrick and associates Joshua G. Schiller and David J. Stanoch represented defendant GSK at the district court level in *Colacicco*. For additional background on the district court's opinion in *Colacicco*, *see DechertOnPoint, District Court Dismisses Failure-to-Warn Claims Based on Implied Preemption and Deference to FDA Position* (June 2006).

law claims at issue stood as an obstacle to, or rendered impossible compliance with, federal law. *See* Slip Op., at 15-17. The Third Circuit stated it "must focus on the effect of the FDA's failure to require a warning that plaintiffs argue was the cause of their injury rather than the effect of a positive regulation." Slip Op., at 28.

While it may be difficult to divine the preemptive effect of agency inaction (i.e., failure to require a plaintiff's proposed warnings), in this case the court had before it numerous public statements by the FDA, which "clearly and publicly stated its position" rejecting the very proposed warnings at issue "prior to the prescriptions and deaths at issue here." Slip Op., at 33. The FDA had both approved the labeling for Paxil® and Zoloft® several times before the events giving rise to the underlying lawsuits without adopting the warnings proffered by the *Colacicco* and *McNellis* plaintiffs and had rejected citizen petitions that sought to require those warnings. *See* Slip Op., at 29-32. While the FDA issued public statements acknowledging new research on suicide and SSRIs, it noted shortcomings in that research and stated that it would continue to review new research and reports. *See, e.g.*, Slip Op., at 31. Moreover, the agency openly rejected stronger adult suicide warnings for SSRIs "for the decade before the prescriptions and deaths at issue in this litigation," including statements issued mere months prior to the deaths of the decedents. *See* Slip Op., at 32.

In an *amicus* brief filed with the district court in *Colacicco*, as well as in the preamble to the agency's 2006 amendments revising its drug labeling regulations,[2] the FDA took the position that its rejections of these warnings preempted state law claims that sought to require them. *See* Slip Op., at 37. The Third Circuit agreed, finding that the FDA's position was entitled to "some degree of deference" under *Skidmore v. Swift & Co.*, 323 U.S. 134 (1944). The Third Circuit further held that, "based on our own review of the FDCA, the FDA's regulations, and the FDA's actions taken pursuant to its statutory authority," the plaintiffs' claims were impliedly preempted due to their conflict with the FDA's regulatory actions. Slip Op., at 41. The appellate court pointedly "express[ed] no view as to the merits of the issue whether SSRIs contribute to adult suicidality. We are not scientists and we do not purport to have any expertise on that issue. That is within the FDA's authority." *Id.*

[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).

The Third Circuit Rejects Plaintiffs' Arguments Against Implied Preemption

The Third Circuit's opinion is notable for its thorough analysis that rejects several arguments often made by plaintiffs in opposition to implied preemption of inadequate warning claims in pharmaceutical product liability litigation:

- *The Presumption Against Preemption in Implied Preemption Cases.* The Third Circuit found that "[a]lthough a presumption against preemption is commonly acknowledged, . . . application of such a presumption is not always appropriate." Slip Op., at 18 (citing *Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48 (2001)). Rejecting plaintiffs' argument that there is a "'virtually irrefutable presumption against implied preemption of private damage remedies,'" Slip Op., at 20 (quoting *Buckman*), the court held that the "lack of Congressional directive expressly approving or rejecting preemption in the context of drug labeling regulations is not determinative." Slip Op., at 22. Rather, implied preemption, by its very nature, "is designed to determine the propriety of preemption where Congress has not explicitly stated its intent." *Id.* Thus, one could not presume at the outset, in the absence of an express provision to the contrary, that Congress's intent was not to impliedly preempt state law.

  Because conflict preemption by definition operates in the absence of statutory language concerning preemption, the "argument that the presumption against preemption is inapplicable in the context of implied conflict preemption has more force." Slip Op., at 22. Thus, while the Third Circuit "recognize[d] the applicability of the presumption against preemption," it noted "the tension between such a presumption, which emphasizes the clear and manifest purposes of Congress, [] and implied conflict preemption, which analyzes preemption in the absence of any explicit intent." Slip Op., at 22 (internal citations and quotations omitted). This discussion in *Colacicco* is the first critical analysis of the presumption against preemption in the implied preemption context by a federal appellate court in product liability litigation. It may signal increased judicial skepticism towards the presumption in implied preemption cases.

- *"Informal" FDA Action Has Preemptive Effect.* Plaintiffs argued that the FDA's various statements about suicide warnings in approval letters, dispositions of citizen petitions, *amicus* briefs, the pre-

amble to the 2006 amendments, and elsewhere were not entitled to preemptive effect because these statements were not contained in formal regulations adopted after notice-and-comment rulemaking. *See, e.g.*, Slip Op., at 32-33. The Third Circuit flatly "reject[ed] the notion that, in order to rise to the level of a conflict in this situation, the FDA's rejection of a warning must be imbued with the formality proposed by the plaintiffs." Slip Op., at 34; *see also id.* at 32 (all "actions taken in accordance with [the FDA's] statutorily granted authority" have preemptive effect).

- *FDA's Position on Preemption Entitled to Deference.* Plaintiffs made a related argument that the FDA's position on the preemptive reach of its own regulations either should not receive any deference or should not be accorded deference unless embodied in a formal regulation. *See, e.g.*, Slip Op., at 38-39. The Third Circuit found these arguments unpersuasive and recognized *Skidmore*-level deference to informal agency positions on the preemptive force of its own regulations. *See* Slip Op., at 38.[3]

- *Failure to Submit Proposed Label Supplement Not Determinative.* The Third Circuit also addressed the frequent argument that failure-to-warn theories survive preemption because an exception in FDA regulations permits manufacturers to strengthen drug warnings, without prior FDA approval, by filing what are commonly referred to as "changes being effected" or "CBE supplements." *See* 21 C.F.R. § 314.70;[4] *see also* Slip Op., at 11-12. Here, the FDA had already concluded that stronger suicide warnings lacked scientific basis. Slip Op., at 33. The court thus rejected any requirement that would require the defendants to file a futile CBE supplement. The law "cannot compel the defendant companies to suggest a CBE supplement that they believe is unnecessary. Nor do we favor encouraging regulated parties to submit CBE supplements for the sole purposes of insulating themselves from liability." Slip Op., at 34. Thus, the FDA's actions regarding proposed warnings may preempt state law claims proposing such warnings even if the FDA did not reject those warnings in the context of the formal CBE supplement process. *See* Slip Op., at 34.

- *Continued Rejection of "Fraud on the FDA" Claims.* The *Colacicco* plaintiffs "further argue[d] that the FDA's failure to require an adult suicidality warning cannot be seen as a rejection of the warning that his lawsuit would require because 'GSK manipulated or withheld information from the FDA.'" Slip Op., at 34-35 (quoting Colacicco Reply Br., at 9). The Third Circuit pointed out that "[t]his contention borders on the charge that GSK defrauded the FDA by manipulating or withholding such information." Slip Op., at 35. Citing *Buckman*, it held that "[s]uch a claim, if supported by sufficient evidence, should be brought before the FDA." *Id.*

Conclusion

In this, the first federal appellate decision to address implied preemption in the context of prescription drugs since FDA's preamble to the 2006 amendments, the Third Circuit held plaintiffs' state law failure-to-warn claims to be preempted. The Third Circuit, however, expressly limited its ruling "to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires." Slip Op., at 33. It thus explicitly left open other preemption scenarios "such as where the FDA had not rejected the substance of the warning sought or where the FDA only stated its position after a lawsuit had been initiated." Slip Op., at 33.

The U.S. Supreme Court will address these larger issues in its upcoming Fall term when it hears arguments in *Levine*. Until then, the Third Circuit's *Colacicco* ruling provides welcome relief to manufacturers of SSRIs and affords manufacturers of other prescription drugs additional guidance on implied preemption of state law claims.

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[3] The dissent would accord FDA's position on the preemptive effect of its regulations only "relatively low level of deference" in light of perceived inconsistencies with other agency statements. *See* Slip Op., at 50. The majority, reviewing the same material, did not find any inconsistency. *See id.*, at 40.

[4] The court noted pending FDA regulatory action that would "limit" the CBE exception to "newly acquired information" that provided "evidence of a causal association" between a drug and an adverse event. Slip Op., at 12 (citing 73 Fed. Reg. 2848 (Jan. 16, 2008)).

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