Legal Backgrounder

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APPEALS COURT RULING HEIGHTENS ANTICIPATION ON STATE DRUG SUIT PREEMPTION

by

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Not so long ago many felt that the U.S. Court of Appeals for the Third Circuit's decision in *Colacicco v. Apotex, Inc*. would provide the preemption panacea: the court would rule on the issue of whether state tort claims for injuries caused by prescription medicines were impliedly preempted by federal law. The preemption issue was squarely presented in a conflict between two trial court orders within the Circuit involving the prescription medicines Paxil and Zoloft. The split was engendered in "the two fine opinions authored by two of the ablest district judges in this circuit".[1] The anticipation was fueled by the Food and Drug Administration's (FDA) publication of the Final Rule "Requirements on the Content & Format of Labeling for Human Prescription Drug and Biological Products" and no less than eight decisions discussing the Rule's intended effect on product liability litigation.[2]

Intervening events, however, began to cloud the significance of the Third Circuit's decision.

First, the Supreme Court took what looked like one step forward on preemption in *Riegel v. Medtronic, Inc.*, 128 S. Ct. 999 (2008), where the majority held that FDA's premarket approval of a Class III medical device expressly preempted tort claims consistent with the provisions of the Medical Device Amendments of 1976. Then the same Court seemingly took a step back in *Warner-Lambert Co., LLC v. Kent*, 128 S. Ct. 1168, where a 4-4 split (resulting from the recusal of Chief Justice Roberts) left in place a Second Circuit decision permitting tort claims to proceed against prescription product manufacturers in certain instances. Specifically, the Michigan law allowed the tort claims to proceed only if the manufacturer of a drug had committed fraud against the FDA in obtaining approval for the therapy and if the drug would

[1] *Colacicco v. Apotex Inc.*, 521 F.3d 253, 2008 WL 927848 (C.A.3 (Pa.), 2008).

[2] *Desiano v. Warner-Lambert & Co.*, 467 F.3d 85 (2d Cir. 2006); *Weiss v. Fujisawa Pharmaceutical Co.*, 2006 WL 3422688 (E.D. Ky. 2006); *Jackson v. Pfizer*, 432 F. Supp. 2d 964 (D. Neb. 2006); *Colaccio v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006); *Perry v. Novartis Pharma. Corp.*, 2006 WL 2979388 (E.D. Pa. 2006); *Ackermann v. Wyeth Pharmaceuticals*, 2006 WL 2591078 (E.D. Tex. 2006); *Levine v. Wyeth*, 2006 WL 3041078 (Vt. 2006); *Conte v. Wyeth*, 2006 WL 2692469 (Cal. Super. Ct. 2006).

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not have been approved if the complete information had been presented. The defendant claimed that *Buckman v. Plaintiffs' Legal Committee*[3] (holding that there is no private claim for fraud committed on the FDA) preempted a Michigan lawsuit for personal injuries where the plaintiff claimed that a fraud had been committed on the FDA. The Second Circuit ultimately held that *Buckman* applied to tort claims based on fraud on the FDA and did not extend to a state law, such as one enacted in Michigan, in which the fraud on the FDA was a part of the exception to a product liability claim rather than an element of the tort claim.

Finally, the Supreme Court's grant of certiorari in *Wyeth, Inc. v. Levine*, No. 06-1249, cert granted, 128 S. Ct. 1118 (Jan. 18, 2008), seemingly stole the Third Circuit's thunder when the Court agreed to decide "Whether state-law tort claims are preempted to the extent that they would impose liability for a drug manufacturer's use of labeling that the Food and Drug Administration approved after being informed of the relevant risk."

After all this, the Third Circuit did file its opinion in *Colacicco v. Apotex, Inc*., 521 F.3d 253, 208 WL 927848 (C.A.3 (Pa.), 2008). The decision, while delayed, is significant and may provide some insights into how the Supreme Court might approach the preemption issue in *Wyeth*. For now, the Third Circuit has found that there is preemption – but "limited to circumstances in which the FDA has publicly rejected the need for a warning that plaintiffs argue state law requires."[4] Specifically, the Third Circuit – in a 2 -1 decision – held:

> . . .based on our own review of the FDCA, the FDA's regulations, and the FDA's actions taken pursuant to its statutory authority, we conclude that the failure-to-warn claims brought by Colacicco and McNellis conflict with, and are therefore preempted by, the FDA's regulatory actions.[5]

As noted, the two wrongful death claims filed in Pennsylvania and New Jersey state courts and consolidated in *Colacicco* involved the antidepressants Paxil and Zoloft. The lawsuit of one plaintiff in *Colacicco* arose from the suicide of a patient taking the brand and generic forms of Paxil. The resulting state law wrongful death claim alleged that the manufacturers of both forms of the therapy failed to include a warning about the increased risk of "emergent suicidality and worsening of depression." The companies' counsel argued that the case was preempted by federal law. The trial court readily dismissed the case on this basis. *Colacicco v. Apotex, Inc.*, 432 F. Supp. 514, 537-39 (E.D.Pa. 2006). Similar allegations were brought by the family of a patient who killed himself in New Jersey while on the prescription medicine Zoloft again based on the same state law allegations of a failure to warn. *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286(JBS), 2006 WL 2819046 (D.N.J. Sept. 29, 2006). In the Zoloft case, the trial court found that there was no preemption and certified this issue for appeal:

> Whether . . . the United States Food and Drug Administration's requirement for the form and content of the labeling for the prescription antidepressant Zoloft preempted New Jersey's failure-to-warn law, under the doctrine of preemption, where the FDA's regulations . . . permit a manufacturer to unilaterally enhance its warning when the manufacturer has reasonable evidence of an association of a serious hazard with a drug.[6]

Faced with this question, two of the threshold issues the Third Circuit had to confront were whether it could apply a presumption against preemption in a case involving FDA regulation and, if so, what effect the presumption might have. These issues were somewhat clouded by the Supreme Court's recent

[3]531 U.S. 341 (2001).

[4]521 F.3d at 276.

[5]521 F.3d at 276.

[6]521 F.3d at 257.

pronouncements on the presumption issue in cases involving the FDA. In *Lohr*, the Court found the presumption applicable as it related to the FDA's regulation of a medical device that had not gone through rigorous pre-market approval. Then in *Buckman*, the Court did not discuss the presumption, apparently content that fraud on a federal agency is exclusively a federal matter. Finally in *Riegel*, the Court found the presumption was supplanted by the express preemption provisions in the Medical Device Act, which reflected Congress's intent on the preemption issue.

To further set the context in *Colacicco*, the Supreme Court had yet to indicate how the presumption might apply when the facts involve the preemptive effect of the FDA's labeling decisions. Unlike the preemption for medical devices discussed in *Riegel*, there is no express statutory preemption for prescription medicines.[7] Both parties in *Colacicco* agreed that the principles of "'conflict preemption'" therefore controlled, "applicable when 'state law is multivaried to the extent that it actually conflicts with federal law,' even though Congress has not displaced all state law in a given area." (Citations omitted).[8]

Plaintiffs' urged that because states traditionally regulate matters involving the public health and safety there would be irrebuttable presumptions against applying federal preemption to their cases. In response, the majority agreed, citing to *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996), that:

> In all preemption cases, and particularly in those in which Congress has legislated in a field in which States have traditionally occupied, we start with the assumption that the historic police powers of the States are not superseded by the Federal Act unless that was the clear and manifest purpose of Congress.[9]

The majority then found that the regulation of prescription medicines was within the historic powers of the states citing to *Hillsborough County*[10] and *Lohr*.[11] Yet, while the majority found the presumption applicable, it also held that it was not dispositive. Rather, the presumption was overcome by the pervasive regulatory authority Congress delegated to the FDA in the area of drug labeling. That delegation in turn provided a clear congressional expression that FDA's labeling decisions were controlling.

The dissent disagreed because it could not find that clear expression, indicating the Congress had not given the FDA the authority to adopt regulations preempting state tort law:

> I would apply the presumption against preemption here. The plaintiffs' failure-to-warn claims stand near the heart of the states' police powers over matters of health and safety. And the existence and detailed nature of the federal scheme does not change our imperative to require clear congressional intent (whether expressed directly in a

[7] 521 F.3d at 262.

[8] 521 F.3d at 261.

[9] 521 F.3d at 262-263. The trial court in the McNellis part of the case found that because New Jersey state tort law did not conflict with FDA's regulations there was no issue of conflict preemption. *Id*.

[10] "The Supreme Court's decision in *Hillsborough County* undermines . . . these arguments. In that case, the Court stated that the 'presumption that state or local regulation of matters related to health and safety is not invalidated under the Supremacy Clause,' [citation]and then proceeded to analyze whether local regulations imposed on blood plasma centers 'conflict with the federal scheme,'" [citation] 521 F.3d at 263.

[11] "The [Lohr] Court referred to the states' police powers to protect the health and safety of their citizens, [citation] the premise of the presumption against preemption, in holding that plaintiff's negligence action was not preempted. A plurality of the Court noted that the statutory language precluded any additional 'requirement,' not any 'remedy,' under state law, [citation] and concluded, by reference to the legislative history, that the statute 'was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions.'[Citation]. We note, however, that the Court did not discuss the presumption against preemption in its recent opinion in *Riegel* considering the same provision of the MDA at issue in *Lohr*." 521 F.3d at 264.

> preemption provision or implied by an authorizing statute enabling an agency to act) to preempt state tort law.[12]

Having "resolved" the presumption against preemption issue, the majority then looked to whether there was a conflict between federal and state law in the regulation of prescription medicine labels. It began its analysis with the finding that "[a] conflict between state and federal law 'arises when compliance with both federal and state regulations is a physical impossibility or when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" Citing to *Hillsborough County v. Automated Med. Labs.*, Inc., 471 U.S. 707 (1985).

The majority found the potential for conflict in the specific evidence showing that the FDA had evaluated the risks of the two drugs:

> The FDA has actively monitored the possible association between SSRIs and suicide for nearly twenty years, and has concluded that the suicide warnings desired by plaintiffs are without scientific basis and would therefore be false and misleading.[13]

Because such a warning would, for statutory purposes, be false and misleading

> a state law obligation to include a warning asserting the existence of an association between SSRIs and suicidality directly conflicts with the FDA's oft-repeated conclusion that the evidence did not support an association. Therefore, under the circumstances of this case, the plaintiffs' failure-to-warn claims are preempted by the FDA's actions taken in accordance with its statutory authority.[14]

The specific evidence of regulatory evaluation and approval then led the majority to conclude that conflict preemption should be applied:

> Although preemption is commonly thought of in terms of statutes and regulations, a federal agency's action taken pursuant to statutorily granted authority may also have preemptive effect over state law. [Citations]. Because the standard for adding a warning to drug labeling is the existence of 'reasonable evidence of an association of a serious hazard with a drug,' 21 C.F.R. § 201.57(e), and the FDCA authorizes the FDA to prohibit false or misleading labeling, a state-law obligation to include a warning asserting the existence of an association between SSRIs and suicidality directly conflicts with the FDA's oft-repeated conclusion that the evidence did not support such an association. Therefore, under the circumstances of this case, the plaintiffs' failure-to-warn claims are preempted by the FDA's actions taken in accordance with its statutory authority.[15]

As this language reflects, the majority's conflict preemption holding is narrowly drawn and tied to the specific evidence of regulatory evaluation, approval and on-going review. It is back to a "wait-and-see" to determine whether the Supreme Court will adopt the *Colacicco* majority view.

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[12] 521 F.3d at 279.

[13] 521 F.3d at 269.

[14] 521 F.3d at 271.

[15] *Id.*