

THE REGULATORY DEFENCE

**THE STATE OF THE LAW IN THE UNITED STATES
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Initial Recognition of the “Regulatory Defence” by a United States Court in a Pharmaceutical Case

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Last year, another colleague and I wrote in this publication about the status of products liability litigation in the United States. Our focus was on the “failure-to-warn” type allegations - allegations that a manufacturer failed to warn physicians (and possibly even consumers) about dangerous side effects of prescription medications. We also addressed the federal statutes and regulations governing the testing, labeling, marketing, and monitoring of prescriptions; namely, the United States Food, Drug, and Cosmetic Act of 1938 (“FDCA”) and its supporting regulations. Particularly, we noted that the Food and Drug Administration (“FDA”) was the federal agency charged with ensuring that all federal regulatory requirements with respect to prescription drug labeling were satisfied. In that role, the FDA, on January 24, 2006, promulgated a Final Labeling Rule entitled, Requirements on Content and Format of Labeling for Human Prescription and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (to be codified at 21 C.F.R. §§ 201, 314, and 601) (effective June 30, 2006) (collectively, “Final Labeling Rule”). The FDA included a preamble to the Final Labeling Rule (“Preamble”) in which the FDA addressed, among other things, the tension between civil plaintiffs’ failure-to-warn claims against prescription medication manufacturers and the role of federal prescription medication labeling regulations (the Final Labeling Rule equally applies to “biologics” such as vaccines). In the Preamble, the FDA announced that it “believes under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.” *Id.* at 3934.

At its most basic level, the doctrine of preemption, which arises from the Supremacy Clause of the United States Constitution, mandates that a plaintiff cannot recover on a state statutory or common law claim if such recovery would impose liability on a defendant for conduct that is otherwise permissible under federal law. In short, there are two bodies of law in the United States, state law and federal law. Federal law preempts, or supersedes, state law in three circumstances: (1) express preemption (i.e., Congress explicitly states that a federal statute or regulations preempt state law); (2) field preemption (i.e., when Congress so pervasively regulates a certain field or industry that, in spite of not explicitly stating that federal law preempts state law, Congress is presumed to have intended to preempt state law); and (3) conflict preemption (i.e., when state law stands as an obstacle to federal law, such that compliance with both is impossible). See, e.g., *English v. Gen'l Elec. Co.*, 496 U.S. 72, 78-79 (1990); *Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1120 (3d Cir. 1990). The preemption discussed throughout this article is conflict preemption, as we focus on whether a party can be held liable under state law for following federal law. In essence, conflict preemption is roughly analogous to European Union Directives, inasmuch as member states’ laws

cannot be at odds with Directives.

Therefore, the import of the FDA’s statement in the Preamble is, at least potentially, that a plaintiff cannot assert a failure-to-warn claim against a prescription drug manufacturer based on the alleged inadequacy of the medication’s specific label if the FDA previously approved that label as compliant with federal labeling regulations.

The Preamble sent shockwaves through the American product liability plaintiffs’ bar because of its far-reaching implications, especially since the Preamble seemed to mark a change in position by the FDA. About eight years prior to the Final Labeling Rule, the FDA seemed to indicate that FDA regulations did not preempt failure-to-warn claims. See, e.g., Prescription Drug Labeling, 63 Fed. Reg. 66378, 66382-84 (Dec. 1, 1998). Given this apparent shift in position, many plaintiffs’ lawyers predicted that courts would not ascribe any weight to the Preamble and would permit failure-to-warn claims to proceed, unfettered by manufacturers’ anticipated preemption arguments based on the Preamble.

No one had to wait very long to find out how courts would interpret the Preamble. On May 25, 2006, one of the first federal district courts to consider the Preamble agreed with the FDA’s statements in the Preamble and held in a long-reasoned opinion that failure-to-warn claims were preempted by FDA regulations. See *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006). This article addresses the ruling in *Colacicco*, the significance of that ruling, and related developments in the wake of that decision.

On October 21, 2005, Plaintiff Joseph Colacicco filed a complaint in the United States District Court for the Eastern District of Pennsylvania alleging that his wife’s suicide was the result of GlaxoSmithKline’s (“GSK”) and Apotex, Inc.’s (“Apotex”) failure to warn of the increased risk of suicidal behaviour linked to the anti-depressant Paxil and/or its generic equivalent, manufactured by GSK and Apotex, respectively. *Colacicco*, 432 F. Supp. 2d at 518. Allegedly, Colacicco’s wife, Lois Ann Colacicco, complained to her physician about symptoms of mild fatigue and depression. *Id.* She was prescribed Paxil, and soon thereafter she began taking Paxil’s generic equivalent. *Id.* Approximately 3 weeks after ingesting the generic version of the drug, Lois Ann Colacicco committed suicide. *Id.*

Plaintiff brought numerous claims against both GSK and Apotex, including failure-to-warn, negligence, negligence per se, fraud, and violation of state consumer protection laws. Plaintiff’s primary argument was that warnings concerning Paxil, “which were disseminated to doctors and the public by GSK, were inadequate to inform adult users of the risk of suicide associated with the drug.” *Id.* at 520. Even though Plaintiff’s decedent had ingested Apotex’s generic equivalent of Paxil, Plaintiff sought to hold GSK liable because the generic equivalent’s label was the same as that for

brand name Paxil, as it was required to be under United States federal regulations. Nevertheless, Plaintiff still sought to hold Apotex liable as well for copying the Paxil label. *Id.*

Both GSK and Apotex moved to dismiss Plaintiff's claims on various grounds, including an argument that Plaintiff's claims were barred by preemption based on the new FDA Final Labeling Rule. The court asked for additional briefing, particularly with respect to preemption. *Id.* at 519. In its supplemental briefing GSK, in particular, focused on the following language in the Preamble:

FDA has learned of several instances in which product liability lawsuits have directly threatened the agency's ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the act.

...
State law actions can rely on and propagate interpretations of the act and FDA regulations that conflict with the agency's own interpretations and frustrate the agency's implementation of its statutory mandate. . . .

Another misunderstanding of the act encouraged by State law actions is that FDA labeling requirements represent a minimum safety standard. According to many courts, State law serves as an appropriate source of supplementary safety regulation for drugs by encouraging or requiring manufacturers to disseminate risk information beyond that required by FDA under the act. [citing cases dating back to 1975.] . . . In fact, FDA interprets the act to establish both a "floor" and a "ceiling," such that additional disclosures of risk information can expose a manufacturer to liability under the act if the additional statement is unsubstantiated or otherwise false or misleading.

State law requirements can undermine safe and effective use in other ways. . . . 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 of approved products or encouraging inappropriate use and undermining the objectives of the act.

...
State law actions also threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs. State actions are not characterised by centralised expert evaluation of drug regulatory issues. Instead, they encourage, and in fact require, lay judges and juries to second-guess the assessment of benefits versus risks of a specific drug to the general public - the central role of FDA - sometimes on behalf of a single individual or group of individuals. That individualised reevaluation of the benefits and risks of a product can result in relief - including the threat of significant damage awards or penalties - that creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required. This could encourage manufacturers to propose "defensive labeling" to avoid State liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilisation of beneficial treatments.

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. . . . [going on to identify six types of inadequate warning state law claims in particular that FDA believes to be preempted.]

Final Labeling Rule, at 3933-3936.

After two rounds of supplemental briefing by the parties, the court,

"due to the novel preemption issues raised in [the] case," requested the FDA itself to submit an *amicus curiae* brief (a "friend of the court" brief filed by a non-party) on preemption, which the FDA did. *Id.*

The FDA's brief echoed the statements in the Preamble, as well as those in two earlier *amicus* briefs it had filed in other cases - both of which predated the Preamble - in which courts found that federal labeling regulations do not preempt failure-to-warn claims. See Br. of *Amicus Curiae* The United States of America ("FDA Amicus Brief"); see also generally *Kallas v. Pfizer*, No. 2:04-CV-0998 (PGC) (D. Utah Sept. 15, 2005); *Motus v. Pfizer*, Nos. 02-55372, 02-55498 (9th Cir. Sept. 3, 2002). The FDA began its brief by noting that it had specifically considered and rejected the exact warning Plaintiff claimed Paxil should have born around the time of his wife's suicide: "[the FDA] had repeatedly determined, based on scientific analysis of available information, that there was inadequate evidence of an association between use of Paxil and other SSRIs by adult patients and a risk of suicide or suicidality to support specific warnings [of an increased risk of suicide or suicidality.]" *Id.* at 7-8. Moreover, in October 2003 - the same month that Plaintiff's decedent committed suicide - the FDA issued a Public Health Advisory concerning Paxil and the risk of suicide or suicidality in *pediatric* patients, but specifically "declined to warn of any similar risk for *adult* patients at that time." *Id.* at 10 (emphasis original). Thus, the FDA had, at the time of the death of Plaintiff's decedent, already considered *and rejected* the very warning Plaintiff claimed the labeling of Paxil and its generic equivalent should have carried - a warning of possible increased risk of suicide or suicidality.

Mirroring its statements in the Preamble, the FDA stated that overwarning of potential risks associated with prescription medications was just as dangerous as underwarning: "[I]t is critical to understand, where warnings are concerned, more is not always better." *Id.* at 13. Adding scientifically unsubstantiated warnings in reaction to court decisions, especially the very warnings rejected by the FDA, would weaken the effectiveness of valid warnings, thereby detracting from the validity and credibility of the valid warnings. *Id.* at 13-14.

With this in mind, the FDA continued to explain that federal labeling regulations are not just a floor, but rather a ceiling and a floor. That is, federal labeling regulations, as interpreted by the FDA, do not merely set forth the minimum warnings that prescription medications must bear. Manufacturers cannot freely supplement approved labels. *Id.* at 16. Allowing such supplementation would compromise the FDA's role as the expert federal agency charged with ensuring public safety and would give rise to the risks of overwarning discussed above. *Id.* The FDA ended its brief by noting that an agency's determination that the regulations it is tasked with enforcing preempt state law is strongly indicative of the regulations' preemptive effect. See *id.* at 18-22.

Following another round of supplemental briefing by the parties, and after hearing oral argument on the matter, the court issued a lengthy, well-reasoned opinion in finding that Plaintiff's claims were preempted. The court began by explaining the federal regulatory process for prescription medications. *Colacicco*, 432 F. Supp. 2d at 522. It then outlined federal preemption principles. *Id.* at 523-24. It next turned to whether any preemptive effect should be accorded to the federal labeling regulations at issue. It began by looking to the FDA's statements in the Preamble and in the *amicus* briefs filed in *Colacicco*, *Kallas*, and *Motus*.

Contrary to Plaintiff's assertion, the court found that Supreme Court precedent directed the court to consider federal agency statements in *amicus* briefs, as well as in preambles such as that in the Final Labeling Rule in which the FDA expressed its position regarding

preemption. *See id.* at 525. The court declined Plaintiff's invitation to second-guess the FDA's position or otherwise afford little or no weight to that position. The court recognised that the United States Congress had imbued the FDA with the power to implement *and interpret* its own regulations promulgated pursuant to the FDCA:

[I]t is not the function of this Court, or a jury empaneled to decide this case, to substitute its judgment for the FDA's about medical issues. Congress has given the FDA broad power, the President has appointed its executives, some subject to the advice and consent of the Senate, and it has rendered its judgment on these issues. 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 530. The court particularly noted that the FDA's position in its *amicus* brief in *Colacicco* was consistent with its past positions in other *amicus* briefs. In fact, the FDA's position with respect to preemption was clear back to at least 2000. *See id.* at 526-27, 531. Finally, the court was not troubled by the apparent retroactivity of the Preamble. That is, the court did not see the fact that the Preamble to the Final Labeling Rule, effective June 30, 2006, was being applied in a legal decision prior to the Final Labeling Rule's effective date. *Id.* at 533-34. The court simply found that the Preamble to the Final Labeling Rule "merely clarif[ie]d" the FDA's long-standing views on preemption; therefore, retroactivity was a non-issue. *Id.* at 534.

Based solely on the FDA's position, as embodied in the Preamble and its *amicus* briefs, the court "would deem any state failure-to-warn claim impliedly preempted." *Id.* at 532. But the court did not stop there. It went on to elaborate that the case implicated the division of judicial and legislative responsibilities:

this is not a case about individual rights or Constitutional interpretation, in which judges have obligations to protect civil liberties, but is essentially a case about economics - whether a drug company should be at risk for damages because of the death of a woman taking its drugs. When Congress established the elaborate system of legislation for the introduction of new drugs, and authorised a federal agency to implement and police its operation, the resolution of claims arising out of alleged shortcomings in drug instructions and labeling should be as allowed by Congress. Congress has not provided for such claims, and the FDA has taken the position that plaintiff's claims based on state law are inconsistent with its statutory-administrative regimen. . . . It is of course true that this Court or any other trial judge with a case such as this could proceed to trial (where a jury would be required to render a verdict based on the same medical judgments considered by the FDA), and appeals by the losing party would wind their way through the court system. However, because preemption is warranted, the case should be dismissed now; if the Court is wrong, Congress can fix this error quickly, and so can the executive branch, by installing different managers at the FDA. Ultimately, this Court believes it is far more desirable that the important issues presented by this case, indeed tragic in its facts, are better addressed by elected officials, legislative and executive, than by appointed judges, a belief which itself has been echoed by the Supreme Court.

Id. at 536. With this in mind, the court ruled that Plaintiff's failure-to-warn claims, and other related claims against GSK and Apotex, were preempted by federal labeling regulations. Therefore, it dismissed the case. For the first time, an American court had

upheld the "regulatory defence" in a pharmaceutical product liability case.

Plaintiff timely appealed the *Colacicco* decision to the United States Court of Appeals for the Third Circuit. *See Colacicco v. Apotex, Inc.*, Case No. 06-3107 (3d Cir. 2006). The gist of Plaintiff's appeal is that the district court erred in deferring to the FDA's interpretation that FDA regulations preempt state failure-to-warn and other related claims. *See Appellant's Br.* at 8. Plaintiff's argument on appeal hinges on three major points: (1) there is a presumption against preemption (i.e., the district court should have assumed at the outset that state law is not nullified unless GSK and Apotex could prove otherwise); (2) Congress has expressed no intent for the FDCA or its accompanying regulations to preempt state law; and (3) the district court abdicated its independent judicial role by wholly deferring to the FDA's interpretation of the preemptive effect of its own regulations. *See id.* at 8-15, 27-33. All three points overlap insofar as they relate to the weight the district court afforded to the FDA's position on the preemption issue.

GSK and Apotex's opposition to Plaintiff's appeal rests on a straightforward, factual argument: the FDA had considered and rejected the very warning Plaintiff alleged should have appeared on Paxil and its generic equivalent. *See Appellees' Br.* at 2, 24-34. To impose liability on GSK and Apotex for failing to feature a label that warned of an increased risk of suicide or suicidality in 2003 would be directly contrary to the FDA's determination at that time. *See, e.g., id.* at 23, 31, 33, 39, 42. Indeed, GSK and Apotex would be in violation of the FDA's misbranding regulations if they applied a warning - a warning already expressly rejected by the FDA - that had not been approved by the agency.

Numerous entities filed *amicus* briefs on behalf of both Plaintiff as well as GSK and Apotex, including the American Tort Reform Association, the Pharmaceutical Research and Manufacturers of America, the Product Liability Advisory Council, Inc., the American Trial Lawyers Association, and the Trial Lawyers for Public Justice. Currently, the appellate case is fully briefed. However, while the case was being briefed on appeal, the Third Circuit received an appeal from another district court decision, *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286(JBS) (D.N.J. Sept. 29, 2006), *on appeal* at Case No. 06-5148 (3d Cir. 2006). The *McNellis* court held the opposite of the *Colacicco* court. It ruled that the FDCA and its attendant regulations do "not preempt a plaintiff from claiming that an FDA-approved warning was inadequate under State law if the plaintiff is able to demonstrate that the manufacturer knew of 'reasonable evidence of an association of a serious hazard with a drug' and thus had a duty to supplement its warning under 21 C.F.R. § 201.57(e)." *Id.* at *13. Given the conflicting rulings in *McNellis* and *Colacicco*, the Third Circuit stayed proceedings in the *Colacicco* appeal so that the *McNellis* appeal could be briefed. The two cases will be heard together by the appellate court probably sometime this year, as the *McNellis* case is now fully briefed as well.

What will happen on appeal is difficult to predict. What is definite, though, is that the Third Circuit's eventual ruling in the combined *Colacicco/McNellis* appeal will be the first statement by an appellate court on the preemption issue following the publication of the Preamble to the Final Labeling Rule. It is very possible that the Third Circuit's decision will be appealed to the United States Supreme Court.

While *Colacicco* and *McNellis* wind their ways through the court system, prescription drug manufacturers are left in a state of uncertainty. At this point, the question of whether federal labeling regulations preempt failure-to-warn and related claims will be decided by individual district courts on an *ad hoc* basis. Indeed, a number of district courts have subsequently ruled both consistent

with, and contrary to, the *Colacicco* court. See, e.g., *Sykes v. Glaxo-SmithKline*, Case No. 2:06-CV-01111-LS (E.D. Pa. Mar. 28, 2007) (finding for preemption); *In re Bextra & Celebrex Mktg. Sales Practices & Prod. Liab. Litig.*, 2006 WL 2374742 (C.D. Cal. 2006) (finding for preemption); *Ackermann v. Wyeth*, 2006 U.S. Dist. LEXIS 64499 (E.D. Tex. 2006) (finding for preemption); *Perry v. Novartis Pharm. Corp.*, 456 F.3d 678 (E.D. Pa. 2006) (finding against preemption); *Weiss v. Fujisawa Pharm. Co.*, 2006 U.S. Dist. LEXIS 86179 (E.D. Ky. 2006) (finding against preemption).

Meanwhile, preemption vis-à-vis *Colacicco* remains a potent weapon with which manufacturers may fend off the glut of failure-to-warn claims that have arisen in recent years. If *Colacicco* is

upheld, preemption will become the most prized weapon in manufacturers' legal arsenals. I noted last year that "while the resolution of [the preemption] issue may take years, the benefit to the industry is well worth the investment." Now, though, that benefit may well be even closer than imagined.

Authors' Note

As the authors acted on behalf of a defendant in the *Colacicco* case, if anyone requires copies of referenced documents, the authors can be reached via e-mail at the addresses shown.




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