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How Will FDA's New Label Rule Impact Drug Litigation?

By Eric G. Lasker, Esq.*

In 1985 the U.S. Supreme Court stated that absent clearly expressed congressional intent to the contrary, the Food and Drug Administration's position on the preemptive scope of its regulatory authority "is dispositive." *Hillsborough County v. Automated Med. Labs. Inc.*, 471 U.S. 707 (1985).

Following *Hillsborough*, courts have routinely given great deference to the FDA on issues of preemption involving a wide variety of FDA-regulated products and conduct. In the area of prescription drug products liability litigation, however, courts have been divided in their understanding of the FDA's preemption position, even after the agency's recent *amicus curiae* arguments in favor of preemption in litigation over antidepressants and other selective serotonin reuptake inhibitors. See *Amicus Briefs* for the United States in *Kallas v. Pfizer Inc.* No. 02-04cv998 (D. Utah Sept. 15, 2005), and *Motus v. Pfizer Inc.*, Nos. 02-55372 and 02-55498 (9th Cir. Sept. 19, 2002).

The FDA ended this debate Jan. 18. In the preamble to its new final labeling rule on prescription drugs, the agency forcefully stated "that under existing preemption principles, FDA approval of labeling under the … [Food, Drug and Cosmetic Act], whether it be in the old or new format, preempts conflicting or contrary state law." *See* FDA Final Rule, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922-3997, at 3934 (Jan. 24, 2006).

The FDA explained that its January 2006 statement "represents the government's long-standing views on preemption, with a particular emphasis on how that doctrine applies to state laws that would require labeling that conflicts with or is contrary to FDA-approved labeling." *Id.*

In light of the strong deference courts extend to the FDA's preemption views, the January statement should have a significant impact in favor of preemption in prescription drug litigation. In this article, I discuss the broad scope of the FDA's January statement in favor of preemption and review the rich line of judicial authority supporting deference to that position.

FDA's January 2006 Statement on Preemption

In its January statement, the FDA explained that the vast majority of claims brought in prescription drug litigation conflict with and accordingly should be preempted by the agency's regulation of prescription drugs.

While the FDA previously has argued in favor of preemption in individual prescription drug cases,[1] its arguments in those cases were arguably limited to the facts at issue, and the agency had not provided courts with specific guidance as to the types of state tort claims that should be precluded in prescription drug litigation generally.

In its January 2006 statement, the FDA provided the courts with a clear roadmap, explaining that "at least" the following six types of claims should be preempted:

- "Claims that a drug sponsor breached an obligation to warn by failing to put in highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling";
- "[C]laims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling," so long as the drug sponsor acted consistently with the FDA's draft guidance on direct-to-consumer advertising;
- "[C]laims that a sponsor breached an obligation to warn by failing to include contraindications or

warnings that are not supported by evidence that meets the standards set forth in this rule";

- "[C]laims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising, the substance of which had been proposed to FDA for inclusion in labeling" but not required by the FDA at the time of the alleged failure to warn (unless the FDA has determined that the drug sponsor had withheld material information from the agency);
- "[C]laims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising"; and
- "[C]laims that a drug's sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug's label (unless FDA has made a finding that the sponsor withheld material information relating to the statement)."

71 Fed. Reg. at 3936.

The FDA stated that its regulation of prescription drug labeling "will not preempt all state law actions," *id.*, but it made clear that the scope of permissible actions was quite narrow. State law claims should be allowed only when based on "requirements that parallel FDA requirements." *Id.* The agency suggested, moreover, that the necessary predicate determination that a drug manufacturer had failed to comply with a federal requirement falls within its primary jurisdiction over prescription drugs. *Id.*

Accordingly, plaintiffs would not be able to bring a "parallel requirement" state law action unless the FDA had expressly determined that the agency's requirement had been violated.

In setting forth its preemption analysis, the FDA specifically rejected the two main arguments routinely made by prescription drug plaintiffs opposing preemption: FDA labeling requirements impose only minimum standards, and drug manufacturers have the ability to unilaterally strengthen warnings in drug labels without FDA approval.

The FDA explained that the "minimum standards" argument is premised on a fundamental misunderstanding of the agency's objectives in approving drug labeling:

> Another misunderstanding of the … [Food, Drug and Cosmetic Act] encouraged by state law actions is that FDA labeling requirements represent a minimum safety standard. … In fact, FDA interprets the act to establish both a "floor" and "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.

Id. at 3934-35.

The FDA explained that the minimum-standards argument is misguided because "[o]verwarning, just like underwarning, can similarly have a negative effect on patient safety and public health." *Id.* at 3935. "Exaggeration of risk could discourage appropriate use of a beneficial drug." *Id.* Further, "labeling that includes theoretical hazards not well-grounded in scientific evidence can cause meaningful information [on the label] to 'lose its significance.'" *Id.*

The FDA warned that state law claims "threaten FDA's statutorily prescribed role as the expert federal agency responsible for evaluating and regulating drugs … [because] 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." *Id.* In so doing, these claims "encourage manufacturers to propose 'defensive labeling' to avoid state liability, which, if implemented, could result in scientifically unsubstantiated warnings and underutilization of beneficial treatments." *Id.*

The FDA likewise explained the flaw in plaintiffs' arguments that additional state law requirements do not conflict with federal law because drug manufacturers can unilaterally augment the warnings on prescription drug labels. This argument is based on 21 C.F.R. § 314.70(c), which provides that drug manufacturers may make temporary changes that strengthen warnings in drug labels, but only if they simultaneously submit the new labels to the FDA for approval.

In its January 2006 statement, the FDA rejects the reasoning of courts that have focused on this regulatory provision, explaining that "the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act." *Id.* at 3934. While a drug manufacturer "may, under FDA regulations, strengthen a labeling warning … in practice manufacturers typically consult with FDA before doing so to avoid implementing labeling changes with which the agency ultimately might disagree (and that therefore might subject the manufacturer to enforcement action)." *Id.*

History of Judicial Deference to FDA Preemption Positions

The long history of judicial deference to FDA positions on preemption indicates that the January 2006 statement

could herald a significant reduction in what has been a major arena of state tort litigation. As noted above, the U.S. Supreme Court has described FDA positions on preemption as dispositive, and the court consistently has followed the FDA's lead when faced with questions of FDA preemption.[2]

Federal appellate and state supreme courts have likewise routinely deferred to the FDA's preemption views in a wide variety of cases. And despite the mixed holdings to date on prescription drug preemption, courts on both sides of the issue have frequently sought to bolster their opinions by reference to FDA statements that they interpreted as supportive of their conclusion.

The Supreme Court has addressed arguments on whether FDA regulation preempts state law in four cases over the past 30 years, and while it did not always accept all of the FDA's arguments, in each case, the court ruled in keeping with the preemption position favored by the agency.

In *Jones v. Rath Packing Co.*, 430 U.S. 519 (1977), the court considered whether a California statute pertaining to the labeling of packaged goods by weight should be preempted. The FDA submitted an *amicus* brief in support of preemption. *See* Brief of the United States as *Amicus Curiae*, 1976 WL 181581 (Aug. 18, 1976).

Although the Supreme Court held that the state statute was not inconsistent with the Food, Drug and Cosmetic Act, it held that the state law would frustrate the FDA's federal goal under the Fair Packaging and Labeling Act of facilitating comparisons among similar products and that the state law thus "must yield to the federal." *Jones*, 430 U.S. at 543.

In *Hillsborough County* the court considered whether FDA regulations preempted local ordinances governing collection of blood plasma from paid donors. 471 U.S. 707. In a statement accompanying the federal regulations, the FDA had specifically disavowed any intent that its regulations preempt such ordinances. As noted above, the Supreme Court found this FDA statement to be "dispositive" and rejected the preemption argument. *Id.* at 714.

The court next considered an issue of FDA preemption in *Medtronic Inc. v. Lohr*, 518 U.S. 470 (1996). In *Medtronic* a pacemaker manufacturer argued that state tort claims involving FDCA Section 510(k) medical devices should be preempted. The court disagreed, noting that the FDA had taken the position that its regulation of medical devices only preempts state law claims where the FDA had imposed specific requirements on the product, a condition not satisfied by the cursory review given to Section 510(k) devices. The court explained that its decision was "substantially informed" by the FDA's preemption position:

> Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the [FDCA], the agency is uniquely qualified to determine whether a particular form of state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress, and, therefore, whether it should be preempted.

518 U.S. at 496 (internal quotations and citation omitted).

The Supreme Court most recently addressed FDA preemption issues in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001). In *Buckman* the court held that state law claims of fraud on the FDA were preempted because they impermissibly interfered with the agency's regulatory authority under the FDCA. Once again, the court's holding was in accord with the position taken by the FDA in its *amicus* brief and argument before the court. *See* Brief for the United States as *Amicus Curiae* Supporting Petitioner, 2000 WL 1364441 (Sept. 13, 2000); Transcript of Oral Argument, 2000 WL 1801621 (Dec. 4, 2000).

Federal appellate courts and state supreme courts have deferred to the FDA's positions on preemption in a wide variety of legal contexts. For example, in *Grocery Manufacturers of America Inc. v. Gerace*, 755 F.2d 993 (2d Cir.), *aff'd*, 474 U.S. 801 (1985), the U.S. Court of Appeals for the 2d Circuit held preempted a New York statute that required labeling for cheese products that conflicted with FDA regulations, an argument espoused by the FDA in an *amicus* brief. *See* 71 Fed. Reg. at 3935.

In *Luna v. Harris*, 888 F.2d 949 (2d Cir. 1989), the 2d Circuit deferred to the FDA in rejecting an argument that a state regulation regarding methadone treatment clinics should be preempted. *Id.* at 954 ("FDA maintains in its *amicus* brief that there is no preemption here, and we are required to accord substantial deference to that view.").

In *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), the 3d Circuit agreed with the FDA's *amicus* argument that state law claims involving Class III medical devices were preempted, noting that the agency is "uniquely qualified to determine whether a particular form of state law … should be preempted." *Id.* at 171 (quoting *Lohr*).

In *National Bank of Commerce of El Dorado v. Kimberly-Clark Corp.*, 38 F.3d 988 (8th Cir. 1994), the 8th Circuit relied on the FDA's understanding of the preemptive scope of its regulation of Class II medical devices (tampons) in rejecting the defendant's preemption arguments. *See id.* at 997 ("We reject this argument as inconsistent with both our and FDA's reading of the Medical Device Act's preemption provision.").

In *Dowhal v. SmithKline Beecham Consumer Healthcare*, 88 P.3d 1 (Cal. 2004), the California Supreme Court found that health warnings mandated by the state's Proposition 65 on over-the-counter nicotine-replacement therapy products were preempted, an argument pressed by the FDA in an *amicus* submission.

And in *New Jersey Guild of Hearing Aid Dispensers v. Long*, 384 A.2d 795, 811 (N.J. 1978), the New Jersey Supreme Court explained that an advisory opinion issued by the FDA's chief counsel was a "very substantial factor" in support of its conclusion that only one section of state regulations regarding the sale of hearing aids was preempted.

Courts on both sides of the issue of preemption in the prescription drug context have also claimed to be following the lead of the FDA. Prior to the agency's issuance of its 2002 *amicus* brief in support of preemption in *Motus*, courts rejecting drug manufacturers' arguments of preemption repeatedly pointed to indirect evidence that the FDA was opposed to preemption.

In *Yugler v. Pharmacia & Upjohn Co.*, No. 104362/98 (N.Y. Sup. Ct. Apr. 5, 2001), for example, the court looked to the FDA's comments in its rules on patient labeling for prescription drugs, stating that "the FDA's own comments regarding labeling requirements, albeit in a somewhat different context, reflect the FDA's own recognition that labeling regulations do not preempt state tort claims, a view that is entitled to considerable weight." *Id.*

Caraker v. Sandoz Pharmaceuticals Corp., 172 F. Supp. 2d 1018, 1036 (S.D. Ill. 2001), cited to a variety of indirect sources as "evidence that the FDA has seen the utility of state products liability claims despite their approval of the prescription drug in question." In *Ohler v. Purdue Pharma L.P.*, 2002 WL 88945, *12-*13 (E.D. La. 2002), the court mistakenly relied on the FDA's comments to its patient labeling rules as "black-and-white" evidence that the agency "has expressly disavowed any intention" that its regulation of prescription drugs preempts state law claims.

Courts that have held prescription drug state law actions preempted since 2002 have pointed to the FDA's pro-preemption arguments in *Motus*. In *Dusek v. Pfizer Inc.*, 2004 WL 2191804, *5 (S.D. Tex. 2004), the court explained, "Supreme Court precedent dictates that the FDA's position as stated in its *amicus* brief is entitled to some deference."

Likewise, in *Needleman v. Pfizer Inc.*, 2004 WL 1773697, *4 (N.D. Tex. 2004), the court cited to the FDA's position in favor of preemption as "compelling." Conversely, courts that rejected preemption after the FDA's *Motus amicus* brief sought to muddy the water, arguing that the agency had "since distanced itself from the substance of the *Motus* brief" by recommending labeling changes to SSRI drugs and asserting that "[t]hus, the court has reason to suspect that the *Motus* brief's interpretation does not reflect the agency's fair and considered judgment on the matter in question." *Witcak v. Pfizer Inc.*, 377 F. Supp. 2d 726, 730 (D. Minn. 2005) (internal punctuation omitted). This contention that the FDA has moved away from its pro-preemption position is, of course, no longer available.

Conclusion

The FDA has clearly stated its position that most state law claims brought in prescription drug litigation conflict with and are thus preempted by the agency's federal regulation of prescription drugs and their labeling. If judicial precedent is any guide, the FDA's January 2006 statement will receive significant deference from courts and mark a new chapter in the history of prescription drug product liability litigation.

Notes

[1] *See Amicus* Brief for the United States, *Kallas v. Pfizer Inc.*, No. 02-04CV0998 (D. Utah Sept. 15, 2005) (on file with author); *Amicus* Brief for the United States, *Motus v. Pfizer Inc.*, Nos. 02-55372 and 02-55498 (9th Cir. Sept. 19, 2002) (on file with author).

[2] The court also has repeatedly explained that federal agency preemption positions set forth in regulatory preambles and responses to comments are entitled to significant deference. *See Fid. Fed. Savings & Loan Ass'n v. de la Cuesta*, 458 U.S. 141, 158 (1982) (relying on preamble to Federal Home Loan Bank Board regulation in finding preemption); *Hillsborough County*, 471 U.S. at 718 (FDA can properly communicate its preemptive intent through statements in "regulations, preambles, interpretive statements and responses to comments"); *Medtronic v. Lohr*, 518 U.S. 470, 506 (1996) (Breyer, J., concurring) (quoting *Hillsborough*).

** Eric G. Lasker is a partner at Spriggs & Hollingsworth in Washington, D.C., where he represents defendants in pharmaceutical products liability cases as well as toxic torts, environmental litigation and constitutional litigation. He can be reached at 202-898-5843 and elasker@spriggs.com.*