Taking on Big Pharma and the FDA

Our American system of drug regulation is heavily frontloaded. The FDA spends a lot of time and energy (though not always enough) evaluating a proposed drug's safety and efficacy before approving it. But this initial evaluation is inherently constrained by the limited data available from clinical trials conducted before the product enters the marketplace. Ultimately, the FDA makes a judgment based on the limited data available about whether a drug should be approved.

Once a drug receives its initial approval, however, the FDA backs way off. In most cases, the agency does not initiate post-marketing reviews of a drug's safety. Instead, the FDA leaves it to the drug manufacturers to alert it when actual use of a product reveals greater hazards. And post-approval enforcement has declined precipitously under the current administration.

Under these circumstances, you might imagine that the FDA would welcome state tort law as a complementary set of protections for consumers of drug products. Indeed, the chief counsel of the agency during the Clinton administration once wrote: "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct, layer of consumer protection." (2)

But under the Bush administration, all that has changed. The FDA has thrown its considerable administrative weight behind a dangerous argument that drug companies are advancing to get out from under state tort liability. The companies argue that state products liability claims--especially claims for failure to warn about a drug's risks--are preempted by federal laws and regulations. And the Bush FDA is backing them up.

Fortunately, these efforts are facing resistance from the plaintiff bar and advocates for drug consumers. The battle is far from over, but several recent decisions suggest that the law may be heading in the right direction.

A little history

For decades, state products liability law and federal regulation of drugs have happily coexisted. State tort actions against drug companies have been recognized for well over a century. When Congress enacted the Food, Drug, and Cosmetic Act (FDCA) in 1934, it decided not to include a private right of action for damages on the ground that it was "unnecessary," because a "common law right of action exists." (3)

In recent decades, the FDA repeatedly acknowledged that there was no conflict between these two systems for consumer protection. In the 1979 preamble to an FDA labeling regulation, for example, the agency expressly acknowledged that "it is not the intent of the FDA to influence the civil tort liability of the manufacturer." (4)

Similarly, two decades later, when the agency issued a regulation concerning medication

guides for prescription drugs, the FDA rejected a drug company suggestion that it preempt "state regulation with respect to civil tort liability claims and other labeling requirements." To the contrary, the FDA said it "does not believe that the evolution of state tort law will cause the development of standards that would be at odds with the agency's regulations." (5)

Drug companies periodically argued in court that some plaintiffs' claims against them were preempted by federal law. But these arguments met with little success.

Things began to change shortly after George W. Bush became president. It started with a series of amicus briefs that the FDA filed in pending tort cases. The Bush FDA began to take the position that certain products liability claims seeking to hold drug manufacturers liable for failure to provide adequate warnings of a drug's dangers conflicted with--and were preempted by--federal drug labeling regulations.

Two things characterized most of these efforts. First, the FDA chose cases in which the agency had already considered the precise warning at issue and decided not to require it. Second, the courts consistently rejected the FDA's position.

In January 2006, the FDA decided to ratchet up its efforts. More than five years earlier, in the waning months of the Clinton administration, the FDA had proposed some revised drug labeling regulations, with the explicit acknowledgement that they would not preempt state law. Now, the Bush FDA was issuing the final labeling regulations. Lo and behold, the preamble to the final rule took the completely contrary position on preemption, reiterating many of the arguments the agency had advanced in its amicus briefs.

The preamble argued that "FDA approval of labeling under the [FDCA] ... preempts conflicting or contrary state law." It took the position, contrary to explicit FDA regulations, that drug companies were not free to strengthen warnings without FDA approval, because "the determination whether labeling revisions are necessary is, in the end, squarely and solely [the] FDA's under the act."

And, the agency argued, federal labeling requirements are not "minimum safety standards"; rather, they "establish both a 'floor' and a 'ceiling,' such that additional disclosures of risk information can expose a manufacturer to liability under the act." (6) The FDA apparently hoped that, by setting forth its preemption position in a regulatory preamble, it could persuade courts to grant it more deference.

Not surprisingly, many drug companies felt emboldened by this FDA action. Companies began to file preemption motions in case after case, regardless of whether the facts revealed any conflict between FDA decisions regarding the drug product involved and the plaintiffs' claims.

The preamble has led to much confusion in the courts. While some judges have correctly recognized that nothing really changed and that state tort law generally complements

federal drug regulation, others have concluded, incorrectly, that they must defer to the agency's expertise on this issue and dismiss plaintiffs' claims. To date, the decisions on preemption are roughly split down the middle.

It became clear that the FDA's regulatory preamble raised the stakes and threatened to undermine plaintiffs' rights to redress under state law. The Center for Constitutional Litigation (CCL) and Trial Lawyers for Public Justice (TLPJ) have defended state law in cases in which preemption has been urged--serving as both cocounsel and amici curiae.

Perry v. Novartis

Perry v. Novartis Pharmaceutical Corp. resulted in one of the most significant anti-preemption rulings to date. (7) In 2003, Andreas Perry was a two-year-old boy who developed lymphoma after using Novartis's topical immunosuppressant, Elidel, to treat his eczema. Andreas's parents were not warned that Elidel could increase their son's risk of developing cancer. Two years later, the FDA required Novartis to add a prominent "black-box" warning about cancer risk to Elidel's label.

Novartis moved to dismiss the Perrys' failure-to-warn suit on federal preemption grounds. The company did not assert that the FDA had prohibited it from providing a stronger warning on Elidel, nor that the agency would have rejected such a warning if Novartis had sought it. Instead, the company merely cited the FDA preamble and asserted that the court must defer to the FDA's judgment that such failure-to-warn claims were preempted.

In opposition to Novartis's motion, the plaintiffs filed a memorandum demonstrating that no conflict existed between their claims and federal law. (8) To begin with, the memo explained, courts have recognized a strong presumption against implied preemption, particularly in areas of traditional state concern such as public health and safety, and especially where preemption would deprive an injured person of all relief. Moreover, in a 1962 amendment to the FDCA, Congress made clear that the act would not preempt state law except in cases of "direct and positive conflict" with federal law. (9)

No such conflict existed here. Federal regulations expressly allow drug companies to add or strengthen a warning without prior FDA approval. Indeed, they require the drug label to be revised as soon as there is "reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." (10) And state products liability claims advance the FDCA's legislative purpose of protecting the public health by creating incentives for drug companies to make their products safer and to provide reasonable warnings about the dangers those products pose.

Specifically with respect to Elidel, the memorandum argued that the FDA itself had expressed concerns about a possible cancer risk during initial approval, had insisted on postapproval studies as a condition of approval, and eventually required the black-box warning. At no time did the agency ever reject a stronger warning about cancer risk or suggest that one would be unfounded.

The memorandum also took on the FDA preamble and explained why it was not entitled to deference by the courts. First, the preamble should be read narrowly, to apply only to cases in which the FDA had explicitly rejected the warning the plaintiffs sought, and not to the Perrys' case. More generally, the memo argued, the preamble was not entitled to heightened deference under Chevron v. NRDC, (11) because it was not formal agency rule-making pursuant to its delegated authority, but only an advisory opinion. Nor was it entitled to respect under the less deferential standard of Skidmore v. Swift & Co. (12) and United States v. Mead Corp., (13) because it lacked the thoroughness, consistency, and validity of reasoning that might give it the "power to persuade."

The memorandum had a salutary effect on the preemption debate, even before the Perry court ruled, by forcing the FDA to clarify its position. After the memorandum was submitted, the Perry court solicited an amicus brief from the agency. The brief the court eventually received represented a significant retreat from the broad preemption position the agency took in the preamble.

The FDA acknowledged that a drug manufacturer is allowed to strengthen warnings without prior approval and "has an obligation to seek FDA approval for a labeling change" where there is "reasonable evidence of a causal association" with a significant hazard. The agency concluded, "A failure-to-warn claim is not preempted merely because it imposes liability for a manufacturer's failure to provide a warning that has not yet been required by the FDA." (14)

The FDA argued that the appropriate legal test for preemption was "whether the warning sought by plaintiff would have rendered the drug misbranded in the agency's judgment at the relevant time, or ... would have been rejected by the agency as unsubstantiated." (15) The FDA conceded that, under this standard, the Perrys' claims could not he dismissed as a matter of law.

Any plaintiff lawyer confronting a preemption motion based on the preamble would he well advised to bring this letter brief to the attention of the court, as it dramatically reveals the limits of the agency's position. (16)

This alone would have represented a significant victory, but the eventual ruling by the federal district court in Pennsylvania went even further. Judge Stewart Dalzell dismissed the 2006 regulatory preamble as an advisory opinion that would not affect his analysis: "[T] he FDA cannot retroactively absolve Novartis of a duty it may have owed the Perrys in 2003." He concluded that the FDA's brief also "overstate [d] the scope of preemption." Instead, the court ruled, "it is more in keeping with the narrow scope of preemption to allow state law to require the addition of warnings so long as there has been no specific FDA determination as to the sufficiency of the scientific evidence to support a particular warning." (17)

Dalzell noted "the recent concerns about the effectiveness of the FDA's safety monitoring of recently approved drugs." Under these circumstances, the court reasoned, "the availability of state law tort suits provides an important backstop to the federal regulatory

scheme."

Perry is an important victory for plaintiffs' rights, but it is only a district court opinion. Other emerging cases may serve as good vehicles to extend and expand this ruling.

Other recent rulings

Courts have handed down other significant rulings on FDA preemption--both for and against--since the preamble was issued.

On the positive side, the Vermont Supreme Court recently rejected a preemption claim that the manufacturer of the drug Phenergan raised in Levine v. Wyeth. The court adopted the argument--similar to that in the Perry case--that the 1962 amendment to the FDCA "essentially removes from our consideration the question of whether common law tort claims present an obstacle to the purposes and objectives of Congress." Thus, in the Vermont court's view, a state tort claim will be preempted only where compliance with both federal and state law is "a physical impossibility." (18)

Also significant, though on somewhat unusual facts, was the Second Circuit's recent decision in Desiano v. Warner-Lambert & Co., in which the court rejected an argument that an exception to Michigan's unique drug manufacturer immunity statute was preempted. Most important, the court's decision concluded that "an agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption." (19)

On the other hand, some rulings have deferred to the FDA preamble and ruled that claims were preempted, at least on the particular facts before them. Probably the two most important of these rulings came from federal district courts in Philadelphia and San Francisco: Colacicco v. Apotex, Inc., and In re Bextra and Celebrex Marketing Sales Practices and Product Liability Litigation, respectively.

The Colacicco court dismissed the plaintiff's claims against the manufacturer of a generic version of Paxil, on the ground that the FDA had expressly determined that the warning the plaintiff sought "was not scientifically supported" and also that Apotex, as a generic manufacturer, was not free to change its label without FDA approval. The court treated the FDA's views on these issues as "dispositive," incorrectly reasoning that "it is not the function of this court ... to substitute its judgment for the FDA's about these medical issues." (20)

Similarly, the district court in the Celebrex case decided that it had to defer to the FDA's position that state laws are preempted "when they purport to compel a firm to include in labeling or advertising a statement that FDA has considered and found scientifically unsubstantiated." (21) On this basis, the court held that Celebrex purchasers were barred from suing the manufacturer, Pfizer, for failure to warn of cardiovascular risk, because the FDA had considered and found the desired warnings to be scientifically unsubstantiated. But it said the plaintiffs could proceed on claims that the company

understated Celebrex's gastrointestinal risks. (22)

While both of these decisions arguably may be limited to their facts, their grant of sweeping deference to the FDA preamble has troubling implications for future cases. The Colacicco case is now on appeal to the Third Circui. (23)

With the growing number of FDA preemption cases, important side issues have begun to emerge. As the Colacicco decision demonstrates, failure-to-warn claims against the manufacturers of generic pharmaceuticals raise their own unique issues, which are of considerable importance given the increasing popularity of generics in our cost-conscious marketplace.

The FDA takes the position that, unlike name-brand manufacturers, generic manufacturers are not free to strengthen the warnings on their labels without prior approval. Some courts have disagreed. (24) In any event, nothing prevents such manufacturers from notifying health care professionals about their product's dangers by other means, such as "Dear Doctor" letters; (25) nor are they precluded, as the Perry decision suggests, from "at least seek[ing] FDA approval for the addition of a new warning" on both the generic and name-brand products. Failure to take either of these steps should still be actionable under state law. (26)

The use of prescription drugs is pervasive in our society and results, inevitably, in injury to thousands of consumers each year. It is critically important that those injured by prescription drugs retain their ability to seek redress through the courts. Major drug companies--and their allies in the Bush administration--must not be allowed to shut off the only avenue to legal redress for these victims through an overreaching interpretation of federal law's preemptive effect. (27)

Notes

(1.) See U.S. House of Reps., Comm. on Govt. Reform--Minority Staff, Prescription for Harm: The Decline in FDA Enforcement Activity (June 2006), www.democrats.reform.house.gov/story.asp?ID=1074 (last accessed Jan. 23, 2007).

(2.) Margaret J. Porter, The Lohr Decision: FDA Perspective and Position, 52 Food & Drug L.J. 7,11 (1997).

(3.) U.S. Sen. Subcomm. of the Comm. on Commerce, Hearings on S. 1944, 73rd Cong., 2d Sess. 400, 403 (1934).

(4.) 44 Fed. Reg. 37434, 37437 (June 26, 1979).

(5.) 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998).

(6.) 71 Fed. Reg. 3922, 3934-35 (Jan. 24, 2006).

(7.) Perry v. Novartis Pharma. Corp., 456 F. Supp. 2d 678 (E.D. Pa. 2006).

(8.) CCL and TLPJ worked together to prepare the memorandum after plaintiffs' counsel, the Law Offices of Larry M. Roth, approached them for assistance. CCL attorneys Francine Hochberg, Jesse Merriam, and I, along with Leslie Brueckner and Leslie Bailey from TLPJ, played active roles in preparing this memorandum. The memo is available at www.tlpj.org/briefs_documents.htm.

(9.) Pub. L. 87-781, Title II, [section] 202, 76 Stat. 793 (1962) (not codified, but set out as a note under 21 U.S.C. [section] 321 (2000)).

(10.) 21 C.F.R. [subsection] 314.70(c), 201.80(e) (2006).

(11.) 467 U.S. 837, 842-45 (1984).

(12.) 323 U.S. 134, 140 (1994).

(13.) 533 U.S. 218, 236 (2001).

(14.) FDA Amicus Curiae Ltr. Br., Perry v. Novartis Pharma. Corp., 456 F. Supp. 2d 678 (E.D. Pa. 2006).

(15.) Id.

(16.) A copy of the FDA letter brief in Perry is available on the Trial Lawyers for Public Justice Web site at www.tlpj.org/briefs/FDA%20 Amicus %20letter.pdf (last accessed Jan. 23, 2007).

(17.) Id. at 685. The FDA essentially adopted this more narrow test for preemption in another recent amicus brief. See Br. of the United States as Amicus Curiae at 22 & n.10, Colacicco v. Apotex, Inc., No. 06-3107 (3d Cir. filed Dec. 4, 2006) ("[W] here an agency's decision not to impose a requirement in a particular setting reflects its judgment that the requirement would be inappropriate or unsound, the agency's decision must be given preemptive effect.... If the agency had made a determination at the relevant time that a particular warning was unsubstantiated or would otherwise render a drug misbranded, then federal preemption bars liability for the failure to provide that warning.").

(18.) 2006 WL 3041078 at [paragraph] 27 (Vt. Oct. 27, 2006).

(19.) 467 F.3d 85, 97 n. 9 (2d Cir. 2006).

(20.) 432 F. Supp. 2d 514, 530 (E.D. Pa. 2006).

(21.) 2006 WL 2374742 at *5 (N.D. Cal. Aug. 16, 2006).

(22.) Id at *10.

(23.) CCL and TLPJ have joined with Public Citizen to submit an amicus brief focused on the flaws in the district court's preemption analysis.

(24.) E.g. Foster v. Am. Home Prods., 29 F.3d 165, 170 (4th Cir. 1994); Laisure-Radke v. Par Pharm., 2006 WL 901657 at *4 (W.D. Wash. Mar. 29, 2006).

(25.) See 44 Fed. Reg. 37434, 37447 (June 26, 1979) ("The issuance of letters directed to health care professionals (e.g., 'Dear Doctor' letters containing such information [about possibly harmful adverse effects]) is not prohibited by these regulations.").

(26.) CCL and TLPJ, along with plaintiffs' counsel Hector Pineiro and Ralph Pittle, recently filed a memorandum addressing these issues in opposition to a preemption motion filed by a generic manufacturer in Kelly v. Wyeth, No. 03-3314-F (Mass. Super. filed Dec. 15, 2006).

(27.) The Supreme Court recently expressed interest in a separate FDA preemption issue concerning medical devices, which are governed by a distinct statutory preemption provision. Ever since the Supreme Court decision in Medtronic, Inc. v. Lohr (518 U.S. 470 (1996)), the lower courts have been divided about whether rigorous FDA premarket approval of a medical device preempts state damages claims. The Bush FDA has reversed the agency's prior position and now supports preemption. The Court asked the solicitor general's office to submit a brief to advise the Court whether it should grant certiorari in a case to resolve the issue. (Riegel v. Medtronic, 127 S. Ct. 575 (2006).)

Louis M. BOGRAD is a senior litigation counsel at the Washington, D.C.-based Center for Constitutional Litigation, which represents plaintiffs in preemption cases and challenges to tort "reform."