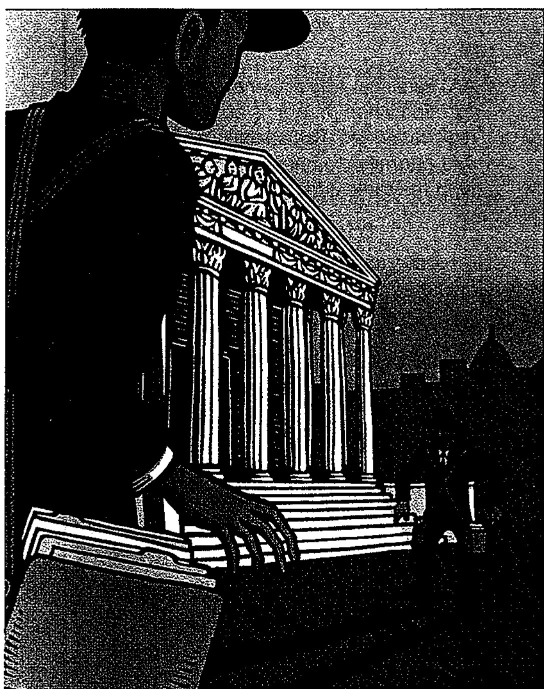
news & trends

Wyeth v. Levine sets up a showdown in the preemption corral

This fall brings a showdown, pitting the doctors and the lawyers against the feds and Big Pharma in the preemption corral. Both sides are fully armed with amicus briefs for *Wyeth v. Levine*, but the U.S. Supreme Court, as sheriff, controls the shots.



GREGORY NEMEC

Oral arguments in the case, in which the Court will decide whether FDA approval of drug labeling preempts state products liability suits against manufacturers of allegedly defective drugs, are set for November 3.

Plaintiff attorneys are holding their breath after last term's express-preemption case, *Riegel v. Medtronic*, in which the Court held that the regulatory approval process for medical devices was comprehensive enough to justify preempting claims that question the sufficiency of a warning label. (128 S. Ct. 999 (2008).)

Consumer advocates and trial attorneys point out that if the court concludes that the FDA's drug-labeling rules preempt state law, consumers injured by drugs won't have any way to hold manufacturers accountable. But many consumers don't clearly understand what federal preemption means for their rights, said Harris Pogust, a lawyer in Conshohocken, Pennsylvania. He represented the family of a woman who took the popular antidepressant Paxil and committed suicide. Earlier this year, the Third Circuit ruled that their failure-to-warn claim was preempted. (*Colacicco v. Apotex, Inc.*, 521 F. 3d 253 (3d Cir. 2008).)

In August, a lower court in that federal circuit distinguished the *Colacicco* decision and declined to find preemption in a case involving an alleged Paxil-related suicide by a teenager. That court said its decision "is consistent with a regulatory system that puts the obligation to warn on the party with the most comprehensive information available: the drug manufacturer." (*Knipe v. Smithkline Beecham*, No. 06-3024 (E.D. Pa. Aug. 28, 2008).)

Pogust said lawyers need to explain preemption in simple terms that everyone can understand. "Tell them a drug company is going to be immune and won't have to pay for its mistakes if you got harmed by a drug you took even if it had information that it knew the drug was dangerous. They'll say, 'That can't be right!'" he said. "But that could be right, if the Court rules for Wyeth."

The plaintiff in the *Wyeth* case, musician Diana Levine, lost an arm to gangrene, caused by an antinausea drug given by "IV push" straight into a vein. She sued the drug maker, Wyeth, for failure to warn of the dangers of administering the drug, Phenergan, this way. Wyeth claimed the case was preempted because the FDA had approved the drug's labeling.

The Vermont Supreme Court upheld a jury award to Levine, finding that a 1962 amendment to the Food, Drug, and Cosmetic Act (FDCA) "removes from our consideration the question of whether common law tort claims present an obstacle to the purposes and objectives of Congress." It found state claims can be preempted only where compliance with both federal and state law is "a physical impossibility." (944 A.2d 179 (Vt. 2006).)

So Wyeth took it to the sheriff, proclaiming to the Court that the suit is barred because the FDA approved the medicine's prescribing information. Both sides filled their holsters with amicus briefs and lined up.

For consumers injured by defective drugs, the best outcome would be a ruling for Levine—and the worst could be the Court's determination that her failure-to-warn claim is preempted because of Phenergan's FDA-approved labeling. But attorneys say it's not that simple.

"There are so many different ways that the Court could decide the case," said Lou Bograd, senior litigation counsel at the Center for Constitutional Litigation and the author of AAJ's amicus brief. If the Court rules for Levine, "it is likely that most failure-to-warn claims against drug companies will not be preempted, though there will still be difficult legal issues to resolve in cases involving generic drugs, as well as those involving warnings [sought by plaintiffs] that were expressly considered and rejected by the FDA." Preemption could still be asserted in such cases.

In the worst case, Bograd said, the Court could rule that all failure-to-warn claims are preempted unless based entirely on new information the manufacturer obtained after FDA approval. "I don't think that the Court is likely to

go that far, but with this Court, you can never be too sure," he said.

Levine's argument is that the FDCA contains no express preemption provision and that there was no evidence that the FDA considered the risks and benefits of the IV push method of administering Phenergan. But Wyeth and its amici—including the Bush administration, the Pharmaceutical Research and Manufacturers of America, the Product Liability Advisory Council, and the U.S. Chamber of Commerce—disagree.

The federal government's brief supporting Wyeth argues that the FDA weighs a drug's risks and benefits when approving its label and that there are narrow circumstances in which a drug maker can change a label without prior approval from the agency. "Because FDA's approval strikes a balance between competing considerations, state laws that strike a different balance conflict with FDA's determination and are impliedly preempted," the government argues.

Other Wyeth amici say that the presumption against preemption doesn't apply to preemption that arises from actual conflict between federal and state law, and at least one brief claims that as more warnings appear on drug packaging, more patients are harmed because the warnings convince them not to take their prescribed medications. One brief depicts various harms to public welfare, such as an increase in measles cases caused by parents failing to have their children vaccinated.

Medical journal speaks out

But a diverse alliance of doctors, public health advocates, and plaintiff and public-interest lawyers reject those arguments. In an indication of the case's importance to the medical community, editors of the *New England Journal of Medicine* filed their first-ever legal brief, supporting Levine's position. With the assistance of the public-interest law firm Public Justice, 10 current and former editors of the journal argue that consumers should be allowed to sue drug makers for failing to warn of dangers even if the FDA approved prescribing literature for the drug.

"The drug companies have withheld key information from the FDA and ardently negotiated against stricter label warnings—all the while continuing to market their unsafe drugs to an unsuspecting public," the editors say in the brief. They cite the withdrawal of Vioxx, Trasylol, fen-phen, and Redux from the market as examples of the pharmaceutical industry's failure to adequately warn consumers of drug hazards even when the manufacturers knew of the risks.

The editors argue that the FDA lacks sufficient information and resources to serve as the sole monitor of pharmaceutical risks, that federal preemption of failure-to-warn claims would pose a serious threat to public health and safety, and that effective monitoring of drug risks requires a robust tort system.

Leslie Brueckner of Public Justice's Washington, D.C., office, who wrote the brief, said a decision wiping out all failure-to-warn claims involving prescription drugs would be "a public health disaster." Her brief argues that "litigation is often the only way to dig up information regarding inadequacy of drug labels. This information can, in turn, spur the agency to put pressure on the manufacturers to improve the labels."

Pogust, echoing Brueckner's brief, said, "In reality, what works is the lawsuits. The FDA doesn't have the subpoena power to do what we do as lawyers. It's not as well equipped to find out bad information as we are. The system was working fine with the FDA and Congress and lawyers working together. . . . We'll lose a big weapon in trying to protect the public health and welfare by removing the chance of litigation."

Pogust hopes that the result of *Wyeth* will be that "the legal system will continue as it has for the last 70 years, with the FDA and the tort system working hand in hand to protect the health and welfare of all citizens."

AAJ's amicus brief highlights the "special circumstances" required for a failure-to-warn claim to succeed against a manufacturer whose label received FDA approval. A plaintiff in such a case "will not prevail . . . unless she can come forward, as Diana Levine did, with evidence that under the circumstances a reasonable drug company would have done more to warn of the dangers posed by its product," Bograd argued in AAJ's brief.

Citing the language of the FDCA, the brief notes that "where such special circumstances exist, a determination of state tort liability against the company cannot be said to be in 'direct and positive conflict' with FDA labeling determinations."

Collyn Peddie, a Houston trial and appellate attorney with an interest in preemption, said a Court finding that only "direct and positive" conflicts lead to preemption would be "the best-case scenario."

"Under this true-conflicts preemption, a drug company must have presented the precise language you urge in a proposed label to the FDA, and the FDA had to have rejected that label as scientifically unfounded," she said. "Most cases don't fit this mold, so most would not be preempted." She cited Vioxx and Paxil as examples.

If the Court is consistent with its decision in *Riegel*, Peddie said, it might rule that "it is impossible for the FDA to do its job and for drug companies to comply with its regulations in the face of state tort claims." However, "there is no express preemption language in the

A brief filed by* New England Journal of Medicine *editors said that preemption of failure-to-warn claims would pose a serious threat to public health and safety.

FDCA, so it will be difficult for the Court to get to this result."

San Francisco plaintiff attorney Lori Andrus is optimistic that "the Court will surprise us." Because the *Riegel* decision was narrowly drawn and the Court is not of one mind on preemption issues, even if it finds preemption, "I sincerely doubt that the Court will foreclose all lawsuits against drug manufacturers," she said.

If the Court rules for Wyeth, "plaintiff attorneys will have to be careful to distinguish their case from the facts of *Wyeth v. Levine*," Andrus noted. They will need to point out when a drug company failed to meet its obligations under various federal regulations or if there are manufacturing defects, she said.

"Plaintiff lawyers are a creative bunch, and we're used to adapting," she said. "They'll keep coming at it from every angle, and so will we." Furthermore, "if the Court's decision in *Wyeth v. Levine* is broad enough to eliminate pharmaceutical accountability altogether, I cannot imagine that ordinary citizens, or our elected officials, would stand for that for long."

Pogust hopes for a quicker fix: "The way the Supreme Court has been lately has worried all of us. You hope they see the light, read these briefs, and do the right thing." ■

—Rebecca Porter

FDA advisory does not preempt failure-to-warn suit, Third Circuit rules

The U.S. Court of Appeals for the Third Circuit has reversed a district court's dismissal, on preemption grounds, of a failure-to-warn lawsuit seeking damages for injuries the plaintiff allegedly sustained from ingesting methylmercury and other harmful compounds in tuna fish.

"This is a situation in which the FDA has promulgated no regulation concerning the risk posed by mercury in fish or warnings for that risk, has adopted no rule precluding states from imposing a duty to warn, and has taken no action establishing mercury warnings as misbranding under federal law or as contrary to federal law in any other respect," the court held. (*Fellner v. Tri-Union Seafoods, LLC,* 2008 WL 3842925 (3d Cir. Aug. 19, 2008).)

"What the Third Circuit did was make very clear that in order for there to be preemption, there needs to be a formal regulation or law that went through normal review, rather than informally without any checks and balances," said William Crutchlow of Edison, New Jersey, who represents the plaintiff, Deborah Fellner.

Fellner has various digestive problems and for a number of years was unable to eat many foods other than tuna. She alleged that she contracted severe mercury poisoning as a result of her ingestion of methylmercury in