

Are Common-Law Product Liability Claims Involving Prescription Drugs Subject to Implied Conflict Preemption?

by James M. Beck

PREVIEW of United States Supreme Court Cases, pages 80–84. © 2008 American Bar Association.

Case at a Glance

Plaintiff lost an arm after a drug manufactured by the defendant was administered. The reaction that resulted in the injury was a known danger and made worse by the method of administration. Prior to the injury, the FDA had evaluated the drug and approved both it and that method of administration. Plaintiff argues that the defendant should have contraindicated the method, even if that meant altering and supplementing the warnings mandated by the FDA. *Levine* will determine whether product liability claims involving FDA-approved products are subject to preemption.

James M. Beck is “of counsel” in the Product Liability litigation group of Dechert, LLP, in the Philadelphia office, where he specializes in defending product liability claims involving FDA-regulated prescription products.

Mr. Beck is one of two regular contributors to the blog <http://druganddevicelaw.blogspot.com/>, which frequently discusses preemption issues. He can be reached at james.beck@dechert.com or (215) 994-2970.

Product liability actions against Food and Drug Administration (FDA)-approved prescription drugs have been a growing area of the law for two decades. Where the defendant’s labeling complies with the FDA’s approved language, there is an inherent tension with product liability claims alleging that the labeling is inadequate. For many years, most courts refused to hold FDA labeling decisions preemptive of state-law tort claims in drug cases because there was no express preemption language in the statute, and because they viewed FDA warnings as minimum standards that states could supplement without conflict in tort litigation. Absent substantial judicial restraint, product liability claims trended to more direct challenges to FDA-approved labeling, and other administrative decisions. *Buckman Co. v. Plaintiffs’ Legal Committee*, 531 U.S. 341 (2001) (holding so-

called “fraud on the FDA” preempted, was a watershed in two ways). *Buckman* was the first decision affirming implied preemption under the Food, Drug & Cosmetic Act (FDCA), and it was the first time the FDA itself went on record supporting preemption.

After the Court agreed with the FDA’s preemption position in *Buckman*, the agency became more aggressive in asserting preemption in certain situations. After meeting with mixed success for several years, in early 2006 the FDA issued a final rule, 71 Fed. Reg. 3922 (FDA Jan. 24, 2006), which took the position that its approved labeling is not a “minimum standard” or a “floor.” Since the 2006 Final Rule there has been an explosion of preemption litigation, and courts deciding the issue have split approximately evenly. The Vermont Supreme Court, in *Levine v. Wyeth*, 944 A.2d 179 (Vt. 2006), was the first state high court to address the issue. The Vermont Supreme Court ruled against preemption, holding that FDA labeling was a minimum standard, that the FDA’s views on preemption were not

WYETH V. LEVINE
DOCKET NO. 06-1249

ARGUMENT DATE:
NOVEMBER 3, 2008
FROM: THE VERMONT
SUPREME COURT



worthy of deference and, further, that certain uncodified statutory language from 1962 precluded preemption by reason of conflict unless simultaneous compliance with both federal and state standards was impossible. The Solicitor General urged the Supreme Court to accept certiorari, and the Court did so in January 2008.

ISSUE

Do the prescription drug labeling judgments imposed on manufacturers by the FDA pursuant to its comprehensive safety and efficacy authority under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq., preempt state-law product liability claims premised on the theory that different labeling judgments were necessary to make drugs reasonably safe for use?

FACTS

Phenergan is a prescription drug made by defendant Wyeth used primarily to treat nausea. The FDA approved Phenergan as safe and effective in 1955. It was approved for administration either by intramuscular or intravenous (IV) injection. Because IV injection was faster, it was useful to patients needing rapid treatment. The fastest approved method of injection was “IV push”—injecting Phenergan using positive pressure on a syringe inserted directly into a patient’s vein.

Phenergan can cause gangrene if injected into an artery. This risk was known and included on the label since 1967. In 1975, the FDA reviewed the risks of arterial injection and instructed defendant to include several specific warnings about IV push and potential gangrene. Defendant did so. In 1976 the FDA prohibited (contraindicated) arterial injection but not other forms of IV use. Again, defendant

complied. The FDA approved further label changes related to gangrene and IV administration in the 1980s, including means to avoid inadvertent arterial injection.

In 1997, the FDA approved additional labeling changes, but instructed defendant to “retain” its “current label” concerning inadvertent arterial injection. Defendant had to use labeling “identical” to what the FDA had approved. By 2000, Phenergan labels contained several approved warnings and instructions concerning IV injection, gangrene and amputation risks, and ways to minimize these risks. Because of these risks, IV push injection was not “preferred,” but it remained a permissible method of administration.

Plaintiff received Phenergan by IV push in April 2000, as a treatment for nausea caused by severe headaches. The preferred method of intramuscular injection was used initially but was not effective. Plaintiff then received a second dose, twice the labeled maximum, by IV push. By mistake, at least some of the drug was injected into an artery, leading to gangrene, and the amputation of plaintiff’s forearm.

Plaintiff sued both her doctor and the defendant. She settled with her doctor and recovered a \$7.4 million verdict against defendant. Plaintiff contended that defendant’s labeling was defective because IV push administration should have been prohibited altogether by stating “do not use this drug intravenously.” Plaintiff claimed that the FDA made a mistake in approving IV use and that its risk/benefit determination was wrong. The defendant unsuccessfully argued that FDA approval of IV use preempted these claims. The jury was instructed that it could reach a different result than the FDA.

On appeal, the Vermont Supreme Court held, first that it was not impossible for defendant to conform to the state standard of care because FDA warnings were “minimum standards” and defendant was free, if it filed a “changes being effected” (CBE) supplement, to change its labeling unilaterally to delete IV administration. Preemption, the court also held, would only exist upon proof that the FDA would have rejected the specific label change sought by plaintiff. The court held that the uncodified language in a 1962 FDCA amendment providing for preemption only in cases of “direct and positive conflict” with state law barred preemption of any conflict less than “impossibility” compliance.

CASE ANALYSIS

Defendant-petitioner Wyeth argues that the respondent-plaintiff’s claims are impliedly preempted by reason of conflict for two reasons. The first basis for preemption is that it was impossible for Wyeth both to contraindicate IV use of Phenergan as a matter of state law, yet also to comply with its FDA approval, which includes, and thus allows, the same use. Under the FDCA, the FDA determines the methods of drug use that are safe and effective, and the manufacturer must label its drug exactly as the FDA directs. After approval, defendant contends, it cannot ordinarily change the labeling absent FDA authorization, and it could not have done so in the fashion plaintiff demanded.

The CBE regulation, according to defendant, is a limited exception to FDA preapproval that does not reach this case because it applies only to newly acquired information about drug risks. There was, defendant argues, no new risk information about IV use of Phenergan to support a label change without prior

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FDA approval. The FDA's instructions to defendant were made with full information about the relevant risks and benefits of the drug. Thus, defendant contends that it could not have made the change that state law required without violating the FDA's regulations.

Defendant's second basis for preemption is that unauthorized state-law label changes are "obstacles" to "the full purposes and objectives of Congress." The FDCA, in defendant's view, contemplates that the FDA will review and approve new drugs in light of specific labeling and will use its expertise to balance such drugs' risks and benefits. The agency determines when the benefits of a particular treatment, such as IV push Phenergan, outweigh their known risks of harm. With respect to drug risks, the FDA decides what information is necessary to use the drug safely and effectively. It did that with Phenergan, defendant argues, balancing the superior efficacy of IV push against its greater risks. The lower court was wrong, defendant argues, in holding that this process merely set minimum standards that a state may supplement at will.

It is also the defendant's position that there should be no presumption against preemption in cases in which preemption arises by virtue of a conflict that brings the Supremacy Clause directly into play. There is little Supreme Court support for applying a presumption in cases involving conflicts, as opposed to express or field preemption. Instead of a presumption, the defendant contends that the scope of the conflict determines the scope of preemption.

Defendant's position is that plaintiff's common law claim would replace expert FDA judgment with decisions by lay jurors based on dis-

parate state law. Jury trials focus on individual injuries rather than the benefits of a drug to society as a whole. That approach inevitably leads to overwarning and underuse of drugs. According to the defendant, a common law claim would also be second-guessing the FDA's risk/benefit analysis and its expert determination of optimal drug labeling—thereby upsetting the expert balance struck by the FDA.

Plaintiff-respondent counters, first, that there must be a clear showing of congressional intent to preempt, which does not exist in this case because Congress was well aware of state-law remedies when it enacted the FDCA. Congress neither provided a private FDCA right of action nor expressly provided for preemption (unlike the act regulating medical devices) in the numerous amendments Congress made to the statute over the past 70 years.

Plaintiff contends that it was possible to comply with both federal and state labeling requirements because the FDA's CBE process allows drug manufacturers to add and strengthen the warnings and instructions on their labeling. Thus defendant could have added stronger warnings against IV push. As long as the new information is true and accurate, the drug cannot be misbranded, and according to plaintiff there is no evidence that a stronger warning about IV push injection would have been rejected.

Plaintiff rejects defendant's other arguments as well. According to the plaintiff, the defendant's critique of jury behavior is erroneous because, under federal law, juries also determine misbranding issues. A strengthened warning would not have made Phenergan an unauthorized new drug, according to plaintiff, because it would retain all its approved intended uses, and the

only change would have been stronger warnings against IV push injection.

The FDA's CBE regulation is key to plaintiff's arguments. That regulation, plaintiff contends, allowed defendant to strengthen the labeling after FDA approval as long as data existed to support the change. Regardless of administrative history, the regulation's text contains no limitation restricting its use to newly discovered information. The FDA's view is entitled to no deference, plaintiff contends, because the language is unambiguous and because the agency is attempting to rewrite the CBE regulation through interpretation. Moreover, even the FDA's view allows for reanalysis of existing information, which plaintiff claims is what defendant should have done with Phenergan.

According to the plaintiff, there is no inherent conflict between paying a damages judgment and opting to retain FDA-approved labeling. There is no claim for injunctive relief; thus any effect on defendant's federal compliance would be incidental rather than mandatory. The plaintiff claims that such incidental consequences do not give rise to preemption, since defendant remains free to sell its drugs and conduct its own cost-benefit analysis concerning whether it should also comply with state law.

Plaintiff also opposed preemption because the complementary safety purposes of both state and federal laws with respect to prescription drugs mean that state law is not obstructing the federal purpose. Federal and state law both require drugs to carry adequate warnings and instructions. State tort claims promote federal objectives by encouraging manufacturers to find and communicate the most current risk information available. State law



respects federal law by allowing evidence of FDCA compliance as a defense to claims alleging failure to warn. State law simply provides the compensatory mechanism that federal law lacks, and that mechanism in and of itself provides additional incentive for manufacturers to provide adequate warnings.

Nor does plaintiff perceive any conflict with any FDA risk/benefit balancing. The record does not reveal that the FDA ever actually balanced risks and benefits specifically with respect to Phenergan and the IV push method of administration. Thus it is plaintiff's position that there was never any deliberate federal judgment to obstruct.

Plaintiff further disputes the government's position that whenever the FDA approves labeling while considering the relevant risk there should be preemption. That position, according to the plaintiff, would lead to overly broad preemption because the risk in this case is not merely that arterial exposure to Phenergan causes gangrene. Plaintiff would not divorce risk from benefit, and considers the knowledge question to turn on whether IV-push use of Phenergan exacerbates the risk of gangrene without any countervailing benefit.

Plaintiff's final argument is that the government's position that the FDCA preempts state tort claims is entitled to no deferential weight. Even the government concedes that only *Skidmore* (*Skidmore v. Swift & Co.*, 323 U.S. 134 (1944)) deference could apply. *Skidmore* deference is nonbinding and limited to how "persuasive" a court finds an agency conclusion. Even such minimal deference, plaintiff contends, is defeated here by the inconsistency and unpersuasiveness of the FDA's positions. For decades the FDA viewed the common law as comple-

mentary to its regulatory mission. Its current position rises, plaintiff asserts, from its view of policy, not the agency's view of the law.

SIGNIFICANCE

Levine is, and deserves to be, one of the most watched civil cases of this term. Prescription drug product liability is probably the largest generator of mass torts. The FDCA's requirements concerning drugs (unlike its more recently enacted provisions relating to devices) have no express preemption language. Therefore, until recently such litigation proceeded with little or no concern for consistency with FDA regulations. *Levine* could change all that.

A preemption ruling in *Levine*, even if narrowly limited to the somewhat unusual facts of the case (most drug litigation does not involve a claimed failure to contraindicate a particular use), would establish the foundational principle that implied preemption does apply to prescription drug litigation—and will probably determine the fate of several other broadly applicable legal propositions asserted by one side or the other. With these propositions established, all subsequent litigation would concern only the scope, not the existence, of preemption. Thus, like the visage of Helen of Troy, a ruling in favor of preemption in *Levine* would launch a plethora of litigation involving whether the preemption defense should extend to other fact patterns.

The facts of *Levine* are relatively favorable to a preemption finding. The risk in *Levine* was the subject of extensive warnings. Furthermore, there are no claims that the defendant misled the FDA or otherwise failed to comply with relevant regulations. The case does not involve a failure to disclose new information.

Moreover, the conflict—between FDA approval of a particular method of drug administration and a common-law allegation that this FDA-approved use should have been prohibited—is more direct than in many other product liability suits involving prescription drug warnings. The converse of facts favorable to preemption is, of course, the likelihood that a ruling against preemption would effectively end any broad role for this defense in the prescription drug arena.

The particular facts of *Levine*, while seemingly favorable to the defendant's objective of establishing the foundations of preemption in this case, could actually benefit plaintiffs in other litigation should they have to argue that a preemption ruling in *Levine* is distinguishable. Many claims, particularly in mass torts, have some or all of the factual attributes that *Levine* lacks.

Finally, because *Levine* involves implied preemption, any decision will inevitably implicate litigation having nothing to do with prescription drugs. A general ruling in *Levine*, such as the fate of the presumption against preemption or the effect of implied preemption on common-law tort claims, will have broad applicability to other regulated products. However the Court rules, its decision will affect tort claims involving federal agencies, such as the National Highway Traffic Safety Administration (NHTSA)—motor vehicles; the Environmental Protection Agency (EPA)—chemicals, pesticides, and herbicides; the U.S. Department of Agriculture (USDA)—agricultural products; and the Consumer Product Safety Commission (CPSC)—many household products, to name a few of the most obvious examples.

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ATTORNEYS FOR THE PARTIES

For Petitioner Wyeth (Seth P. Waxman (202) 663-6000)

For Respondent Diana Levine (David C. Frederick (202) 326-7951)

AMICUS BRIEFS

In Support of Petitioner Wyeth

Chamber of Commerce of the United States of America (Alan E. Untereiner (202) 775-4500)

DRI - The Voice of the Defense Bar (Daniel E. Troy (202) 736-8000)

Generic Pharmaceutical Association (Jay P. Lefkowitz (212) 446-4800)

John E. Calfee et al. (W. Mark Lanier (713) 659-5200)

Pharmaceutical Research and Manufacturers of America (Robert A. Long Jr. (202) 662-5612)

Product Liability Advisory Council, Inc. (Product Liability Advisory Council, Inc. (202) 263-3000)

United States (Gregory G. Garre, Solicitor General (202) 514-2217)

Washington Legal Foundation et al. (Eric G. Lasker (202) 898-5800)

In Support of Respondent Diana Levine

AARP et al. (Charles L. Becker (215) 772-1000)

American Association for Justice (Louis M. Bograd (202) 944-2803)

Anju Budhwani, M.D., et al. (Stanley D. Bernstein (212) 779-1414)

California Medical Association (Collyn A. Peddie (713) 230-2200)

Center for State Enforcement of Antitrust and Consumer Protection Laws, Inc. (Thomas W. Merrill (203) 436-8990)

Citizens Commission on Human Rights (Kendrick L. Moxon (213) 487-4468)

Constitutional Accountability Center (Elizabeth B. Wydra (202) 296-6889)

Constitutional and Administrative Law Scholars (Ernest A. Young (919) 613-8506)

Consumers Union of the United States (Mark R. Savage (415) 431-6747)

Daniel Paul Carpenter et al. (Gregory S. Coleman (512) 533-0150)

David B. Ross, M.D., and Stefan P. Kruszewski, M.D. (Michael J. Quirk (215) 557-0099)

DES Action (Aaron M. Levine (202) 833-8040)

Former FDA Commissioners Dr. Donald Kennedy and Dr. David A. Kessler (David C. Vladeck (202) 662-9540)

Kim Witezak, Sara Bostock, and Healthy Skepticism (W. Mark Lanier (713) 659-5200)

Members of Congress (Jonathan S. Massey (301) 915-0990)

National Coalition Against Censorship (Erwin Chemerinsky (949) 824-7722)

National Conference of State Legislatures (Elizabeth J. Cabraser (415) 956-1000)

New England Journal of Medicine Editors and Authors (Gerson H. Smoger (510) 531-4529)

Senior Citizens League (John S. Miles (703) 356-5070)

Texas Medical Association et al. (R. Brent Cooper (214) 712-9500)

Torts Professors Mark P. Gergen and Michael D. Green (Michael F. Sturley (512) 232-1350)

Vermont et al. (Aaron M. Levine (202) 833-8040)