Legal Backgrounder

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FDA SHOULD PROPOSE RULE ON FEDERAL PREEMPTION OF FAILURE-TO-WARN LAWSUITS

by

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A week before Victor Motus' suicide, Dr. Trostler, an internist, had diagnosed Mr. Motus as moderately depressed and prescribed the anti-depressant drug 'Zoloft.' Dr. Trostler filled this prescription by giving Mr. Motus a free sample of Zoloft.

The package insert for Zoloft, as approved by the Food and Drug Administration (FDA), warned that suicide is a risk for depressed patients and noted that suicide attempts had occurred during the clinical trials of Zoloft, although these attempts were "not necessarily caused by" Zoloft. Dr. Trostler, however, did not read the package insert for Zoloft until after Mr. Motus committed suicide. While Dr. Trostler had heard claims that antidepressants of the same general type as Zoloft were linked to increased risk of suicide, his clinical experience led him to not believe these claims. Still, he testified that he would have warned Mr. Motus of the suicide risk if he had been told that this risk existed.

Background of Motus v. Pfizer

Mr. Motus' tragic suicide is a fault line on which an earthquake may be about to rumble through pharmaceutical product liability law. His widow sued Pfizer, the manufacturer of Zoloft, alleging that Pfizer failed "to adequately warn the medical community," and that "Zoloft was not accompanied by proper warnings" about the risk of suicide. The district court granted Pfizer summary judgment on the ground that there was no evidence that a different warning about suicide would have changed Dr. Trostler's decision to prescribe Zoloft for Mr. Morus. *Motus v. Pfizer, Inc.*, 196 F. Supp. 2d 984, 996 (C.D. Cal. 2001), *appeal pend'g,* No. 02-55372 (9th Cir.).

Pfizer, however, had also moved for summary judgment on the ground that FDA had approved

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the package insert for Zoloft, including the suicide-related warnings, and, consequently, Mr. Motus' widow's claim that "Zoloft was not accompanied by adequate warnings" should be preempted by federal law. The district court rejected this argument, primarily because, as it read FDA's regulations, Pfizer was free to strengthen the warnings in the package insert without prior FDA approval. *Motus v. Pfizer, Inc.*, 127 F. Supp. 2d 1085, 1094 (C.D. Cal. 2000), *cross-appeal pend'g,* No. 02-55372 (9th Cir.). While the court recognized that some suicide-related warnings might violate the Food, Drug and Cosmetic Act (FDCA), it still held out the possibility that some such warning, in addition to those actually in the package insert, might be consistent with federal law. This, according to the district court, meant that there was no necessary conflict between the widow's failure-to-warn claim and FDA's regulations, and hence no preemption.

In reaching this holding, the district court fell into rank with dozens of other courts that have rejected claims that FDA regulation of the warnings given for prescription drugs, no matter how pervasive, is merely "minimal" and does not preempt state law failure-to-warn claims. The district court in *Motus* was unusual only in focusing on the specific FDA regulations governing approval of the package insert and in giving consideration to whether those regulations would prohibit "any and every suicide-related warning that might be required under state law." Many other courts facing this issue have known little and cared less about FDA's regulations and function. In particular, the courts have not recognized the irony that both state product liability law and Congress in the FDCA have used the exactly the same term — "adequate" — to describe the warnings that must be given of the risks of a prescription drug. *Compare Motus*, 196 F. Supp. 2d at 990 ("It is well-settled that a manufacturer of prescription drugs owes to the medical profession the duty of providing adequate warnings . . . ."), *with* 21 U.S.C. § 352(f) (requiring "adequate" warnings against any use dangerous to health).

FDA's Persuasive Amicus Brief

In *Motus*, both sides appealed to the U.S. Court of Appeals for the Ninth Circuit, which is scheduled to hear oral argument on October 10, 2003. In a novel and important development, FDA submitted an *amicus* brief to the circuit court in support of Pfizer's argument that plaintiff's failure-to-warn claim is preempted. While FDA has submitted *amicus* briefs in the past in cases involving express preemption, or involving prospective injunctive relief, the appeal in *Motus* is the only case where FDA has submitted an *amicus* brief in support of the argument that the FDCA preempts by implication a failure-to-warn tort action for damages brought under state law. The Ninth Circuit has granted both FDA and Ralph Nader's Public Citizen group (which filed an *amicus* brief opposing preemption) leave to participate in the *Motus* oral argument on October 10, which should make for an interesting sporting event.

FDA's first argument in *Motus* is simple: "The Supremacy Clause bars a state from demanding that the manufacturer of a drug choose either to avoid tort liability or comply with the FDCA." This is red-blooded "conflict" preemption: if state law and federal law conflict so that a party cannot comply with both, the state law is preempted. The key question, though, is whether Pfizer — as the district court thought — could have strengthened the suicide warning in the package insert without violating the FDCA. In its *amicus* brief, FDA argued that Pfizer could *not* have strengthened this warning, because "the agency three times considered and rejected claims that [anti-depressant drugs of the same class as Zoloft] cause suicide." In FDA's view, "had Pfizer given a warning as to a causal relation between Zoloft and suicide, FDA would have disapproved that warning." Thus, contrary to the district court's conclusion, Pfizer could not have strengthened the suicide-related warning without violating the FDCA and FDA's regulations.

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The suicide-related warning at issue in *Motus* is unusual because FDA not only approved the package insert for Zoloft, as is required for any prescription drug that is the subject of an approved New Drug Application, but also specifically and repeatedly considered the suicide risk on a 'class' basis — that is, whether anti-depressant drugs of the same general type as Zoloft carry an increased suicide risk. Having considered this issue, FDA concluded these drugs did not increase this risk. The case for conflict preemption under these facts is especially strong: any jury verdict for Mr. Motus' widow would flatly contradict FDA's express scientific judgment on a matter Congress has placed squarely in FDA's regulatory lap.

FDA's second argument, though, has far broader implications: in addition to conflict preemption, FDA also argued that Mr. Motus' widow could not pursue her failure-to-warn claim because to do so would prevent "the accomplishment and execution of the full purposes and objectives of Congress." True, FDA tip-toed into this argument with only two pages at the end of its twenty-five page *amicus* brief, but these two pages might prove to be a case of the number of words being inversely related to the importance of the issue. FDA, in this second argument, asserts that its regulations are "designed to ensure each drug's optimal use through requiring scientifically substantiated warnings." Warnings that are "scientifically unsubstantiated" could "deprive patients of beneficial, possibly lifesaving treatment," which would frustrate the purpose of federal regulation.

The implication of FDA's second argument is that Congress has made FDA the 'gatekeeper' in charge of deciding which warnings are scientifically substantiated, and which are not. To permit Mr. Motus' widow to argue to a jury that a different warning should have been made available to Dr. Trostler would circumvent FDA's gatekeeper role and so frustrate the congressional purpose. This frustration-of-congressional-purpose argument does not depend on FDA having made any express scientific determination on a particular warning. Instead, it hinges on whether Congress, in enacting the FDCA, meant to allocate any scientific decision-making role to state-law juries. This frustration-of-purpose argument is more nuanced and far-reaching than simple conflict preemption.

In *Motus*, the Ninth Circuit may sidestep the preemption issue altogether and instead focus on the state-law implications of Dr. Trostler's decision to prescribe Zoloft — a decision he made without reference to the FDA-approved package insert. If, however, the Ninth Circuit decides the preemption issue in favor of Pfizer and FDA, its decision likely will undercut the legal basis of many pharmaceutical product liability cases — at least in the Ninth Circuit. The result would be that plaintiffs in, for example, Illinois, might then be entitled to pursue failure-to-warn claims against drug manufacturers, but plaintiffs in, say, Washington State would not. The U.S. Supreme Court would be likely to grant certiorari, and the stage then would be set for a major constitutional fight.

Beyond Amicus: Codify Preemption of State Claims Through a Rulemaking

In light of its *amicus* position in *Motus* that the FDCA preempts all or at least some failure-to-warn claims, FDA should begin a notice-and-comment rulemaking on a proposed regulation that would set out the precise boundaries of state-law failure-to-warn claims that are preempted. If FDA, as it has argued to the Ninth Circuit, is of the opinion that its regulation, pursuant to the FDCA, of the warnings given physicians about prescription drugs preempts all or some failure-to-warn product liability claims, then that view should have the force of law in a validly-adopted regulation that has uniform effect across the country.

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It may be that FDA assumes that, one way or another, this issue is one for the U.S. Supreme Court, and so pushing along the right case — *Motus*, for example — is the most efficient way to arrive at a final answer. There are, however, two reasons FDA should not rely on litigation alone to bring this issue to a head. First, FDA's position in its *Motus amicus* brief, standing alone, may not be entitled to deference under *Chevron U.S.A., Inc. v. NRDC,* 467 U.S. 837 (1984), because FDA's interpretation of the preemptive effect of the FDCA in its *amicus* brief may not have been adopted in exercise of its authority to make rules with the force of law. A regulation adopted through notice-and-comment rulemaking, in contrast, should be entitled to *Chevron* deference. *Chevron* deference is the home court advantage for administrative agencies, and FDA should insist on playing this game at home.

Second, some plaintiffs have argued that FDA, in the preamble to its final regulation on patient medication guides, 63 Fed. Reg. 66378, 66384 (Dec. 1, 1998), affirmatively disclaimed any contention that the FDCA preempted state tort law. FDA in that preamble stated that its regulations "establish . . . minimal standards," and that states may authorize "additional labeling," as long as they do not alter "FDA-required labeling." *Id.* These statements, however, were made in the context of state laws requiring pharmacists to counsel patients about prescription drugs. FDA may not have meant these statements to apply more broadly to failure-to-warn claims, but still they might be read to suggest that FDA has now changed its interpretation of the law without an appropriate explanation and opportunity for comment. In any event, FDA's 1998 statements about preemption predated *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861 (2000), where the Supreme Court held that a products liability claim was preempted by implication because of a federal safety standard, even though the federal agency adopting the standard never asserted that the standard had preemptive effect. Geier broadened significantly the scope of preemption of product liability claims. The solution is to conduct a rulemaking that would clarify or revoke this preamble statement.

FDA should consider in a rulemaking the potential situation where a plaintiff submits a citizen petition to FDA, under 21 C.F.R. §10.30, seeking FDA's reconsideration of whether an FDA-approved warning is adequate. The proposed rule could offer any plaintiff the opportunity to submit such a petition that would contain all relevant data, as well as proposed language for a warning that, in the plaintiff's view, would have been adequate. (The district court in *Motus* noted that Pfizer was at a disadvantage in the litigation because Mr. Motus' widow never staked out exactly what warning she contended Pfizer should have given.) If any party disagreed with FDA's disposition of the petition, the remedy would be a petition for judicial review under the Administrative Procedure Act. The final determination of the petition would be binding on the court in plaintiff's failure-to-warn case. The case law supports recognizing FDA's primary jurisdiction in this context. *Bernhardt v. Pfizer, Inc.*, 2000 WL 1738645 (S.D.N.Y. Nov. 22, 2000) (finding that FDA had primary jurisdiction of claim by product liability plaintiff that defendant should be ordered to send a "Dear Doctor" letter).

Motus may prove to be an historic case. FDA, though, should not wait for the courts to hold that the FDCA preempts failure-to-warn claims against manufacturers of prescription drugs. FDA has expressed its views in an *amicus* brief; now is the time to do so in the *Federal Register.*

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