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A legal update from Dechert's Mass Torts and Product Liability Group

FDA Supports Implied Preemption of Certain Warning Claims in Product Liability Litigation Involving Prescription Drugs and Biologics

Introduction

On January 18, 2006, the Food and Drug Administration issued a final rule modifying its labeling requirements for prescription drugs and biological products.[1] The new rule—the first significant change in the FDA's drug labeling requirements in more than 25 years—was designed to make labels easier to read and understand for physicians and patients. But the FDA's action will likely also impact product liability litigation against the pharmaceutical industry because the FDA used the new rule as an opportunity to formally state its view that federal drug labeling requirements preempt certain state law claims.

While there is no guarantee that courts will accept the FDA's view on preemption, the new rule will likely strengthen the pharmaceutical industry's defense of failure to warn claims with courts and juries. Under the *Chevron* doctrine, courts will be required to give great deference to the FDA's formal determination that certain state law claims are preempted.

In addition, federal law requires courts to take judicial notice of the contents of the Federal Register. Defense counsel therefore should be able to present to juries the many helpful factual findings about the labeling process contained in the rule. While it is no panacea to the ongoing litigation threats the pharmaceutical industry faces, the new rule will likely be an important tool for defense counsel in the coming years.

Background

The preemption defense is grounded in the Supremacy Clause of the U.S. Constitution. Because federal law is supreme, in certain circumstances states cannot take legislative or judicial action that conflicts with federal legislation or regulation. These circumstances include:

- **Express Preemption**—In some instances, Congress has explicitly stated that federal law precludes state action. Perhaps the best-known example of such express preemption is the federal regulation of cigarette labeling.[2]

- **Implied Preemption**—In other instances, Congress has not expressly stated that state action is preempted, but preemption is nonetheless implied—either because state action would "conflict" with federal action, or because the federal scheme "occupies the field" leaving no room for state action. For example, in *Geier v. American Honda Motor Co.*,[3] the Supreme Court held that federal law preempted a state-law design defect suit against a car manufacturer for failing to install airbags. The Court found that the Department of

[1] *See* Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (FDA Jan. 24, 2006).

[2] *See* 15 U.S.C. § 1331 *et seq.; Cipollone v. Liggett Group, Inc.,* 505 U.S. 504 (1992).

[3] 529 U.S. 861 (2000).

Transportation had considered and rejected a regulation that would have required airbags in all cars. Holding the manufacturer liable under state law therefore posed "an obstacle to" the DOT's deliberate policy decision not to require airbags.[4]

- **Fraud on the FDA**—In *Buckman v. Plaintiffs' Legal Committee,*[5] the Court held that so-called "fraud on the FDA" claims are preempted. In *Buckman*, the plaintiffs claimed that an orthopedic bone screw manufacturer had won approval for its product by making fraudulent misrepresentations to the FDA. Had those misrepresentations not been made, the product never would have been approved and plaintiffs would not have been injured. Such claims are preempted, however, because they "inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives."[6]

For some time now, the FDA has maintained that many—if not most—state-law failure to warn claims are impliedly preempted because they conflict with its drug labeling regulations. Before the new labeling rule, however, that position was set forth only in a handful of *amicus curiae* briefs that the Agency had filed in courts around the country with mixed results.

In formulating the new labeling rule, however, the FDA has taken a more forceful stance on the issue. In an attempt to make labels more useful and more readable, the new rule does not emphasize all risks equally. For example, new labels will include a summary section in the beginning labeled "Highlights." In response to the initial version of the rule, the pharmaceutical industry had warned that the selective highlighting of some risks would leave manufacturers open to state-law failure to warn claims by plaintiffs alleging they were not adequately warned of some of the risks. The FDA heeded this warning and included a formal statement of its view of the preemptive effect of such regulations in the final version of the rule.

4 Id. at 881.

5 531 U.S. 341 (2001).

6 *Id.* at 350.

The New Rule

In the new labeling rule, the FDA states that its authority over drugs is "comprehensive" and its review process is "thorough and scientifically rigorous."[7]

> An NDA ["New Drug Application"] must contain proposed labeling and all information about the drug (whether favorable or unfavorable) that is pertinent . . . . FDA scientists evaluate this information, and may request additional information as necessary . . . . Under the act and FDA regulations, the agency determines that a drug is approvable based not only on an abstract estimation of its safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's benefits and risks . . . . The centerpiece of risk management for prescription drugs is generally the labeling, which reflects thorough FDA review of the pertinent scientific evidence and communicates to health care practitioners the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively.[8]

The Agency was particularly concerned with two types of product liability claims that it saw as likely to arise from its overhaul of drug labeling. First, as was discussed above, because new labels will include a "Highlights" section,[9] there were concerns that inadequate warning claims would be based upon material, contained elsewhere in the labeling, necessarily being omitted from the "Highlights" section.[10] Second, since the new labeling was not applicable to all drugs,[11] there was concern that older labeling would be considered "inadequate" in comparison to the FDA's new requirements.[12]

7 71 Fed. Reg. at 3967.

8 *Id.* at 3968.

9 *Id.* at 3933.

10 *Id.* at 3933-34.

11 The new labeling requirements apply to all newly approved drugs and biologics and to all drugs and biologics that the FDA initially approved (or approved an efficacy statement) after June 30, 2001. *Id.* at 3928.

12 *Id.* at 3934.

The FDA formally stated its view, however, that implied preemption principles apply and its judgments about the format and content of labeling cannot be obstructed by state product liability litigation:

> FDA believes that under existing preemption principles, FDA approval of labeling under the act, whether it be in the old or new format, preempts conflicting or contrary State law.[13]

The FDA first took the position that its regulations concerning supplementation of safety information without prior Agency approval do not preclude preemption. The FDA stated:

> While a sponsor is permitted to add risk information . . . without first obtaining FDA approval . . ., FDA reviews all such submissions and may later deny approval of the supplement, and the labeling remains subject to enforcement action . . . . Thus, in practice, manufacturers typically consult with FDA prior to adding risk information to labeling.[14]

Because any such revisions are reviewed by the Agency, and the Agency must approve them, this option does not detract from FDA control over warnings for preemption purposes:

> In fact, the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act. A manufacturer may, under FDA regulations, strengthen a labeling warning, but in practice manufacturers typically consult with FDA before doing so to avoid implementing labeling changes with which the agency ultimately might disagree.[15]

The FDA also declared the view that its "labeling requirements represent a minimum safety standard" to be a "misunderstanding."[16] Rather, the Agency views its labeling regulations as "both a floor and a ceiling" because of problems caused by over-warning:

> In fact, FDA interprets the act to establish both a "floor" and a "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. Given the comprehensiveness of FDA regulation of drug safety, effectiveness, and labeling under the act, additional requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use. Exaggeration of risk could discourage appropriate use of a beneficial drug.[17]

The FDA also found that product liability litigation could "conflict with" and present an "obstacle" to its enforcement of the FDCA[18] for a number of reasons. Primarily:

> If State authorities, including judges and juries applying State law, were permitted to reach conclusions about the safety and effectiveness information disseminated with respect to drugs for which FDA has already made a series of regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted.[19]

The FDA offered a number of examples of the kind of disruption caused by product liability litigation:

- It "creat[es] pressure on manufacturers to expand labeling warnings to include speculative risks"

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13 *Id.*

14 *Id. See also id.* at 3968.

15 *Id.* (disagreeing with *Eve v. Sandoz Pharmaceutical. Corp.*, No. IP 98-1429--C-Y/S 2002 WL23965 (S.D. Ind. Jan. 28, 2002); *Olher v. Purdue Pharmaceutical L.P.*, C.A. No. 01-3061, 2002 WL 88945 (E.D. La. Jan. 22, 2002); *Motus v. Pfizer Inc.*, 127 F.Supp.2d 1085 (C.D. Cal. 2000); *Bansemer v. Smith Laboratories, Inc.*, C.A. No. 86-C-1313, 1990 WL 132579 (E.D. Wis. Sept. 12, 1988); and *McEwen v. Ortho Pharmaceutical Corp.*, 270 Or. 375, 528 P.2d 522 (Or. 1974)).

16 *Id.*

17 *Id.* at 3935.

18 *Id.* This is the formulaic language of Supreme Court decisions, such as Geier, recognizing implied conflict preemption.

19 *Id.* at 3969.

- It "lead[s] to labeling that does not accurately portray a product's risks, thereby potentially discouraging safe and effective use of approved products or encouraging inappropriate use"

- It "encourage[s] . . . lay judges and juries to second-guess [FDA] assessment of benefits versus risks of [] specific drug[s]"

- It "creates pressure on manufacturers to attempt to add warnings that FDA has neither approved nor found to be scientifically required," leading to "defensive labeling"[20]

Thus, the FDA listed six specific types of product liability claims involving inadequate warning allegations that it believes to be barred by implied preemption:

- Claims asserting that a manufacturer "fail[ed] to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling"

- Claims concerning direct-to-consumer advertising that assert that a manufacturer "fail[ed] to include in an advertisement any information the substance of which appears anywhere in the labeling" where the manufacturer "used Highlights consistently with" the Agency's draft guidance on "brief summaries" in such advertising

- Claims asserting that a manufacturer "fail[ed] to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule" regarding scientific proof of risk

- Claims asserting that a manufacturer "fail[ed] to include a statement in labeling or in advertising" that "had been proposed to FDA" and that the FDA had "not required . . . at the time" the plaintiff claims the warning should have been given (unless the FDA first determined that material information had been withheld)

- Claims asserting that a manufacturer was obligated to include information "the substance of which FDA has prohibited"

- Claims asserting a manufacturer was obligated not to "mak[e] statements that FDA approved for inclusion in the . . .label" (unless the FDA first determined that material information had been withheld)[21]

The Agency concluded its analysis by noting that not all state-law labeling claims may be preempted. Specifically, plaintiffs may be able to assert claims based upon state law requirements that are "parallel" to FDA requirements—though such claims could run afoul of *Buckman* preemption.[22]

Practical Effects

The new labeling rule is likely to have two immediate effects on product liability litigation in the pharmaceutical industry.

First, although it is far from outcome determinative, the FDA's pronouncements will strengthen the argument that state-law failure to warn claims that fall within the relatively broad categories set forth in the Preamble are preempted. There are, however, two caveats. First, as mentioned above, the FDA's views on preemption have previously been stated by the agency in a number of *amicus curiae* briefs, and those earlier pronouncements have been met with mixed results.

Second, although the *Chevron* doctrine requires courts to give substantial deference to an agency's pronouncements regarding the scope and effect of its implementing legislation and regulations, it is unclear what level of deference will be accorded here, where the FDA's view is enunciated in the Preamble to a rule—not a codified regulation. *Cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 500 (1996) (deferring to FDA interpretive regulation concerning scope of express preemption). And, in any event, *Chevron* only requires substantial dereference to an agency's pronouncements: it does not absolutely bind courts to the agency's view. The FDA's firm stand makes it more likely that the preemption issue will eventually be decided by the U.S. Supreme Court, a court

20 *Id.* at 3935.

21 *Id.* at 3936. The Agency did not intend these specified instances of preemption to be exclusive. *Id.* ("at least the following claims would be preempted").

22 *Id.*

that has been increasing willing to find that state law is preempted in recent years.[23]

Regardless of how the legal issue is eventually decided, the new rule should have immediate effects in pharmaceutical product liability trials. Federal law provides that the contents of the Federal Register are subject to mandatory judicial notice in all state and federal courts.[24] Juries will therefore presumably hear the important factual findings contained within the new rule through a defense expert and/or arguments of counsel.

For example, the rule makes strong statements (quoted above) about the thoroughness and scientific rigor of the NDA process, the reality that the FDA is intimately involved in evaluating risk information and determining appropriate warnings, the FDA's practice that manufacturers pre-clear any supplemental warning language with the FDA, and the dangers to public health of over-warning. While these points are typically common themes in pharmaceutical product liability trials, the new rule (together with the requirement of judicial notice) will assure that juries hear from the FDA on these important issues.

Conclusion

The FDA's clarification of its actions as both a ceiling and floor should help correct misimpressions about the role of FDA action and the limited discretion on the part of pharmaceutical companies regulated by it. This long-needed and express clarification benefits everyone.

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[23] *See generally Geier*, 529 U.S. at 861; *Buckman*, 531 U.S. at 341. *But see Sprietsma v. Mercury Marine*, 536 U.S. 921 (2002).

[24] 44 U.S.C. § 1507 ("[t]he contents of the Federal Register shall be judicially noticed . . .").

Practice group contacts

If you have questions regarding the information in this legal update, please contact the Dechert attorney with whom you regularly work, or any of the attorneys listed. Visit us at www.dechert.com/productliability.

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