

## Client Alert

# New FDA Rule on Prescription Drug Package Inserts

Recent years have witnessed a proliferation of product liability actions against pharmaceutical and medical device manufacturers. Frequently, those actions include claims for failure to warn and/or warning defect. One area in which the case law is evolving is the extent to which such claim may be deemed preempted where the manufacturer included in its product labeling the information approved by the United States Food and Drug Administration (“FDA”). FDA recently prefaced a new labeling rule in the Code of Federal Regulations with a statement indicating its belief that many such products liability claims should indeed be so preempted.

On January 18, 2006, FDA announced that it has revised the regulations governing prescription drug labeling (also known as “package inserts” or “professional labeling”), effective June 30, 2006. (*See* 71 Fed. Reg. 3922-3997 (Jan. 24, 2006).)<sup>1</sup> While most of the new requirements apply by their express terms to the labeling of only new and recently approved drugs, some apply to the labeling of older drugs.<sup>2</sup>

Importantly, within the “supplementary information” or preamble document released with (and preceding) the text of the revised regulations, FDA states that **“under existing preemption principles, FDA approval of labeling under the [Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 et seq. (hereinafter, the “Act”)], whether it be in the old or new format, preempts conflicting or contrary State law.”** (*See* 71 Fed. Reg. 3934.)

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<sup>1</sup> The revised regulations will be found at 21 CFR Parts 201, 314 and 601.

<sup>2</sup> The revised regulations impose new requirements governing the content and format of labeling for “new and recently approved” drugs, that is, for all drugs with a new drug application (NDA), biologics license application (BLA) or efficacy supplement that (1) was approved between June 30, 2001 and June 30, 2006; (2) is pending on June 20, 2006; or (3) is submitted anytime on or after June 30, 2006. Perhaps the most important of these new requirements is the addition of introductory prescribing information, called a “Highlights” section. (*See* 71 Fed. Reg. 3986-3996.)

The revised regulations also impose some new requirements on older prescription drugs (that is, on all those other than the “new and recently approved” drugs). (*See* 71 Fed. Reg. 3996-3997.) Manufacturers of older drugs now have the option of either reprinting the FDA-approved patient labeling information immediately following the last section in the package insert -- the requirement in the old rule -- or having the FDA-approved patient labeling accompany the package insert. Further, the new rule for older drugs now expressly prohibits a package insert from including any language that implies or suggests an indication, use or dosing regimen that has not been expressly included in the “Indications and Usage” or “Dosing and Administration” section, and that is not “supported by substantial evidence of effectiveness based on adequate and well-controlled studies as defined in § 314.126(b) ... unless the requirement is waived....”

As explained by FDA, federal prescription drug labeling is “[t]he centerpiece of risk management for prescription drugs” because it “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.” (*See* 71 Fed. Reg. 3934 and 3968.) Further, contrary to what some courts have concluded, federal prescription drug labeling requirements represent both a “floor” and a “ceiling,” according to FDA. (*See* 71 Fed. Reg. 3934-3935.) Thus, “the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA’s under the act,” and, accordingly, state law product liability claims that assert that manufacturers should have strengthened a drug’s warnings without first obtaining FDA approval “frustrate the agency’s implementation of its statutory mandate.” (*See* 71 Fed. Reg. 3934.)

FDA’s statements about preemption arise in the context of its response to comments it had requested from the public concerning the product liability implications of the proposed revised regulations. (*See* 71 Fed. Reg. 3933.) As noted by FDA in its response, one of these comments included a specific request “that the agency state in the final rule that FDA approval of labeling, whether it be in the old or new format, preempts conflicting or contrary State law, regulations, or decisions of a court of law for purposes of product liability litigation.” (*See* 71 Fed. Reg. 3933-3934.)<sup>3</sup>

FDA provides a detailed discussion of its position on preemption in two different sections of the preamble. (*See* 71 Fed. Reg. 3933-3936 and 3967-3969.) Therein, FDA explains how it implements its charge under the Act, both before and after it grants approval for marketing (*see* 71 Fed. Reg. 3934 and 3967-3969); how “product liability lawsuits have directly threatened the agency’s ability to regulate manufacturer dissemination of risk information for prescription drugs in accordance with the [A]ct” (*see* 71 Fed. Reg. 3934 (citing decisions)); how many courts have misunderstood FDA’s charge under the Act (*see* 71 Fed. Reg. 3934-3935 (citing decisions)); how state law actions “can rely on and propagate interpretations of the [A]ct and FDA regulations that conflict with the agency’s own interpretations and frustrate the agency’s implementation of its statutory mandate” (*see* 71 Fed. Reg. 3934); and how its position on preemption complies with an executive order that imposes requirements on federal agencies when “taking action that preempts State law” (*see* 71 Fed. Reg. 3967-3969 (citing Exec. Order No. 13132, 64 Fed. Reg. 43255-43259 (Aug. 4, 1999))). FDA concludes that its work will be “disrupted” if state law claims are not preempted:

“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

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<sup>3</sup> FDA does not identify the commentator who made this request. FDA does note that 97 comments were received from “prescription drug manufacturers and related companies; trade organizations representing prescription drug manufacturers and other interested parties; professional associations and organizations representing health care practitioners; health care and consumer advocacy organizations; individual physicians, pharmacists, and consumers; and others.” (*See* 71 Fed. Reg. 3929.) FDA also notes that it had extended the comment period at the request of the Pharmaceutical Research and Manufacturers of America (to June 22, 2001, some six months after the revised regulations were proposed in late December 2000). (*See* 71 Fed. Reg. 3922, 3923.)

regulatory determinations based on its considerable institutional expertise and comprehensive statutory authority, the federal system for regulation of drugs would be disrupted.”

(*See* 71 Fed. Reg. 3969.)

In its discussion of the preemption issue, FDA expressly addresses the situation in which a state law product liability claimant seeks to compel a manufacturer to include in labeling “a statement that FDA has considered and found scientifically unsubstantiated” and states that “including [such a] statement in labeling or advertising would render the drug misbranded under the act (21 U.S.C. §352(a) and (f)),” and, thus, such a claim is preempted. (*See* 71 Fed. Reg. 3935.) FDA also expressly addresses the situation in which a state law product liability claimant seeks to compel a manufacturer to omit from labeling or advertising “a statement that is included in prescription drug labeling” and, thus, such a claim is also preempted. (*See* 71 Fed. Reg. 3935.) FDA does not directly address the situation in which it has not expressly considered a statement a claimant alleges should have been included in the labeling.

FDA goes on to say that “at least” six specified types of state law failure-to-warn claims are preempted:

- “(1) [c]laims that a drug sponsor breached an obligation to warn by failing to put in Highlights or otherwise emphasize any information the substance of which appears anywhere in the labeling”;
- “(2) claims that a drug sponsor breached an obligation to warn by failing to include in an advertisement any information the substance of which appears anywhere in the labeling, in those cases where a drug’s sponsor has used Highlights consistently with FDA draft guidance regarding the ‘brief summary’ in direct-to-consumer advertising...”;
- “(3) claims that a sponsor breached an obligation to warn by failing to include contraindications or warnings that are not supported by evidence that meets the standards set forth in this rule, including § 201.57(c)(5) (requiring that contraindications reflect ‘[k]nown hazards and not theoretical possibilities’) and (c) (7)”;
- “(4) claims that a drug sponsor breached an obligation to warn by failing to include a statement in labeling or in advertising the substance of which had been proposed to FDA for inclusion in labeling, if that statement was not required by FDA at the time plaintiff claims the sponsor had an obligation to warn (unless FDA has made a finding that the sponsor withheld material information relating to the proposed warning before plaintiff claims the sponsor had the obligation to warn)”;
- “(5) claims that a drug sponsor breached an obligation to warn by failing to include in labeling or in advertising a statement the substance of which FDA has prohibited in labeling or advertising”; and
- “(6) claims that a drug’s sponsor breached an obligation to plaintiff by making statements that FDA approved for inclusion in the drug’s label (unless FDA has made a finding that the sponsor withheld material information relating to the statement).”

(See 71 Fed. Reg. 3935-3936.)

However, FDA also acknowledges that “certain State law requirements that parallel FDA requirements may not be preempted,” and thus “FDA’s regulation of drug labeling will not preempt all State law actions.” (See 71 Fed. Reg. 3936.)

It can be anticipated that the preemption language of the new FDA rule will be invoked by prescription drug and medical device manufacturers confronting product liability lawsuits presenting warning claims. How the courts will interpret and apply preemption principles in the wake of this new rule remains to be seen.

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