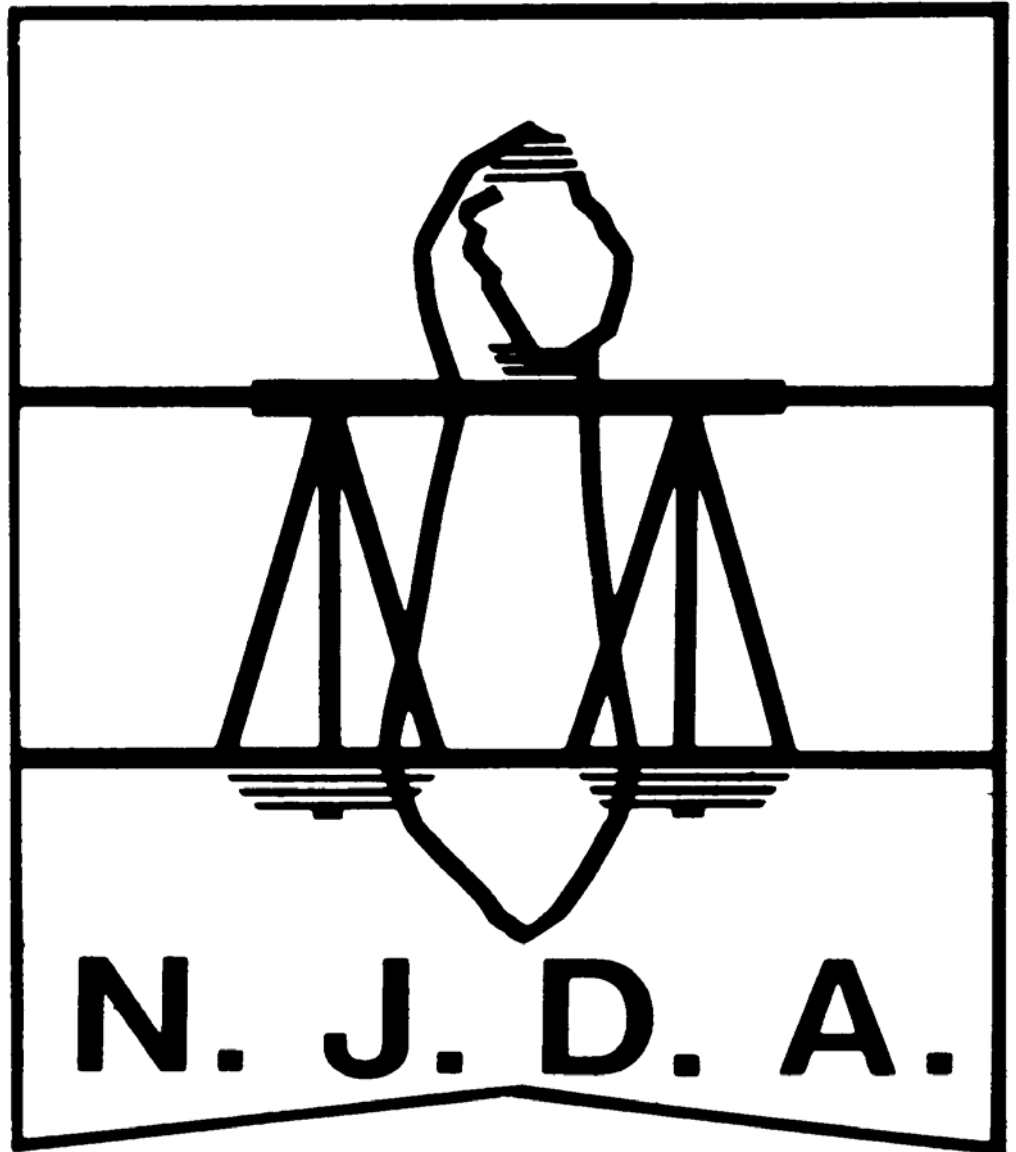


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*A special reprint edition
for
Norris, McLaughlin & Marcus, P.A.*

inside...

**FDA REAFFIRMS ITS FIRM
STAND ON PREEMPTION**
*Hon. William A. Dreier, M. Karen Thompson and
Steven A. Karg, Esq.¹*

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On January 24, 2006, the Food and Drug Administration published its proposed Final Rule (“Final Rule”) for amendments to 21 CFR, Parts 201, 314 and 601 under docket number 2000N-1269, as well as extensive commentary in a Preamble.² Principally, the Final Rule revises 21 CFR §§ 201.56 and 201.57, establishing the content and format requirements for drug labeling. There is, however, a minor specific revision of 21 CFR § 314.70,³ the warning amendment section of the FDA regulations, which is discussed in detail in an article by Judge Dreier entitled “Liability for Drug Advertising, Warnings, and Frauds,” to be published in the spring edition of the *Rutgers Law Review*. This article summarizes an addendum to that article, necessitated by the promulgation of the Final Rule after the article had been submitted. The authors refer the interested reader to the full article.

Various plaintiffs have claimed, some successfully, that individual states and even individual juries are free to impose their own warning requirements, notwithstanding that the label warnings to health care professionals (and even consumers) have been approved by the FDA. There are very limited instances under § 314.70 in which a manufacturer may temporarily increase label warnings; but these plaintiffs have claimed that the manufacturer’s failure to provide plaintiffs with an additional warning is a basis for liability, notwithstanding FDA compliance. FDA’s Preamble, however, confirms in no uncertain terms the agency’s position concerning the scope and applicability of the FDA’s warnings approval. Specifically, the FDA intends there to be preemption of state law in most instances.⁴

The new rules will not be effective until June 30, 2006, and the rules or comments may

be revised or withdrawn.⁵ Yet the statements and text are of sufficient importance that they should be studied to understand the FDA’s thinking in an area of regulation committed to its jurisdiction.

There is nothing new in the FDA’s strong statements of preemption. As explained in the forthcoming *Rutgers Law Review* article, in various *amicus* briefs and responses to direct inquiries from various courts, the FDA has expressed these same views for the last few years.⁶ Unfortunately, some courts have ignored these statements, claiming they were applicable solely to the cases in which the briefs were filed or where statements were received. Although the Preamble speaks of preemption of *state actions*, a careful analysis indicates that what was meant was the preemption of liability based upon most *state-law-based claims* in any action, whether in state or federal courts.

The Final Rule introduces a new requirement for labeling, namely that certain information be contained in a “Highlights” section.⁷ This amendment requires that any change in the new “Highlights” section receive *prior* FDA approval, while leaving the manufacturer the limited right to make a temporary increased warning in other portions of the label. Affording manufacturers the right to make such temporary changes is vastly different from exposing them to liability claims in specific cases for failure to make such temporary changes. According to the FDA, most of such claims are preempted.

The Preamble lists six specific areas of preemption:

1. A claim that a drug sponsor failed to warn by failing to put in the Highlights section or otherwise emphasize any information the

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- substance of which appears anywhere in the labeling;
2. A claim that such a sponsor failed to warn by including in an advertisement any information appearing in the labeling, but where the sponsor used the Highlights consistent with the FDA draft guidance regarding the “brief summary” in direct-to-consumer advertising;
 3. A claim that a sponsor failed to include a contraindication or warning that is not supported by evidence meeting the “known hazards and not theoretical possibilities” standard of § 201.57c(5) and (c)(7);
 4. A claim that the sponsor failed to include a statement in labeling or in advertising the substance of which had been proposed to the FDA for inclusion if that statement was not required by the FDA at the time a plaintiff claims the sponsor had an obligation to warn, unless the FDA has made a finding that the sponsor withheld material information before the plaintiff claims the sponsor had this obligation to warn;
 5. A claim that a sponsor breached an obligation by failing to include in labeling or in advertising any statement which the FDA has prohibited in such labeling or advertising; and
 6. A claim that the sponsor breached an obligation by making a statement that the FDA has approved for inclusion in the label, unless the FDA found that the sponsor withheld material information relating to the statement.⁸

The Preamble provides these protections not only to drug manufacturers but also to health-

care practitioners for failing to inform their patients of risk information beyond that which is included in the labeling.⁹

With the exception of “fraud on the FDA” claims, specifically prohibited by *Buckman Co. v. Plaintiff’s Legal Committee*,¹⁰ state law actions are not preempted to the extent that state law requirements parallel FDA requirements. In other words, if a state law requirement merely provides specific remedies but does not regulate a manufacturer’s or advertiser’s conduct, the state may still assert jurisdiction outside of the area of “fraud on the FDA.”¹¹

The Preamble reviews in detail various mistaken judicial decisions concerning the FDA’s intended scope of preemption, making it clear that

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.¹²

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Thus, the Preamble refutes unequivocally arguments made in many cases that FDA regulation is only a minimum standard, that states may therefore add to warning requirements, and that a manufacturer is free to revise a warning without FDA approval pending the FDA's review of the change.¹³ The FDA states unequivocally: "In fact, the determination whether labeling revisions are necessary is, in the end, squarely and solely FDA's under the act." (Emphasis added)¹⁴

Even after this rule change, a manufacturer may still make some emergent increased warning changes in a drug's labeling, pending FDA approval. Specifically, the Preamble states that the sponsor of a supplemental new drug application seeking an increased warning in the labeling is required to explain the basis for the change fully, but may make the change under the CBE (changes being effected) provisions, after notification but prior to approval. These changes in labeling are generally not actionable, as they will fall within one of the six explicit preemptions. "FDA reviews all such submissions and may later deny approval of the supplement, and the labeling remains subject to enforcement action if the added information makes the labeling false or misleading under Section 502(a) of the Act (21 U.S.C. 352). Thus, in practice, manufacturers typically consult with FDA prior to adding risk information to labeling." (Emphasis added). Under the new regulation however, "a sponsor may not use a CBE supplement to make most changes to Highlights."¹⁵ Such a change requires prior FDA approval.

FDA also reaffirms its position that it has primary jurisdiction to hear a claim that a manufacturer withheld information from FDA. FDA opines that the Constitution precludes

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 has been proposed to FDA for inclu-

sion 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).

71 FR at 3936 (emphasis added). FDA confirms that it, and not a court, is in the best position to determine whether it has been defrauded by a manufacturer during the approval process.

Although the Preamble and draft changes encompass many pages of fine print, the most relevant Preamble is contained in limited sections (71 FR 3933-36 &, 3967-3969). FDA expects to issue four draft Guidances for Industry explaining the new regulations. Only the first two covering the Adverse Reactions and Clinical Studies sections have been promulgated at the time of this writing, but neither bears upon this subject.

How the courts deal with FDA's reaffirmation of its stand on preemption will bear watching. Although FDA's assessment should be entitled to substantial deference, plaintiffs might attempt to challenge it as outside the scope of its regulatory authority and inconsistent with its original commentary accompanying the proposed rule amendments in 2000. At the time of submission of this article for publication, the only known New Jersey court to reach the issue has ruled in favor of preemption. *Abramowitz v. Cephalon, Inc.* BER-L-617-04 (Honorable Richard J. Donahue, J.S.C., March 3, 2006) ("It is clear that FDA has assumed authority over the regulation and approval of pharmaceutical labels in the United States, and therefore, any state claim that would challenge an FDA approved warning is preempted.")

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ENDNOTES

¹ The authors are members of Norris McLaughlin & Marcus, P.A., and are frequent lecturers in the area of Products Liability law. Judge Dreier has been the principal author of New Jersey Products Liability and Toxic Tort Law (Gann 2006) since 1977. The authors are members of the NJDA Products Liability Committee.

² Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 FR 3922 (proposed Jan. 24, 2006)(to be codified at 21 C.F.R. pts. 201, 314, 601).

³ 21 CFR § 314.70[©](6)(iii) governs changes pending FDA Approval. The introductory portion of this paragraph is to be amended by the proposed rule to read:

“(iii) changes in the labeling, except for changes to the information required in § 201.57(a) of this chapter (which must be made pursuant to paragraph (b)(2)(v)(C) of this section), to accomplish any of the following:”

71 FR 3997.

⁴ Comments on Product Liability Implications of the Proposed Rule, (hereinafter, “Preamble”), 71 FR 3922, 3933-36.

⁵ Implementation, 71 FR 3928.

⁶ The original (2000) edition of the proposed rules did not provide the detailed commentary provided in the Preamble of the Final Rule, *see* 65 FR § 81082, which is now presented in final form. In the original proposal, the FDA stated “Because enforcement of these labeling provisions is a Federal responsibility, there should be little, if any, impact from this rule, if finalized, on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of Government. In addition, this proposed rule does not contain policies that have federalism implications or that preempt State law.” *Id* at 81103(emphasis added).

⁷ Proposed 21 CFR § 201.57 (a).

⁸ Preamble, 71 FR at 3936.

⁹ *Id.*

¹⁰ 531 U.S. 341, 352-53 (2001)

¹¹ Preamble at 3936.

¹² *Id* at 3935.

¹³ *Id* at 3934.

¹⁴ *Id.*

¹⁵ *Id.*: revised 21 CFR § 314.709(c)(6)(iii).