FDA Notice Clarifies Past Federal Preemption Policy Statements

October 6, 2011

The Food and Drug Administration ("FDA") recently completed an evaluation of the legal basis for federal preemption policy statements the agency has issued under the Federal Food, Drug & Cosmetic Act ("FDCA") during the past 10 years. FDA initiated the review in response to a memorandum issued by President Obama in May 2009 which directed federal agencies to undertake a review of their policy statements concerning federal preemption to ensure that such statements have "a sufficient legal basis." In follow-up to the agency's review, on October 5, 2011, FDA issued a notice that is intended to clarify past FDA federal preemption policy statements. Such statements characterize the scope of implied and express federal preemption that applies to FDA regulations implementing particular FDCA provisions that concern prescription drug and biological product labeling, nonprescription drug products, food standards of identity, and food and dietary supplement product labeling.

Implied Federal Preemption and FDA Regulation of Prescription Drug and Biological Product Labeling

The FDA notice identifies three instances in which the agency's review has determined that federal preemption policy statements are "not legally justified." These statements appear in the rulemaking record associated with FDA regulations governing prescription drug and biological product labeling. Specifically, the federal preemption policy statements appear in the preamble accompanying the FDA final rule, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products" (the "Physician Labeling Rule")[1], issued in 2006, and is referenced in the preambles accompanying two other FDA rules issued in 2007 and 2008.[2]

The Physician Labeling Rule requires, among other things, that labeling for new and recently-approved prescription drug products include highlights of prescribing information that enable health care practitioners to more easily read and use the label information. The federal preemption policy statement in the preamble to the Physician Labeling Rule addresses drug manufacturers' concerns over product liability for certain drugs that fall outside the scope of the rule by stating that "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."[3] The preamble also asserts that "the determination whether [prescription drug/biological product] labeling revisions are necessary is, in the end, squarely and solely FDA's under the act."[4]

The FDA notice effectively retracts the federal preemption policy statement that appears in the preamble to the Physician Labeling Rule and clarifies the current FDA policy in response to the Supreme Court decision in *Wyeth v. Levine*, 129 S.Ct. 1187 (Mar. 2009). In *Wyeth*, the Court upheld a state tort claim concerning a manufacturer's failure to provide adequate warnings on its prescription

drug label. The Court ruled that the tort claim was not impliedly preempted by the FDCA or FDA's labeling requirements, stating that Congress's "silence on the [preemption] issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." 129 S.Ct. at 1200. The Court further noted that some State law claims could conflict with congressional objectives; however, the "failure-to-warn" claims at issue in *Wyeth* did not "obstruct the federal regulation of drug labeling." 129 S.Ct. at 1204.

In light of the Supreme Court's decision in *Wyeth*, FDA has concluded that its characterization of the scope of federal preemption under the FDCA with respect to prescription drug labeling requirements in the preamble to the Physician Labeling Rule and related FDA rules no longer can be justified as a matter of law.

Express Federal Preemption and Nonprescription Drug Products

The FDA notice also clarifies the agency's past policy statements characterizing the express federal preemption provisions of FDCA section 751 which apply to FDA regulation of nonprescription (*i.e.*, over-the-counter (OTC)) drug products, including the following:

Currently, [§751(a) of the FDCA] operates to preempt States from imposing requirements related to the regulation of nonprescription drug products (See section 751(b) through (e) of the act for the scope of the express preemption provision, the exemption procedures, and the exceptions to the provision) . . . . Although this final rule would have a preemptive effect, in that it would preclude States from issuing requirements related to these [OTC] drug products that are different from or in addition to, or not otherwise identical with a requirement in the final rule, this preemptive effect is consistent with what Congress set forth in section 751 of the act. Section 751(a) of the act displaces both State legislative requirements and State common law duties. . ."[5]

The FDA notice expresses concern that such statements as the one quoted above may be misconstrued to suggest that FDA gives more significance to FDCA section 751(a), which establishes the *breadth* of the express federal preemption provisions that apply to FDA's nonprescription drug requirements under the FDCA, than to other statutory provisions that establish *limits* on the scope of federal preemption, including section 751(e), which provides that there is no federal preemption with respect to actions brought under state product liability laws.[6] The notice emphasizes that FDA construes the federal preemption provisions of FDCA section 751 "as a whole" and construes each subsection in conjunction with all other subsections.

Express Federal Preemption and Food and Dietary Supplement Product Labeling

The FDA notice also clarifies the agency's prior federal preemption policy statements characterizing the scope of the express federal preemption provisions that apply to FDA labeling requirements for food and beverage products and dietary supplements. The notice addresses the following policy statement characterizing FDCA section 403A(a)(1)[7] , the provision which establishes the broadest scope of express federal preemption for food products that are governed by FDA standards of identity[8]:

"Although this rule has a pre-emptive effect, in that it would preclude states from issuing any. . . requirements. . . that are not identical to those required by the final rule, this pre-emptive effect is consistent with what Congress set forth in Section 403A of the [FD&C] Act. . . ."[9]

The FDA notice explains that the above quoted FDA policy statement addresses the scope of express federal preemption established under FDCA section 403A(a)(1), but does not address section 6(c)(2) of the Nutrition Labeling and Education Act ("NLEA"), which operates to limit the scope of express

federal preemption under the FDCA. NLEA section 6(c)(2) provides that FDCA section 403A "shall not be construed to apply to any requirement respecting a statement on the labeling of food that provides for a warning concerning the safety of the food or component of the food."[10] The FDA notice clarifies that the federal preemption policy statements it has issued in the past should have addressed NLEA section 6(c)(2) in addition to FDCA section 403A.

Kelley Drye & Warren LLP

Kelley Drye's team of Food and Drug lawyers strives to integrate our clients' business strategies with FDA compliance and to help resolve regulatory enforcement matters when they arise. Working side-by-side with business development and marketing professionals, we provide comprehensive regulatory counseling and assist in developing products, labels, and promotional materials that achieve our clients' goals without running afoul of regulatory requirements. With close knowledge of FDA's enforcement priorities and deep experience with the FTC's regulation of advertising, our team can provide comprehensive legal advice with an eye towards giving clients a competitive edge.

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[1] Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 26, 2006).

[2] *See* Exceptions or Alternatives to Labeling Requirements for Products Held by the Strategic National Stockpile, 72 Fed. Reg. 73589, 73595 (Dec. 28, 2007); Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 49603, 49605-49606 (Aug. 22, 2008).

[3] 71 Fed. Reg. at 3934 (Jan. 24, 2006).

[4] *Id.*

[5] *See*, *e.g.*, Astringent Drug Products that Produce Aluminum Acetate, 74 Fed. Reg. 9759 (Mar. 6, 2009); Skin Protectant Drug Products for Over the Counter Use, 73 Fed. Reg. 6015 (Feb. 1, 2008); Over- the-Counter Vaginal Contraceptive and Spermicide Drug Products Containing Nonoxynol 9 - Required Labeling, 72 Fed. Reg. 71769 (Dec. 19, 2007).

[6] 21 U.S.C. § 751(e): "Nothing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State."

[7] 21 U.S.C. § 343-1(a)(3)(providing that ". . .no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce any requirement for the labeling of food of the type required by section 403(b), 403(d), 403(f), 403(h), 403(i)(1), or 403(k) that is not identical to the requirement of such section. . . .").

[8] FDA standards of identity regulate the ingredients, manufacturing methods ("make procedures"), and labeling for "standardized foods."

[9] *See*, *e.g.* Milk and Cream Products and Yogurt Products; Proposal to Revoke the Standards for Lowfat Yogurt and Nonfat Yogurt and to Amend the Standard for Yogurt, 74 Fed. Reg. 2443 (Jan. 15, 2009)(proposing to amend statements of identity that are subject to express federal preemption under FDCA section 403A(a)(1)).

[10] Public Law 101-535, section 6, 104 Stat. 2353 (1990) (emphasis added).