



cc: files
Morphy ✓
McGinnis
Williams
Colborn
White
Reading

U.S. Department of Justice
Office of Legal Counsel

Retrieval (colborn) prop65.workinggroup (AMICUS)

Office of the
Assistant Attorney General

Washington, D.C. 20530

SEP 19 1988

MEMORANDUM

TO: Working Group on Federal Preemption

FROM: Douglas W. Kmiec *DK*
Acting Assistant Attorney General
Office of Legal Counsel

SUBJECT: FDA Authority to Preempt California Proposition 65

As the Department of Justice representative on the working group, I thought it might be helpful to share with you our views on one of the issues the working group will have to confront: the authority of the Food and Drug Administration (FDA) to preempt California Proposition 65 (Prop 65).

As discussed below, we believe that the FDA has authority to preempt Prop 65; however, consistent with the principles of the Federalism Executive Order (E.O. 12612), the exercise of that authority is necessarily dependent upon the compilation of a rulemaking record which contains "firm and palpable evidence . . . [that] the exercise of State authority directly conflicts with the exercise of Federal authority under the Federal statute." Section 4(a), Federalism Executive Order. In our judgment, California's current implementation of Prop 65 provides an insufficient factual basis for a finding that Prop 65 presents a direct conflict. This is because, as a general matter, California has agreed for now to use FDA standards. If California departs from this approach, we believe that the FDA may preempt. It may be appropriate to initiate a rulemaking proceeding as a method of further developing the factual record concerning California's implementation.

There are three bases for preemption: (1) express preemption; (2) implied preemption; and (3) conflict preemption. In the Prop 65 context, we believe that an argument can be made for implied FDA authority, but that the stronger basis, more consistent with the Federalism Executive Order, is conflict preemption.

1. Express Preemption

Unlike the Department of Agriculture, which regulates meat and poultry inspections pursuant to statutes that expressly preempt state requirements that are in addition to (or different from) federal requirements, no statute that the FDA enforces contains an express preemption provision that is applicable to the Prop 65 situation.

2. Implied Preemption

It may be argued that Congress intended the FDA to occupy the field of food and drug regulation to the exclusion of all state regulation. However, nothing in the FDA's statutes demonstrates to our satisfaction that "[t]he scheme of federal regulation" established by Congress is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." Rice v. Sante Fe Elevator Corp., 331 U.S. 218, 230 (1947).

Noting that "the laws and regulations of the different states are diverse, confusing and often contradictory[,] the House report on the original Food, Drug and Cosmetic Act stated that "[o]ne of the hoped-for good results of a national law on the subject of pure foods is the bringing about of a uniformity of laws and regulations on the part of the states within their own several borders." H.R. Rep. No. 2118, 59th Cong., 1st Sess. 5-6 (1906). While surely this statement is somewhat probative of Congress' intent, it has long been the view of this Office that agencies should be quite reluctant to rely on legislative history as the basis for expansive grants of preemptive authority. Moreover, the FDA has never asserted across-the-board preemption in this area, but rather has proceeded on a case-by-case basis, and the courts have not found an occupation of the field. See, e.g., Cosmetic, Toiletry and Fragrance Ass'n v. Minnesota, 440 F. Supp. 1216, 1220-1225 (D. Minn. 1977), aff'd, 575 F.2d 1256 (8th Cir. 1978); cf. Hillsborough County v. Automated Medical Laboratories, Inc., 471 U.S. 707, 714-720 (1985) (no FDA occupation of the field under the Public Health Service Act).

A slightly different occupation of the field preemption argument might be advanced on the basis of the FDA's past approach with respect to warning labels. The FDA generally does not require warning labels because it believes that any product it permits to be on the shelf should be understood as safe without warning, and warnings for safe products might be

confusing and misleading to the public.¹ The FDA might therefore be said to have a general policy against warning label requirements that occupies the field. This argument, however, stretches implied preemption theory because the FDA has never announced this as a general policy. Indeed, on occasion, the FDA has required warning labels.² Moreover, while FDA has on several occasions preempted state warning requirements,³ on another it declined to preempt because it found no "genuine need to stop the proliferation of inconsistent requirements between FDA and the States."⁴ It would therefore appear that the FDA does not operate pursuant to an established policy against all warning labels that occupies the field, but rather proceeds on a case-by-case basis.

3. Conflict Preemption

Absent express or implied preemption, what remains is conflict preemption. There are two kinds: (a) when "compliance with both federal and state regulations is a physical impossibility," Florida Lime & Avocado Growers, Inc. v. Paul, 373 U.S. 132, 142-143 (1963), or (b) when state regulation "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." Hines v. Davidowitz, 312 U.S. 52, 67 (1941). Unless the FDA were to elevate its case-specific preference against warnings to a general policy, it would be difficult to contend that compliance both with FDA requirements and with more stringent California requirements would be a "physical impossibility." Therefore, the focus should be on the "frustration of federal purposes" basis for preemption.

Federal agency authority to issue regulations preempting state law that would frustrate the purposes of the agency's

¹ See, e.g., 44 Fed. Reg. 59509, 59513 (Oct. 16, 1979) (warning requirements for foods with carcinogens were rejected because "[s]uch warnings would be so numerous they would confuse the public, would not promote informed consumer decisionmaking, and would not advance the public health"); 47 Fed. Reg. 54750, 54753 (Dec. 3, 1982) (warnings for over-the-counter and prescription drugs "must be used judiciously so that they do not lose their effectiveness").

² See, e.g., 47 Fed. Reg. 50442 (Nov. 5, 1982) (tamper-resistant feature of over-the-counter drug packaging); 51 Fed. Reg. 8180 (Mar. 7, 1986) (aspirin for chicken pox and flu symptoms in children).

³ See, e.g., the rulemakings cited in footnote 2, supra.

⁴ 51 Fed. Reg. 25012, 25016 (July 9, 1986) (presence of sulfiting agents in food).

regulations is well established: "The statutorily authorized regulations of an agency will pre-empt any state or local law that conflicts with such regulations or frustrates the purposes thereof." City of New York v. Federal Communications Commission, 108 S. Ct. 1637, 1642 (1988). Moreover, where a federal agency has broad regulatory authority in an area, that agency's decision to preempt inconsistent state regulation is owed considerable deference by the courts.⁵

FDA's regulatory authority is broad and it extends to the subjects regulated by Prop 65. As to its authority to issue preempting regulations, however, the FDA has previously set forth the framework that governs its decision on whether to preempt inconsistent state and local requirements:

FDA is authorized to assure the safety of drugs and cosmetics marketed in interstate commerce in this country. The manufacturing and distribution system for these products is national in scope and the measures adopted by FDA to regulate this national system should be adequate to safeguard the interests of the entire population. While State and local requirements for products may on occasion be appropriate and necessary, such measures should not interfere with FDA's accomplishing those purposes that are within its Congressionally mandated area of responsibility.

47 Fed. Reg. 50442, 50448 (Nov. 5, 1982). It is clear in the Prop 65 context that inconsistent California warning requirements potentially could come into conflict with the purposes of federal regulation. Therefore, the preemption determination should turn on two basic factual questions: (1) whether California actually enforces conflicting warning requirements; and (2) if so, whether the effects of such requirements are such that the requirements "stand as an obstacle to the accomplishment and execution of the full purposes" of the FDA regulations. Hines v. Davidowitz, 312 U.S. at 67.

⁵ "It has long been recognized that many of the responsibilities conferred on federal agencies involve a broad grant of authority to reconcile conflicting policies. Where this is true, the Court has cautioned that even in the area of pre-emption, if the agency's choice to pre-empt 'represents a reasonable accommodation of conflicting policies that were committed to the agency's care by the statute, we should not disturb it unless it appears from the statute or its legislative history that the accommodation is not one that Congress would have sanctioned.'" City of New York, 108 S. Ct. at 1637, quoting United States v. Shimer, 367 U.S. 374, 383 (1961).

The major point to be made at this time is that the answer to the first question appears to be "no." As a general matter, California is not currently requiring conflicting warnings.⁶ At least in the short run, potentially carcinogenic products that comply with FDA requirements are deemed to comply with California requirements and therefore need not bear a special California warning. (The situation with respect to reproductive toxins is less clear.) Should there come a time when Prop 65 is implemented in such a way that warnings are required in California that are different from FDA-required warnings, or warnings are required where the FDA does not require warnings, the second step of the preemption determination will then arise as to what problems are created for the various consumer, industry, and other interests that the FDA is charged with addressing. The FDA would have to determine at that time whether any such inconsistent California requirements frustrate the purposes of FDA regulation.⁷

In light of the uncertainty of California's Prop 65 implementation, and of its impact on FDA regulation, the working group might consider whether the FDA should publish a notice of proposed rulemaking requesting information and comments on whether it is necessary to preempt Prop 65. The notice could make it clear that the FDA will only issue a preempting regulation if the facts developed during the rulemaking proceeding justify a determination that inconsistent California requirements are frustrating the purposes of FDA regulation.⁸

⁶ See 22 California Code of Regulations § 12713 (adopted effective February 27, 1988).

⁷ Should it ultimately be determined that Prop 65 conflicts with federal law, it will be necessary as a matter of federalism process, pursuant to subsections 4(c)-(e) of the Federalism Executive Order, that FDA consult with California in an effort to avoid the conflict, and if after consultation it is decided to proceed with preemption, the preemption "shall be restricted to the minimum level necessary to achieve the objectives of the statute pursuant to which the regulations are promulgated."

⁸ In the rulemaking cited in footnote 4, supra, the FDA declined to preempt state sulfite labeling requirements because it was "not persuaded" that there was "a genuine need to stop the proliferation of inconsistent requirements between FDA and the States," but the FDA also indicated that, notwithstanding that present determination, "[t]he agency will . . . evaluate any information concerning a need for Federal preemption that is submitted to it and will take appropriate action." 51 Fed. Reg. at 25016.