*New Federal Initiatives Project*

# Executive Order on Preemption

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On May 20, 2009, President Obama issued a Memorandum for the heads of executive departments and agencies on preemption.[1] The purpose of that Memorandum was to declare the new Administration's "general policy" to be that "preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption."[2] The President explained that, even though the Federal Government's role in promoting the general welfare is "critical," the States play a concurrent and often more aggressive role in protecting the health and safety of their citizens and the environment.[3] He stated that overreaching by the Federal Government with respect to preemption limits the ability of the States to "apply to themselves rules and principles that reflect the[ir own particular] circumstances and values."[4]

Accordingly, the President directed the recipients not to include preemption statements in "regulatory preambles . . . except where preemption provisions are also included in the codified regulation" or in "codified regulations except where such provisions would be justified under legal principles governing preemption, including the principles outlined in Executive Order 13132."[5] The President also instructed the recipients to "review regulations issued in the last 10 years that contain statements in regulatory preambles or codified provisions intended . . . to preempt State law, in order to decide whether such statements are justified under applicable legal principles governing preemption."[6]

Executive Order 13132 is a Clinton Administration order that, among other things, identifies policymaking criteria that are to be applied to agency actions that have federalism implications. More generally, Executive Order 12988, another Clinton Administration order which the Obama Memorandum does not cite, requires agencies that are formulating regulations to "make every reasonable effort . . . specif[y] in clear language the preemptive effect, if any, to be given to the regulation."[7]

Executive Order 13132 instructs agencies to take national action limiting the prerogatives of the States "only when there is constitutional and statutory authority for the action and the national activity is appropriate in light of the presence of a problem of national significance."[8] With respect to preemption, agencies are instructed that they should construe a Federal statute to preempt State law only where (1) the statute expressly preempts State law; (2) "there is some other clear evidence that the Congress intended preemption of State law"; or (3) "where the existence of State authority conflicts with the exercise of Federal authority under the Federal statute."[9] Implied preemption is appropriate only where there is a direct conflict or Congress intended that the agency have the power to preempt State law. Finally, the scope of regulatory preemption is limited to the "minimum level necessary to achieve the objectives of the statute" that supports preemption.[10]

The Obama Memorandum's focus on the preamble to regulations speaks to one of the issues in the Supreme Court's decision in *Wyeth v. Levine*.[11] There, the Court held

that the Food and Drug Administration's approval of the warning label for Phenergan, an anti-nausea drug, did not preempt a state law claim that the warning was defective. The Court rejected Wyeth's reliance on the preamble to a 2006 FDA regulation governing the content and format of prescription drug labels. In that preamble, the FDA characterized its controlling legislation with respect to labeling as a "ceiling" and a "floor" and stated that its approval of labeling preempted conflicting State law.[12] In addition, the FDA asserted that certain state-law actions, like failure-to-warn claims, "threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs."[13]

The controlling legislation, the Food, Drug, and Cosmetic Act, does not expressly preempt state-law actions, so the FDA was asserting a form of implied preemption.[14] In *Wyeth*, the Court gave short shrift to the preamble. It explained that while it had previously "given 'some weight' to an agency's views about the impact of tort law on federal objectives when 'the subject matter is technical[l] and the relevant history and background are complex'", its deference to an agency's conclusion that state law is preempted is limited.[15] In this case, the preamble had not been subjected to the notice-and-comment process of administrative rulemaking and, according to the Court, was inconsistent with the FDA's "own long-standing position. . . ."[16]

The Obama Memorandum discourages Federal agencies from asserting that their actions preempt state law claims. Some, like the Bush Administration's FDA, see that discouragement as inconsistent with the expertise agencies have developed over time. That expertise is consistent with Congress' creation and assignment of responsibilities to the FDA. Justice Alito noted in his dissent in *Wyeth*, that the FDA's action involved consideration of the costs and benefits of the uses of Phenergan,[17] and a state court lawsuit like Levine's considers only the costs of a catastrophic injury. The FDA might conclude that the benefits of the use of a drug outweigh the risks of harm. In the case of Phenergan, which has been taken off the market in the wake of the Supreme Court's decision, the decision of the jury in Vermont trumped the agency's balancing and affected the rest of the country.

Critics of *Wyeth* argue that preemption has a constitutional grounding just as federalism interests do. The Commerce Clause empowers Congress to "regulate commerce . . . among the several states."[18] When Congress exercises that power, the Supremacy Clause makes its enactments "the supreme law of the land . . . anything in the . . . laws of any state to the contrary notwithstanding."[19]

They assert that the preemption of multiple independent state court lawsuits and the potentially conflicting standards they may create aid in the development of a uniform national market. Uniform national standards can make it more efficient and less costly to manufacture and distribute products because the same product can be sold in more markets. Economies of scale may produce lower costs and more consumer choice may be two of the products of such a uniform market. These broadly distributed benefits are not considered in a state court failure-to-warn lawsuit like Levine's.

Even so, as it noted in *Wyeth*, the Court's analysis of preemption cases begins with a presumption against preemption that is grounded in the Constitution. It explained that "respect for the States as 'independent sovereigns in our federal system' leads us to assume that 'Congress does not cavalierly pre-empt state-law causes of action.'"[20] Justice Thomas would go farther. In his *Wyeth* opinion concurring in the judgment, he argues that consideration of the purposes and objectives of Congress as part of the analysis of implied preemption claims lacks Constitutional grounding.[21] The presumption against preemption also has policy support. As the President notes, preemption may choke off the benefits of experimentation in policy approaches in the several states.[22] In essence, although a national rule results, the opportunity to explore new and perhaps better policy approaches may be lost.

The President's Memorandum discouraging regulatory preemption comes against a backdrop of calls from Congress and others for increased regulation in a variety of areas. If put into law, market participants will have to shoulder greater regulatory burdens, but they will not receive immunity from state court lawsuits by doing so unless Congress provides for such immunity.

Its general inclination against preemption notwithstanding, the Administration will not be immune from the need to make difficult decisions. On June 8, 2009, for example, the Supreme Court asked the Solicitor General's Office for its views regarding the scope to which the National Childhood Vaccine Injury Act of 1986 preempts state court lawsuits against the manufacturers of vaccines.[23] In pertinent part, that law states that "[n]o vaccine manufacturer shall be liable in a civil action" if the injury "resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings."[24] The Administration's decision is complicated by the fact that, in the 1980s, the costs and risks of product liability litigation drove several vaccine manufacturers from the market and caused shortages of some vaccines, and Congress passed the Act in response.

For their part, with the President's Memorandum in effect, producers and distributors can expect their compliance with any new regulatory requirements to be seen as a "floor" but not a "ceiling" if they are sued in s ate court and will have to deal with the resulting uncertainty.

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1 74 Fed . Reg. 24693 (2009).
2 Id.
3 Id.
4 Id.
5 Id.
6 Id.
7 Exec. Order 12988 (Feb. 5, 1996), 61 Fed. Reg. 4727,4732.
8 Exec. Order 13132 (Aug. 4, 1999), 64 Fed. Reg. 43255, 43256.
9 Id., 64 Fed. Reg. at 43257.

[10] Id.
[11] 129 S. Ct 1187 (2009).
[12] See 71 Fed. Reg 3922, 3934-35 (2006).
[13] Id., at 3955.
[14] The Medical Device Amendments of 1976 to the Food, Drug, and Cosmetic Act expressly preempt state law claims that relate to some medical devices. See 21 U.S.C. § 360(k). In *Riegel v. Medtronic, Inc*., 128 S. Ct. 999 (2008), the Court held the FDA's premarket approval devices for medical devices preempted state common-law with respect to a balloon catheter Medtronic manufactured that ruptured when used to dilate Riegel's coronary artery. The Medical Device Safety Act of 2009, which Senator Specter has introduced, would reverse the holding in *Riegel*. See S. 540, 111th Cong. (2009), H.R. 1346, 111th Cong. (2009); see also von Spakovsky, "Killing Americans by Stifling Medical Innovation: The Medical Device 'Safety' Act of 2009," Heritage Foundation Aug. 4, 2009 (available at www.heritage,org/Research/LegalIssues/lm0046.cfm).
[15] 129 S. Ct. at 1201 (quoting *Geier v. American Honda Motor Co*., 120 S. Ct. 1913, 1926 (2000)).
[16] Id.
[17] See 129 S. Ct. at 1227 ("Given the 'balance' that the FDA struck between the costs and benefits of administering Phenergan via IV-push, *Geier* compels the pre-emption of tort suits (like this one) that would upset that balance.") (Alito, J., dissenting)
[18] Art. I, § 8, cl. 3, U.S. Const.
[19] Art. VI, U.S. Const.
[20] 129 S. Ct. at 1195, n. 3 (quoting Medtronic, Inc. v. Lohr, 116 S. Ct. 2240, 2250 (1996)).
[21] 129 S. Ct. at 1204-1218 (Thomas, J., concurring in the judgment).
[22] 74 Fed. Reg. at 24693. The President states, "As Justice Brandeis explained more than 70 years ago, 'It is one of the happy incidents of the federal system that a single courageous state may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." Id.
[23] See *American Home Products Corp. v. Ferrari*, No. 08-1120, 129 S. Ct. 2786 (U.S. June 8, 2009).
[24] See 42 U.S.C. § 300aa-22(b)(1).

## Related Links:

Executive Order 13132 http://www.epa.gov/fedreg/eo/eo13132.htm
Executive Order 12988 http://www.epa.gov/fedreg/eo/eo12988.htm