

“What keeps you up at night?”

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The Obama administration issues executive department directive on preemption

By Mark C. Levy and Gregory J. Wartman

After promising in January to issue an executive order that would halt the use of agency rulemaking and policy change to promote federal preemption, the Obama Administration did just that. President Obama issued a Memorandum For the Heads of Executive Departments and Agencies on May 20, 2009. For the full text of the Memorandum, go to http://www.whitehouse.gov/the_press_office/Presidential-Memorandum-Regarding-Preemption/. The Memorandum reverses the Bush Administration's aggressive policy of advocating federal preemption of state tort law claims – especially in the context of prescription drugs and medical devices. The plaintiffs' bar has hailed this Memorandum as a “landmark achievement” attributable in part to its lobbying efforts.

For eight years, the Bush Administration attempted to expand the scope of federal preemption of state law failure to warn claims against the manufacturers of prescription drugs and devices. It did so in two ways. First, FDA submitted amicus curiae briefs in prescription drug and device litigation that argued in favor of preemption. Second, FDA issued a preamble to the 2006 amendments to prescription drug labeling regulations – the Preemption Preamble — announcing the Administration's view that FDA labeling regulations were both a floor and a ceiling. In March 2009, the United States Supreme Court decided *Wyeth v. Levine*, ruling that the plaintiff's failure to warn claims are not preempted where FDA has not specifically considered the warning advocated by the plaintiff. In doing so, the Court ruled that FDA's Preemption Preamble was not entitled to judicial deference.

As a sign that change was coming, the Obama Administration had withdrawn the pro-preemption amicus brief it previously submitted in the Third Circuit case — *Colacicco v. Apotex, Inc.* — a brief that court had relied upon in part in finding preemption. The *Colacicco* case had been before the Court when it decided *Wyeth*. However, it remanded the case back to the Third Circuit for further review in light of *Wyeth*. In doing so, the Solicitor General adopted a cautious tone explaining that FDA had not evaluated the implications of the *Levine* decision on that case or the class of drug involved (SSRIs).

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President Obama's recent memo announces a fundamental break from prior administration policy. The memo explains, “The purpose of this memorandum is to state the general policy of my Administration 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.” President Obama quotes Justice Brandeis in a passage that illustrates just how different his views on preemption are from former President Bush: “[i]t 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.”

The memo directs federal agencies not to include statements that “the department or agency intends to preempt State law through the regulation” unless the regulation itself includes preemption provisions. When it comes to including preemption provisions in codified regulations, the memo cautions departments and agencies against doing so unless “such provisions would be justified under legal principles governing preemption, including the principles outlined in Executive Order 13132.” The memo goes one step further, instructing departments and agencies to review regulations from the last ten years to determine whether regulatory preambles “are justified under applicable legal principles governing preemption.”

While this change in policy will no doubt chill further preemption efforts, it is not likely to affect all case precedent. For example, the memo does not directly affect the United States Supreme Court's ruling in *Riegel v. Medtronic, Inc.*, which held that state law tort claims seeking to impose additional or different requirements on PMA-approved medical devices are preempted. *Riegel* is based on the express preemption clause found in the MDA. Therefore, arguably it would take an act of Congress to overturn *Riegel*.

However, one can expect more challenges to federal preemption in device cases citing to this Order.

The Supreme Court's ruling in *Levine* arguably controls the scope of preemption in the prescription drug context. However, it is safe to say that FDA will not be submitting amicus briefs advocating preemption of state law failure to warn claims involving FDA approved drugs. Where a drug does not have an extensive regulatory history, FDA's “new” silence could make it more difficult for prescription drug manufacturers to prove that FDA conducted the type of specific evaluation of a proposed warning necessary to trigger preemption under *Levine*. Undoubtedly, the American Association for Justice will use this Memorandum to defeat any effort to argue intent to preempt that is based on language outside the strict language of a relevant statute.

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