



Formerly the Association of Trial Lawyers of America (ATLA®)

March 16, 2009

Office of Information and Regulatory Affairs
Records Management Center
Office of Management and Budget
Room 1013, NEOB
725 17th Street, NW
Washington, DC 20503

Re: Federal Regulatory Review

Dear Sir or Madam:

The American Association for Justice (AAJ), formerly known as the Association of Trial Lawyers of America (ATLA), hereby submits comments in response to the Office of Management and Budget's (OMB) notice seeking recommendations to improve the federal regulatory process and principles governing regulation. *See* 74 Fed. Reg. 8819.

AAJ, with members in the United States, Canada and abroad, is the world's largest trial bar. It was established in 1946 to safeguard victims' rights, strengthen the civil justice system, promote injury prevention, and foster the disclosure of information critical to public health and safety. AAJ is very pleased that the OMB is seeking comments on federal regulatory review to improve the regulatory process. During the last several years, AAJ has been concerned about the lack of rational attention given to preemption issues during the regulatory review process. While Executive Order 13132 was designed to address preemption, federal agencies under the Bush Administration did not strictly comply with the Order's consultation procedures. In many instances, federal agencies included language seeking to preempt state tort law claims without consulting with state governmental organizations or providing an opportunity to comment to interested parties. The Supreme Court's recent decision in *Wyeth v. Levine*¹ provides a roadmap for the Administration regarding preemption issues. AAJ recommends that the Obama Administration implement the *Wyeth* decision's regulatory holdings and ensure that agencies promptly consult stakeholders affected by the regulation.

I. OMB's New Regulatory Process Should Embody Principles Stated in *Wyeth v. Levine* Decision

During the Bush Administration, under the guise of implementing Executive Order 13132, opined in the preamble accompanying federal regulations that the agency's action

¹ *Wyeth v. Levine*, No. 06-1249, *slip op.* (Mar. 4, 2009).

preempted state law, including state tort law. Agencies offered these overbroad opinions about the preemptive effects of their regulatory actions often without giving interested parties notice of their intent to preempt state law or the opportunity to comment on that issue. In many instances, agencies just asserted a preemptive effect without giving an analysis of why state and federal law could not coexist.

The Bush Administration's approach to Executive Order 13132 and to the preemption issue generally must be reversed. Doing so would enhance OMB's stated objectives for this regulatory review which include: (1) increasing disclosure and transparency; and (2) encouraging public participation.² AAJ believes the Obama Administration should instruct agencies to implement the principles regarding preemption and tort law expressed in *Wyeth*. The Administration's implementation of the *Wyeth* regulatory holdings would increase transparency within the agencies, avoid unnecessarily trampling state tort law, and increase the protections for consumers, workers, and the environment from harm.

A. The Civil Justice System and the Federal Regulatory System Serve Complementary Functions

The Supreme Court's decision in *Wyeth* recognizes that the state civil justice system is critical to ensure consumer protection.³ "State tort suits uncover unknown [product] hazards and provide incentives for [] manufacturers to disclose safety risks promptly."⁴ When a federal agency needlessly, and often without statutory authority, suggests its actions preempt state tort law, the agency puts consumers, workers and the environment at risk, because the federal regulatory actions often set minimal safety standards which are not adequate to protect against all safety hazards. While regulations are a necessary first step, the state civil justice system provides important checks and balances when government regulations fail.

B. Agencies Must Limit Reliance on *Geier* Decision and May Only Preempt When Directed to Do So By Congress

Wyeth made clear that agencies must limit their attempts to preempt state law. Instead, agencies and courts must assume that state law is not preempted unless Congress has indicated its intent to preempt. The Supreme Court rejected Bush agency preamble statements relying on *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000) to claim that federal regulations impliedly preempt tort law. The Supreme Court made clear that *Geier* is only meant to preempt state tort law claims in very limited circumstances.⁵ Agencies may rely on *Geier* as a basis for preemption only when the agency has actually weighed the pros and cons of an issue and adopted a policy, by rule, which is at odds with the policy underlying state law. And, even in those limited cases, agencies should no longer include boilerplate statements preempting state

² *Federal Regulatory Review*, 74 Fed. Reg. 8819, 8819 (Feb. 26, 2009).

³ The Court noted that the FDA has "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth v. Levine*, No. 06-1249, *slip op.* at 23 (Mar. 4, 2009).

⁴ *Id.*

⁵ *Id.* at 19-20.

tort law without providing a reasoned explanation. Justice Thomas' concurring opinion went one step further to disclaim the notion of implied preemption, stating that he "can no longer assent to a doctrine that preempts state laws merely because they 'stan[d] as an obstacle to the accomplishment and execution of the full purposes and objectives' of federal law."⁶ OMB should insist these principles are carried over to the regulatory review process.

C. Agencies Must Provide Notice and Comment for All Preemption Pronouncements

In many instances, Bush Administration agencies included preemption language in the preamble to the final rule only, so interested parties were never given an opportunity to comment on whether state and federal law were compatible. The agencies used this process for numerous safety regulations from automobiles to drugs to railroads.⁷ Given the Obama Administration's goal to increase transparency, the OMB should prevent federal agencies from opining about preemption in the preamble to final rules without notice of its intent to consider the issue. The Supreme Court criticized the FDA for finalizing its drug labeling rule and including language seeking to preempt state tort law claims "without offering State or other interested parties notice or opportunity for comment, [and] articulated a sweeping position on the FDCA's preemptive effect in the regulatory preamble."⁸ The Court found that the FDA's views were "inherently suspect" given the lack of opportunity for comment.⁹ The same should be true of regulations issued by any agency.

II. Effective Consultation with Stakeholders Would Improve Transparency and Public Participation in the Regulatory Process

The OMB also would achieve its goals of increasing disclosure and transparency by improving enforcement of Executive Order 13132 and requiring effective consultation with stakeholders. Executive Order 13132 requires a federal agency to notify and have meaningful consultation with impacted state and local government organizations when it seeks to preempt state law. However, in recent years, federal agencies have not strictly complied with these consultation requirements. For example, in a May 16, 2008 letter from the National Conference of State Legislatures (NCSL) to the Pipeline Hazardous Materials Safety Administration (PHMSA) regarding a potentially preemptive rule, NCSL explained

no other member of our state and local government coalition (which includes the National Governor's Association, the National League of Cities, the National

⁶ *Concurring op.* at 24.

⁷ Some of these regulations included preemption language to the preamble to the final rule, which was in direct contradiction to the language in the proposed rule. *See, e.g.*, Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products; Docket No. 2000N-1269, Final Rule, 71 Fed. Reg. 3922 (Jan. 24, 2006); Door Locks and Door Retention Components, Docket No. NHTSA-2006-23882, Final Rule, 72 Fed. Reg. 5385 (Feb. 6, 2007).

⁸ *Wyeth, slip op.* at 21.

⁹ *Id.*

Association of Counties, and the U.S. Conference of Mayors) recalls receiving any follow-up about this proposed rule from PHMSA.

NCSL characterized PHMSA's attempts at proper notice and consultation as "feeble at best and disingenuous at worst."¹⁰ Effective notice and consultation with state and local government groups would increase the transparency among federal agencies and encourage their direct participation. These organizations are in a unique position to opine whether federal regulations will ensure the safety of their citizens.

When an agency asserts that its rules preempt state tort law, additional consultation with victims or their representatives also may be necessary to ensure a meaningful opportunity to comment is presented to those whose interests will be affected. Usually, state executive and legislative officials will have an interest in preserving state law. Sometimes, however, such officials are not aware of the impact implied preemption may have on tort claims. Those whose rights would be adversely affected by preemption should have the opportunity to voice their concerns before the federal government takes action to cut off their right to recovery.

AAJ appreciates the opportunity to submit these comments regarding the Office of Management and Budget's federal regulatory review. If you have any questions or comments, please contact Gerie Voss, AAJ's Director of Regulatory Affairs at [REDACTED].

Sincerely,



Les Weisbrod
President
American Association for Justice

/gv

¹⁰ Letter from Carl Tubbesing to William Schoonover Re: Interim Final Rule on Hazardous Materials: Enhancing Rail Transportation Safety and Security for Hazardous Materials Shipments, Docket No. PHMSA-RSPA-2004-18730 (May 16, 2008).