



American Association for Justice Transition Notebook – Executive Summary

The American Association for Justice (AAJ) has put together the attached information to aid the Obama Transition Team as it plans for the new Administration. This notebook contains memoranda describing AAJ's key concern, turning back Bush efforts to give corporate wrongdoers immunity from consumers lawsuits, and its suggestions for several federal agencies.

Key Priorities to Address Preemption

While AAJ believes that all of the attached ideas are crucial to reinvigorate consumer safety and the civil justice system, the organization's most pressing concern has been the Bush Administration's attempts to use preemption to afford complete immunity to corporations. In order to fully address this pervasive issue, AAJ recommends that the new Administration take the following steps:

1) Develop a comprehensive, executive branch-wide plan to roll back corporate immunity from lawsuits

During the Bush Administration, the Office of Management and Budget (OMB) has orchestrated a comprehensive scheme to preempt consumer lawsuits against manufacturers of dangerous products. Preemption of consumer lawsuits is similar to the preemption of lawsuits challenging predatory lending practices which contributed to the economic crisis facing the Nation. To roll back the damage created by the Bush preemption agenda, we urge the Obama Administration to: (1) issue a memorandum immediately to federal agencies requiring that any pending or recently completed rules be stayed and have no effect on state tort law; and (2) issue an Executive Order stating that no federal agency shall take action to preempt state law, including state tort law, unless Congress has unequivocally indicated its intent to do so. To accomplish these goals, we urge the Obama Administration to establish a new office within the OMB whose job is to monitor compliance with a revised Executive Order on federalism and coordinate the affirmative work the new Administration must do to clean up the preemption problem that the Bush Administration leaves for consumers. It also would make certain that powerful corporations remain accountable to consumers and state governments through the use of the civil justice system.

AAJ believes the first step toward reinvigorating consumer rights is to prevent pending or recently completed regulatory actions that seek to preempt state tort law claims from becoming effective. Just as Andrew Card did for the Bush Administration, the new Chief of Staff must issue a memorandum to the current heads of agencies on January 20, 2009. This memorandum shall indicate that federal agencies stay all pending rules for sixty days (which should include those that are still subject to a Petition for Reconsideration as the rule then would not have taken effect).

AAJ believes the next, and perhaps most important step, toward reinvigorating consumer rights is to revise Executive Order 13132 to adequately address preemption. The revised Executive Order should articulate the Obama Administration policy that agency action should not preempt state tort law unless Congress clearly intended to do so. (See Section C.)



A revised Executive Order would govern the preemption issue prospectively. It will not affect final rules which include preemption language in the text of the regulatory rule, as indicated in the National Highway Traffic Safety Administration's designated seating positions rule. It also will not impact the Food and Drug Administration's attempt to change the prescription drug and medical device labeling process, which clearly was designed to preempt state law claims. Both rules are discussed at length in their respective agency sections.

2) Utilize the rulemaking process within the Food and Drug Administration to prevent manufacturers from claiming complete immunity via preemption

The Bush Administration's efforts to preempt consumer lawsuits against the manufacturers of dangerous products have severely limited the ability of consumers to recover for injuries caused by defective medical devices and prescription drugs. Protecting consumer safety requires both government regulation and civil justice remedies. This is particularly true in the FDA, whose own Science Board has stated that the agency is understaffed, underfunded and ill-equipped to fully police the all of the medical product manufacturers under its jurisdiction. Further, the Supreme Court's recent decision in *Riegel v. Medtronic*, 128 S. Ct. 999 (2008), which misconstrued the Medical Device Amendments of 1976, affords complete immunity to medical device manufacturers from claims regarding their Class III pre-market approved devices. Therefore, AAJ recommends that the new Administration open a rulemaking proceeding to reinstate Congressional intent to maintain both federal regulation and the civil justice system to protect consumers who use medical devices.

In addition, the FDA should withdraw its August 2008 final rule regarding labeling, which discourages medical device and prescription drug manufacturers from updating warning labels with hazard information without prior FDA approval. This rule only bolsters preemption claims, because the manufacturers argue that the FDA prohibits them from updating warning labels even if it may take the FDA several months to evaluate potential new hazards. This is an extremely dangerous measure for consumers who may not have been properly warned of dangers since this rule took effect in 2008. This rule, which was a clear departure from prior FDA process, was likely issued as a component to the Bush Administration's preemption agenda and to influence the Supreme Court's decision in *Wyeth v. Levine* (argued November 3, 2008). Therefore, it is not only critical that the agency withdraw this rulemaking but it is also imperative that the Obama Administration open a rulemaking to clarify Congressional intent regarding the ability of injured consumers to hold prescription drug manufacturers accountable for their injuries.

Summary of Attached Documentation

Each section of this transition notebook contains a brief memorandum and supporting documentation, which includes expressions of Congressional concern. The notebook is structured as follows:

- A) Overview of Corporate Immunity From Lawsuits –This section provides an overview of the Bush Administration's attempt to use preemption to afford complete immunity to corporations from state regulatory and common law and to prevent injured Americans from seeking recourse from the civil justice system.



- B) White House Office to Coordinate Federalism Issues – This section explains why the OMB needs a new office to ensure agency action to preempt state law is consistent with Congressional intent.
- C) Limiting Federal Agency Preemption: Recommendations for a New Federalism Executive Order – This brief paper from the Center for Progressive Reform explains the changes that the Obama Administration should make to Executive Order 13132 on “Federalism.”
- D) Food and Drug Administration – This section suggests that the Administration take immediate action on several vital health and safety issues: (1) withdraw its August 2008 final rule regarding drug and device labeling; (2) restore Congressional intent to maintain both federal regulation and the civil justice system to protect consumers; (3) issue an Executive Order to address rulemakings containing complete immunity preemption language in the preamble; and (4) revise guidance to prohibit manufacturers from using medical journal articles to inappropriately promote off-label uses.
- E) National Highway Traffic Safety Administration – This section explains the need for a new roof crush rule and Executive Order to address the agency’s inclusion of complete immunity preemption language in the preamble to federal rules.
- F) Federal Railroad Administration – This section addresses the need for an Executive Order to address the agency’s inclusion of complete immunity preemption language in the preamble to federal rules. It also indicates that the Administration should encourage additional Congressional oversight.
- G) Federal Aviation Administration – This section explains a newly developing preemption issue regarding aviation safety. It also recommends that the agency amend its regulations to ensure that airworthiness certificates do not afford immunity to manufacturers or airlines.
- H) Social Security Administration – This section recommends that the agency take the following steps to ensure that claimants remain adequately represented before the agency, namely: (1) revise regulations to raise cap on authorized fees in fee agreements in accordance with cost-of-living adjustments; (2) revise regulations regarding fee petition process for delegation of authority to authorize fees; and (3) issue a Memorandum to the SSA General Counsel’s office to ensure that the Equal Access to Justice Act is interpreted properly.
- I) Centers for Medicare and Medicaid Services – This section explains that the agency must amend its interim final rule regarding Medicare Secondary Payer to address a 2006 Supreme Court decision. The agency also should take certain actions to improve the effectiveness of the Medicare system.
- J) Federal Motor Carrier Safety Administration – The Administration should direct the agency to issue a rulemaking to increase the current minimum insurance requirements for motorcoach operators. This would ensure that those injured in motorcoach accidents could obtain sufficient recourse from claims brought against coach operators.