

AMERICAN BAR ASSOCIATION
TORT TRIAL AND INSURANCE PRACTICE SECTION
REPORT TO THE HOUSE OF DELEGATES

RECOMMENDATION

1. RESOLVED, that absent Congressional authorization, the American Bar
2. Association opposes the promulgation by federal agencies of rules or regulations
3. that pre-empt state tort and consumer protection laws in instances where the state
4. laws hold parties to a higher or stricter standard than that being promulgated by
5. a federal agency.

REPORT

Background:

Over the past several decades, many state legislatures have passed numerous laws that are more stringent in protecting people's rights than corresponding federal laws. Federal agencies have recently sought to foreclose the states' long standing authority to govern a broad range of issues. Supporters and detractors alike call it the "silent tort reform" movement.

In recent months, various federal agencies have proposed/adopted regulations that would either limit, or entirely preempt laws in many states. These state laws allow individuals and state attorneys general to apply the higher standards set forth in state laws and state court precedents. It is a bi-partisan conclusion that the efforts by the federal regulators may wind up doing more than Congress to change state laws.

Proposed Federal Agencies' Regulations:

Examples of just a few of the numerous proposed federal regulations that affect state laws are set forth below:

In January 2006 the Food and Drug Administration (FDA) approved a drug label rule that preempts state laws. While the regulation requires manufacturers to better organize and simplify directions on package inserts, it also provides that companies that comply with the new standards may not be sued in state courts by patients injured by their products. Federal Register, Vol.71, No.15, Tuesday, January 24, 2006, pp 3921-3997. The National Conference of State Legislatures contends that the FDA went back on earlier assurances that the labeling rule would not pre-empt state or local laws - then refused to provide state legislators with a copy of the revised language or extend the period reserved for the public to comment.

The Consumer Product Safety Commission has been persuaded to adopt a rule over the objections of safety groups that would limit the ability of consumers to win damages under state laws for mattresses that catch fire, when the companies comply with new federal standards. Federal Register, Vol. 71, No. 50, Wednesday, March 15, 2006, pp 13472-13523. This is the first instance in the Commission's 33-year history that it took action to limit the ability of consumers to bring cases in state courts.

Pending before the National Highway Traffic Safety Administration (NHTSA) are proposals announced last year by the agency that would pre-empt state laws on the safety standards for car roofs and seat positions. These rules would shield automobile manufacturers from suits arising from injuries incurred in rollover crashes, as long as the carmakers comply with new federal standards for roof strength. Federal Register, Vol. 70, No. 162, Tuesday, August 23, 2005, pp 49223, 49245.

State prosecutors and state lawmakers have lodged objections. Attorneys general in 26 states, including New York, California and Massachusetts, recently sent a letter to the National Highway Traffic Safety Administration about the effort to preempt roof safety rules. "The state

common law court system serves as a vital check on government-imposed safety standards" the state prosecutors said. They concluded that the proposal "is likely to erode manufacturer incentives to assure that vehicles are as safe as possible for their intended use."

The new regulations are likely to face court scrutiny in the coming years. But the regulatory agencies have engineered the new rules in a way that they hope will make them less vulnerable to immediate challenge. In the case of several of the new rules, including those for drug labels and car construction, regulators placed the language protecting manufacturers in the preamble, which does not customarily deal with changes and is usually treated as accepted fact, not subject to public comment. By putting the pre-emption language in the preambles of the new rules, the agencies make it difficult for the pre-emptions to be challenged by the affected states and parties.

Summary of Federal Preemption Law:

Under the Supremacy Clause, U.S. CONST. art. VI, cl. 2, the federal government may, within constitutional limits, preempt state law and require states to apply federal law. Even so, the Supremacy Clause jurisprudence recognizes that **"States are independent sovereigns in our federal system, [and, presumptively,] Congress does not cavalierly pre-empt state-law causes of action."** *Medtronic, Inc. v. Lohr*, 518 U.S.470, 485 (1996). In areas traditionally regulated by the states, the courts will find federal preemption only when Congress has made such an intention "clear and manifest." *New York State Conf. of Blue Cross & Blue Shield Plans v. Travelers Ins. Co.*, 514 U.S. 645, 655 (1995)(citation omitted).

The U.S. Supreme Court has recognized three circumstances in which preemption exists: (1) the federal law may contain an explicit preemption provision (express preemption), *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990); (2) the federal law is so comprehensive that it is apparent Congress intended to occupy an entire field of regulation because there is no room for supplementary state regulation (implied or field preemption), *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995); and (3) the federal law, though not entirely displacing state law, still creates an actual conflict with a particular state regulation. *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

Express preemption exists in liability-altering legislation when "the federal statute at issue provide[s] the exclusive cause of action for the claim asserted and also set forth procedures and remedies governing that cause of action." *Beneficial Nat'l Bank v. Anderson*, 539 U.S. 1, 8 (2003). When Congress undertakes to enact that "unusually 'powerful'" kind of preemptive statute, it provides a remedy for any plaintiff's claim to the exclusion of existing state remedies. *Id.* at 7.

Occupy-the-field preemption presupposes a "scheme of federal regulation . . . so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," or where an Act of Congress "touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

Finally, "actual conflict" preemption exists where a party cannot comply with both state and federal law, see, e.g., *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963), or where state law "stands as an obstacle to the accomplishment and execution of

the full purposes and objectives of Congress." *Hines*, 312 U.S. at 67. Thus, conflict preemption will be found only if the need for it is clear. *Pokorny v. Ford Motor Co.*, 902 F.2d 1116, 1122 (11th Cir. 1989).

Federal Preemption as it Applies to Proposed Federal Regulations:

The examples cited above of federal agencies' regulations treading into the purview of state tort and consumer laws are just a few of the scores of pending regulations currently being generated. Different federal statutes are cited by the various federal agencies in support of regulations preempting state laws. Whether or not such federal regulations actually warrant preemption is questionable. By way of example, one such regulatory scheme is explained below:

The FDA's preamble to the final drug label rule asserts broad and vague federal preemption of state drug labeling, advertising, and product liability laws. Federal Register, Vol. 71, No.15, Tuesday, January 24, 2006 at 3935. Such an assertion is inconsistent with long-standing Food and Drug Administration practice and Congressional intent. In fact, the preamble to the proposed rule, originally published in the Federal Register on December 22, 2000, explicitly stated then that "this proposed rule does *not* preempt state law." 65 Fed.Reg. 81082, 81103 (December 22, 2000). Whether the agency has the legal authority to now reverse its position and preempt state requirements is questionable.

The FDA asserts that it has the authority to impliedly preempt state law because its regulations are promulgated pursuant to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(a). However, when Congress enacted the Federal Food, Drug, and Cosmetic Act in 1938, it specifically rejected a proposal to include a private right of action for damages caused by faulty or unsafe products regulated under the Act, **on the ground that such a right of action already existed under state common law**. See, e.g., Hearings before Subcommittee of Committee on Commerce on S. 1944, 73d Cong., 2d Sess. 400, 403 (1933); Adler & Mann, Preemption and Medical Devices, 59 Mo. L. Rev. 895, 924 & n.130 (1995).

In Section 202 of the Drug Amendments of 1962, Congress stated that "[n]othing in the amendments made by this Act to the Federal Food, Drug, and Cosmetic Act shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless **there is a direct and positive conflict between such amendments and such provision of State law**." Since 1938, Congress has never chosen to preempt State product liability actions through amendments to the Act.

It is doubtful whether the FDA could meet the burden of proof required under actual conflict preemption. "Consideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Bldg. & Constr. Trades Council of Metro. Dist. v. Assoc. Builders & Contractors of Mass./R.I., Inc.*, 507 U.S. 218, 224 (1993) From 1938 until 2001, state court liability actions for injuries resulting from approved drugs proceeded uninterrupted by FDA or Congress. As the Supreme Court stated only last year in a case rejecting a claim that the federal pesticide label broadly preempted state law:

"The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against preemption. If Congress had intended to deprive

injured parties of a long available form of compensation, it surely would have expressed that intent more clearly.”

Bates v. Dow, 544 U.S. 388 (2005)

If the FDA drug labeling regulations are allowed to preempt state law, the effect will likely be far reaching. For example, it is likely that such FDA regulations would bar the hundreds of state court cases that have been brought against Merck for its failure to warn patients who suffered strokes and heart attacks after using Vioxx. This example is just the tip of the proverbial iceberg of state court drug litigation.

Again, this analysis of the FDA’s drug labeling regulations is given by way of example. These FDA regulations are but one of scores of regulations being promulgated by federal agencies seeking to preempt various state consumer protection and tort laws.

Existing ABA Policy and Effect of the Proposed Recommendation

This recommendation is consistent with long standing concerns of the Association for the preservation of our federal system. It furthers existing ABA policy that, with few exceptions, opposes enactment of broad federal product liability legislations¹. Other ABA policy opposes federal legislation abolishing seller liability.

However, existing ABA policies do not address regulatory agency pre-emption of state law on an industry-by-industry, product-by-product or agency-by-agency basis such as now occurring in federal agencies. Specific ABA policy, such as that advocated by this recommendation, is needed in order for the ABA to advocate that absent Congressional authorization, the ABA opposes the promulgation by federal agencies of rules or regulations that pre-empt state tort and consumer protection laws in instances where the state laws hold parties to a higher or stricter standard than that being promulgated by a federal agency.

Respectfully submitted,

Sandra R. McCandless, Chair

Tort Trial and Insurance Practice Section

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¹ ABA supports federal legislation with respect to claims arising out of occupational diseases in certain instances and supports federal legislation that allocates product liability risks between the federal government and its contractors.