PRESIDENT'S COLUMN

Federal Preemption – The Latest Assault on Consumer Rights

by Kenneth M. Sigelman

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In 2006, Stephen Labaton, writing for the *New York Times*, referred to federal preemption as "silent tort reform" ("'Silent Tort Reform' Is Overriding States' Powers," March 10, 2006). Over the 2 ½ years since that article was published, federal preemption of state law remedies for a wide variety of torts has ceased to fly under the radar. Federal preemption via unprecedented federal agency actions and right wing activist jurisprudence by "originalist" judges is at the core of ongoing attacks by big business and the insurance industry on the civil justice system. If this trend is not reversed, the damage to consumer rights will be immeasurable.

Federal preemption of state law under the Supremacy Clause can be express or implied. Express preemption occurs when Congress explicitly states, within the subject statute, that it preempts state and/or local law regarding the same subject matter. Implied preemption may be based upon any of the following: (1) "conflict preemption" when the federal statute and the state or local law are mutually exclusive, such that compliance with both would be impossible; (2) "exclusivity preemption" based on congressional intent that federal law was meant to be exclusive on a particular subject; and (3) "obstacle preemption" when state or local law presents an obstacle to achieving the primary goals of federal law on the subject. The current preemption crisis (a fair characterization based upon what is at stake) has largely been fueled by expansion of the obstacle preemption doctrine.

Perhaps the best known current battle regarding preemption of state law remedies by federal law is in the area of medical devices and prescription drugs. The sources of the controversy are the Medical Device Amendments of 1976 ("MDA") which were passed in response to widespread harm resulting from unsafe medical devices such as the Dalkon Shield. Comment 360 k(a) to the MDA contained an express preemption provision that "no State . . . may establish or continue in effect with respect to a device intended for human use any requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device . . . ."

For more than two decades, the Food and Drug Administration ("FDA") took the position that the MDA did not preempt product liability actions based on state law. However, in 2002, the FDA reversed its stance. The agency began intervening in state court cases on behalf of defendant medical device manufacturers, arguing that the MDA's preemption provision eliminated plaintiffs' rights to sue manufacturers under state law. Once the FDA began filing *amicus* briefs on behalf of

defendants in medical device cases, a split of authority developed among federal courts on the preemption issue. Accordingly, the United States Supreme Court granted review in *Riegel v. Medtronic, Inc.* (2008) 552 U.S. ___ . In *Riegel*, an Evergreen Balloon Catheter ruptured during performance of a coronary angioplasty, resulting in complete heart block, necessitating life support and requiring emergency coronary artery bypass surgery. The manufacturer moved for summary judgment based upon MDA preemption. The Supreme Court held that the MDA did preempt the plaintiffs' state law claims because the device had received pre-market approval from the FDA, and affirmed the granting of summary judgment. Since the MDA preemption provision, unlike most other federal statutes with express preemption language (such as the federal Vaccine Act), did not provide for any federal remedy to replace the preempted state causes of action, the Riegels were left with no legal remedies for the harm suffered.

Several months ago, the United States Supreme Court granted review in *Wyeth v. Levine* (Vt. 2006) 944 A.2nd 179, *cert. granted*, (U.S. 2008) 128 S.Ct. 1118. In *Wyeth*, the Court will decide whether, as drug manufacturers, and, now, the FDA, claim, FDA drug labeling regulations preempt state law claims in prescription drug cases based on failure to warn. In *Wyeth*, plaintiff Diana Levine received an injection of Phenergan to treat migraine-induced nausea. The drug was administered via a technique known as "IV push" which involves a rapid injection rather than an IV drip in which the drug is mixed with a bag of fluid and infused over time. While the FDA-approved label for Phenergan warned that contact with arteries could cause gangrene, and cautioned against administration by IV drip, the label was silent regarding use of the IV push method. Unfortunately, the needle penetrated an artery in Ms. Levine's arm, and, due to the toxic effects of Phenergan, she developed gangrene, ultimately requiring amputation of her arm.

A state court jury found that Wyeth was liable for failure to warn of the risks associated with the IV push method and awarded Ms. Levine $6.7 million in damages. The Vermont Supreme Court affirmed, holding that requiring Wyeth to provide additional warnings beyond those contained on the FDA-approved label would not have presented an obstacle to realization of any of the goals of the Federal Food, Drug and Cosmetic Act. In its petition for certiorari, Wyeth, and *amicus* FDA, contended that the FDA label approval process was analogous to the pre-market approval process for medical devices, and, accordingly, the federal preemption rationale of *Riegel* applied.

The Supreme Court will hear oral argument in *Wyeth* around the time this column is published. A decision is expected in early 2009.

Victims of defective medical devices and drugs are not the only ones who may lose their access to justice based on federal preemption. The National Highway Traffic Safety Administration ("NHTSA"), packed with automotive industry-connected and/or industry-friendly appointees, has claimed that its vehicle safety standards preempt state tort law with regard to (1) roof crush resistance; (2) rearview mirrors on trucks; and (3) designated seating positions (which determine seatbelt or airbag protection requirements). Independent experts contend that NHTSA's standards evolve too slowly in response to new information, and that the coziness between agency political appointees and industry further hinders enactment of appropriately stringent safety standards. The NHTSA regulatory preemption language is contained in preambles to the regulations, despite the fact that the federal Motor Vehicle Safety Act contains a savings clause which states expressly that compliance with a NHTSA standard does not exempt a person from common law liability. The Act

also specifies that NHTSA standards are minimum standards that manufacturers may exceed.

As this column goes to press, a new roof crush standard is scheduled to take effect on October 1, 2008. Originally, the standard was to have taken effect on July 1, 2008. However, vigorous protests by such consumer advocates as Ralph Nader, as well as some United States senators, that the proposed standards would not save nearly enough of the more than ten thousand lives that are lost each year in rollover crashes, led to NHTSA's agreeing to perform additional analysis before finalizing a new rule. It is significant to note that the rule that is currently in place was adopted more than 35 years ago.

In recent years, the Consumer Product Safety Commission ("CPSC") has also jumped on the federal preemption bandwagon. In 2006, the CPSC adopted a rule regarding mattress flammability which, according to the preamble, has displaced state common law remedies. The CPSC's "preemption by preamble" is unprecedented in the agency's history. Indeed, the agency's enabling statute, the Flammable Fabrics Act, included preemption language only with regard to federal exclusivity regarding establishment of a flammability standard. Nothing in the Act preempts state law tort suits regarding mattresses that burn. The CPSC's preemption language was included in the final version of the rule notwithstanding a well-established body of law holding that the Flammable Fabrics Act does not preempt state tort law remedies.

The Treasury Department has also been heard from on the subject of preemption. Its Office of Thrift Supervision successfully challenged a Montgomery County, Maryland law intended to reduce discriminatory lending practices. In addition, the Comptroller of Currency, with the urging of large banks, has moved to block enforcement of pro-consumer lending laws in several states, including California.

One week before this column went to press, a federal district judge in the Southern District of New York dismissed a lawsuit against now-bankrupt mortgage lender IndyMac Bancorp, Inc. The plaintiff claimed that IndyMac had inflated the appraised value of homes and misled borrowers into paying higher closing finance costs. The judge's ruling was based upon federal preemption pursuant to the Home Owners' Loan Act. Under the Act, the federal Office of Thrift Supervision (see above) has principal responsibility for regulating federally chartered savings associations such as IndyMac.

The FDA's most recent assault on consumer rights is its proposed regulation on warning label requirements that includes a preamble preempting state product liability lawsuits by women who are pregnant or breast-feeding, even if a warning label fails to disclose the dangerous side effects for those women if they use those products. Several days before this column went to press, the American Association for Justice ("AAJ"), formerly known as ATLA, filed an objection over the proposed wording, on the ground that it contradicts express congressional intent.

AAJ has been strongly advocating congressional righting of the judicially and administratively created preemption wrongs of the past several years. On May 15, 2008, the House Committee on Oversight and Government Reform held hearings on the subject of federal preemption. Given the upcoming election, there is no realistic prospect of legislative reform this year. However, AAJ fully intends to continue pressing this issue with the new Congress. Based on everything that I have read and heard, I am cautiously optimistic that a meaningful legislative solution can be achieved within

the next year or two.

For the present, **we must all be aware of the enormous threat that federal preemption raises for consumers**. Based upon the present state of the law, tens of thousands of severely injured victims, and families of victims, of corporate misconduct will be deprived of any remedies. Corporate wrongdoers will be free to market unsafe products and mistreat, mislead, and injure the public. As consumer attorneys, it is our responsibility to raise public awareness regarding these issues, and to be strong, proactive voices in support of a solution.