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REPORT

Federalism

Agencies Move to Override State Law As Part of Federal Rulemaking Process

In a new approach that critics call ''silent tort reform,'' federal agencies under the Bush administration have mounted an aggressive effort in recent months to nullify state product liability laws.

While White House officials deny there is any coordinated effort, just since January agencies as diverse as the Food and Drug Administration, National Highway Traffic Safety Administration, and Consumer Product Safety Commission have issued major regulations stating explicitly that they are intended to override state law, including even decisions of state courts.

''It's a massive effort at the federal level to chip away at state tort law and federalize it,'' said Susan Frederick, a senior director with the National Conference of State Legislatures (NCSL), which is attempting to mobilize state opposition to the sweeping assertions of federal preemption in the new regulations.

Joining the fray, state attorneys general from 26 states wrote to the administrator of NHTSA in December, objecting to NHTSA's attempt to preempt state law in a proposed vehicle roof crush standard, which was published in August 2005.

''It's a massive effort . . . to chip away at state tort law.''

SUSAN FREDERICK, NATIONAL CONFERENCE OF STATE LEGISLATURES

''NHTSA's preemption position impinges directly on state court jurisdiction in an area traditionally and historically reserved for the states,'' the attorneys general wrote. ''The state common law court system serves as a vital check on government-imposed safety standards. Vehicles and equipment can contain hazardous features and still meet federal minimum safety standards. NHTSA's proposal is likely to erode manufacturer incentives to assure that vehicles are as safe as possible for their intended use.''

Reflecting the growing concern, the NCSL will hold a three-day conference April 6-8 in Washington, where one of the discussion topics for state legislators will be ''federal preemption of innovative state public policy.''

Over the past several years, major business groups and other tort reform advocates have worked with mixed success to get Congress to provide legislative relief from what they view as an onerous tort law system in the states. In the face of strong opposition from Democrats, the trial lawyers' lobby, and consumer advocates, a major effort to enact comprehensive product liability reform foundered in the late 1990s.

Last year, Congress did pass a measure making it easier to transfer state class actions into federal court, as well as a bill to provide immunity for gun manufacturers. But a years-long push to enact liability reform for asbestos claims remains stalled in the current Congress.

Preemption Asserted by Three Agencies. As evidence of the growing trend toward preemption by agencies, critics point to regulatory proceedings initiated by the FDA, NHTSA, and CPSC in recent months.

A final FDA rule covering prescription drug labeling, issued in January (71 Fed. Reg. 3,922-3,397) said the rule would preempt state law because ''if State authorities, including judges and juries applying State law, were permitted to reach conclusions about [drug labeling requirements], the federal system for regulation of drugs would be disrupted.''

NHTSA included similar language in its proposed rule establishing roof crush standards issued last August (70 Fed. Reg. 49,223).

More recently, NHTSA, in a final rule issued March 29 to increase fuel economy standards for larger ve-

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hicles (rule not yet published), the agency repeated earlier assertions that the new rule overrides any attempt by states to impose greenhouse gas emissions limits on new vehicles. Greenhouse gas emissions limits amount to fuel economy requirements, NHTSA said in the final rule, adding that Congress made the federal government the sole authority to regulate fuel economy.

The CPSC, in issuing a final regulation on mattress flammability standards March 15 (71 Fed. Reg. 13,472), also stated that its rule ''would preempt all conflicting State common law requirements, including rules of tort law.''

'Sneak Attack' on Consumers, Advocates Say. Consumer advocates say the agency statements on preemption are simply an effort to achieve tort reform on the sly. ''This is a sneak attack on consumer rights,'' said Joan Claybrook, president of the consumer advocacy group Public Citizen.

For their part, industry groups and corporate counsel defend the preemption efforts, saying they represent long-sought recognition by federal agencies that corporate regulatory compliance becomes increasingly difficult with a patchwork of laws and regulations across the 50 states.

''In general, federal uniformity is a good thing instead of standards set by state regulators or state juries of six or twelve people,'' said David Price, senior counsel with the Washington Legal Foundation, a conservative legal reform group.

In the case of the CPSC proposed mattress flammability standard, for example, the proposed rule generally tracks similar requirements set by California officials last year. When other states began to consider issuing their own mattress safety standards, lobbyists from the International Sleep Products Association, the industry's trade group, went to the CPSC to ask for a ''national standard that is followed coast to coast,'' in the words of Ryan Trainor, the association's general counsel.

Preemption in Rules New, Experts Say. Administrative law experts say that, while the issue of whether federal regulations preempt state law or regulations is not new, recent moves by agencies under the Bush administration mark the first concerted attempt to write preemption language into the regulations themselves.

Historically, agencies have tended to argue preemption on a case by case basis, depending on the particular issue being litigated in court, said Jeffrey Lubbers, who teaches administrative law at the American University Washington College of Law.

Indeed, FDA attorneys have spent the past several years filing legal briefs in courtrooms across the country arguing that FDA rules should preempt state law. But often courts have discounted these briefs ''as setting forth nothing more than legal argument by counsel,'' said Eric G. Lasker, a food and drug law attorney with Spriggs & Hollingsworth in Washington, D.C.

Placing preemption language into the body of a regulation is a new twist, Lubbers said. ''Perhaps the agencies believe they can achieve more deference from courts if they argue preemption more proactively by placing the language in a rule,'' he added.

In the past, federal agencies ''have been fairly agnostic'' about whether their regulations override state law, said Thomas McGarity, an administrative law professor at the University of Texas School of Law. Congress often writes language into a statute saying that no state may impose requirements that are inconsistent with the law or by setting a minimum level of compliance that states are free to exceed, McGarity said.

''But where this administration has been different—and really quite aggressive—is by attempting to override, through regulation, not just state regulations but decisions of state courts as well,'' he told BNA.

OMB Denies Coordinated Effort. Officials at the Office of Management and Budget deny any suggestion that the recent spate of preemption language in agency rules is part of an administration strategy.

''State courts and juries often lack the information, expertise, and staff that the Federal agencies rely upon in performing their scientific, risk-based calculation,'' wrote OMB spokesman Alex Conant in an e-mail to BNA. ''In each case, the agency with the appropriate authority and expertise makes the determination whether a uniform national standard would best protect the public health and safety.''

While promoting uniformity, any regulatory effort to preempt state tort lawsuits could have some significant disadvantages, at least in the eyes of plaintiffs' lawyers and consumer advocates. For one thing, it could blind regulatory agencies to corporate misbehavior that might only be discovered as part of a lawsuit.

''There's no other process that puts the pieces together of what a company knew and when it knew it,'' said Karen Barth Menzies, a plaintiffs' lawyer who is handling a major product liability suit against GlaxoSmithKline PLC over use of the antidepressant Paxil.

The discovery process in the litigation revealed ''just mounds and mounds of documents'' that FDA never saw, Barth Menzies told BNA. The suit alleges that GlaxoSmithKline failed to warn that the drug has been associated with causing suicidal thoughts among users.

''Preemption would close off one of the few avenues by which we learn of safety and efficacy information that pharmaceutical companies do not publish and even hide from the FDA,'' said Barth Menzies, a partner with Baum Hedlund in Los Angeles.

Agency efforts to cut off state tort law could also deprive consumers of compensation for injuries or economic harm at a time when federal regulation of industry in general is being cut back, said Brian Wolfman, director of the Public Citizen Litigation Group.

''What's ironic is that these steps by agencies are not happening at a time when federal regulators in general are doing a bang-up job protecting consumers,'' Wolfman told BNA. ''We're living in an era of less regulation across the board.''

Moreover, while federal agencies can penalize companies with fines or remedial orders for regulatory violations, the state tort law system is often the only means available to provide direct compensation to individuals harmed as a result of corporate misdeeds, he noted.

Little Public Comment From Agency Officials. Beyond the published regulations themselves, agency officials have offered little in the way of public comment explaining the push toward preemption.

In February, when the CPSC issued its final mattress flammability rule, CPSC chairman Hal Stratton issued a statement praising the rule for offering manufacturers ''flexibility,'' but he did not address the preemption issue.

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However, in a separate statement, Stratton's fellow commissioner, Thomas H. Moore, a Democratic appointee, slammed the rule's preemption language, saying: ''It makes no sense to risk eliminating sources of new information that might come from private litigation. Just as litigation informs our compliance activities, so should we allow it to inform our regulatory process.''

Noting the absence of express CPSC preemption authority from Congress that would extend to state court proceedings, Moore added, ''Absent a clear mandate from Congress, the Commission should not put its thumb on the scale of justice to tip it one way or the other.''

Sen. Daniel Inouye (D-Hawaii) also shared his concerns about the CPSC mattress standard in a Feb. 13 letter to Stratton, stating, ''Safety advances . . . moved steadily, due in part to the accountability provided by the civil justice system and state courts.''

''Removing a significant incentive for industries to improve outside of meeting the federal standard may have a chilling effect on industries integrating new safety technology into their products,'' he warned.

Senate Judiciary Members Question NHTSA Rule. After NHTSA issued its proposed rule on roof crush resistance for vehicles last year, both the chairman and the ranking Democrat of the Senate Judiciary Committee—Sens. Arlen Specter (R-Pa.) and Patrick Leahy (D-Vt.)—wrote to NHTSA acting Director Jacqueline Glassman in November. The senators asked for an explanation of ''how NHTSA concluded that preemption of state law was the intent of Congress when it passed the Transportation Equity Act,'' which authorized NHTSA to promulgate the regulation. Court decisions on whether to uphold agency preemption claims often hinge on statements of congressional intent, contained either in a statute or in a statute's legislative history.

In a reply sent two months later, Glassman responded, acknowledging that the issue of preemption ''was an important one,'' without further elaboration. In a reference to the procedural difficulties agencies might encounter by waiting to argue preemption in later court proceedings, Glassman told the senators, ''We wanted to raise the possibility of preemption during the rulemaking process, when there is a chance to obtain and consider public comments, rather than after the fact during possible litigation.''

House Member Mounts Attack. In one of the few congressional efforts to stem the agency preemption practice, Rep. Maurice Hinchey (D-N.Y.) in February 2004 tried to strip funding from the FDA Chief Counsel's Office in an attempt to prevent FDA lawyers from arguing preemption in court. Hinchey's effort, which came nearly two years before FDA began its current practice of writing preemption into regulations, failed.

Hinchey's move was directed at then-FDA Chief Counsel Daniel Troy, who is described by consumer advocates as the architect of the FDA's preemption strategy. Before joining FDA at the beginning of the Bush administration, Troy was a partner with Wiley, Rein & Fielding in Washington, D.C., where he represented Pfizer and other major drug manufacturers.

Hinchey charged that Troy, while at FDA, entered into a ''pattern of collusion'' with drug companies, soliciting product liability cases in which FDA could intervene and make its preemption arguments in court. Troy has since left the FDA and is now a partner with Sidley & Austin.

Contacted by BNA, Troy denied that he originated FDA's strategy, saying that companies ''were coming to us anyway and asking how to handle the preemption issue.'' Moreover, the FDA had argued preemption in earlier cases during the Clinton administration with the support of career FDA staff, he maintained.

''This was not a one-man show,'' he said, noting that all the FDA's legal briefs on preemption had to make it up the approval chain at the Department of Justice.

In July 2005, Hinchey introduced a bill that would require the FDA to cease arguing preemption in state court cases, among its other provisions. Hinchey's ''Food and Drug Administration Improvement Act'' (H.R. 2090) was referred to the House Energy and Commerce Committee's health subcommittee, which has taken no action on the measure.

Measures in Congress Favor Preemption. Apart from Hinchey's bill and the recent written expressions of concern by a handful of lawmakers, Congress as a whole does not appear to be inclined to curb the preemption practices of federal agencies. To the contrary, lawmakers in the current Congress seem to be on a preemption spree of their own, writing strong preemption language into several recent pieces of legislation.

For example, in March the House passed the National Uniformity for Food Act (H.R. 4167), which would preempt state food safety and labeling laws that are stronger than federal law. Other bills that would preempt state action include the Chemical Facility Anti-Terrorism Act (S. 2145), which would override stronger state laws on chemical plant security; the Responsible Lending Act (H.R. 1295), which would preempt any state law regulating mortgage lending activities; and the Notification of Risk to Personal Data Act (S. 1326), which would preempt all state and local laws relating to electronic information security standards.

Groups working on behalf of the states see little they can do on the legislative front to stem the preemption tide in Washington. ''We're really Daniel in the lion's den,'' said Frederick with the National Conference of State Legislatures. ''Too many people in Congress and the agencies believe in preemption,'' she said. ''It's a federal power grab and they're going to go for it.''

Court Challenge Could Take Time. As a result, the main battle over the recent regulations may well take place in the courts. But it could take some time, experts said. Industry is unlikely to mount a court challenge to the new rules, at least on the preemption issue, because it favors business interests.

Any legal challenge to preemption brought by opponents of the regulations may have to wait until a state court decides that a plaintiff's claim is actually preempted by the new regulations, said Richard Pierce, who teaches administrative law at George Washington University Law School.

''It can happen that an agency rule can't be challenged for years,'' Pierce said, noting there can be a substantial time lag between when a regulation takes effect and when a state court judge rules that a plaintiff's tort claim is preempted because of the rule.

The threshold issue for a court involves the ''extremely fact-rich legal concept known as standing,'' Pierce said. To have standing in a lawsuit, a party must demonstrate that it has been directly affected by a law

or regulation, he explained. For that reason, he believes the most likely way a legal fight over preemption will play out will be in the context of a traditional state tort lawsuit.

Lawyers Prepare Legal Strategies. With that in mind, lawyers on both sides are planning their next moves. Not surprisingly, corporate defense attorneys intend to seize on the new preemption language coming from the agencies as support for their arguments against state law claims.

In fact, corporate counsels have already begun citing FDA's preemption language in pending court cases, said Lasker, who defends against food and drug lawsuits with Spriggs & Hollingsworth. The FDA labeling rule will not take effect until June. Lasker believes the FDA's preemption statement in the rule ''should significantly bolster'' preemption arguments in court litigation.

Within days of the publication of FDA's new labeling rule in January, the Washington Legal Foundation released a ''Counsel's Advisory,'' stating, ''The key issue now is to take maximum advantage of the courts in these cases as forcefully as possible.''

The advisory, which was written by James Dabney Miller, a partner with King & Spalding, concluded, ''The goal should be to see that law students in 2016, when they hear about past pharmaceutical product liability cases, chuckle to themselves over this curious historical anomaly.''

The central argument corporate defendants will use in fighting product liability lawsuits will be based on a legal concept known as ''implied conflict preemption,'' said Lasker.

The concept, which is well-established in administrative law, bars state claims when they would conflict with a federal regulation, either by making it impossible for a party to comply with both federal and state requirements or by creating an impediment to compliance with federal requirements, Lasker explained.

The same legal argument was used by FDA when it sought to intervene in product liability suits on a case by case basis beginning early in the Bush administration, said Troy, the former FDA chief counsel.

However, FDA's efforts to preempt state lawsuits on a piecemeal basis achieved only mixed success, with some state judges questioning whether the agency was fully behind the preemption arguments, Lasker noted.

As a result, FDA decided to insert the preemption language into the preamble of the new labeling rule to signify that the agency endorsed the argument as ''official policy,'' Troy told BNA.

''It's a no-lose situation for the companies.''

PLAINTIFFS' LAWYER KAREN BARTH MENZIES

Critics Craft Legal Arguments. Plaintiffs' lawyers and public interest advocates, for their part, acknowledge that they face an uphill fight. said Barth Menzies with Baum Hedlund in Los Angeles.

Corporate defendants in a tort lawsuit will move to dismiss any product liability suit filed in state court based on the federal preemption language contained in the new regulations, she said. ''A motion to dismiss will be the first thing out of the box—before a judge ever has a chance to look at the merits of a case,'' Barth Menzies predicted.

Moreover, a judge facing the potential burden of handling a huge mass tort case that touches on one of the new regulations ''may simply decide to use the new agency preemption language to get the case off his docket,'' Barth Menzies added.

As for challenging the preemption arguments on their merits, critics of the regulations believe they have the law on their side. While acknowledging that implied preemption makes sense in some cases, the key issue in dispute with the new regulations is whether state tort lawsuits actually conflict with the regulations, said Wolfman at Public Citizen. He believes they do not.

In the case of the NHTSA roof crush standard and the CPSC mattress flammability standard, for example, Wolfman and other consumer advocates maintain that the agencies simply set a minimum safety standard. A finding by a state court jury that a manufacturer was negligent for not increasing safety protections in a particular case ''in no way conflicts'' with the federal regulation, Wolfman asserted.

The same argument holds true with respect to the new FDA labeling rule, said Barth Menzies in Los Angeles, who contends that courts over the past several decades ''have consistently held that the FDA's regulations regarding prescription drugs set forth minimum standards.'' As a result, FDA's preemption effort contradicts existing legal precedent and ignores the important parallel roles played by FDA and tort liability law, she said.

Critics Question Preamble Language. Another flaw in the agencies' approach is the fact that they inserted the preemption language into the preamble section—instead of the body—of the rules, said James T. O'Reilly, a former chairman of the American Bar Association's Administrative Law Section, who now teaches at the University of Cincinnati College of Law.

''The preemption language . . . looks like it was wedged in with a shoehorn.''

JAMES T. O'REILLY, UNIVERSITY OF CINCINNATI COLLEGE OF LAW

''The preemption language doesn't fit in the preamble; it looks like it was wedged in with a shoehorn,'' O'Reilly said of the FDA's labeling rule.

He added, ''If the FDA wanted to do the credible thing, they would have included the preemption language in the rule itself and put it out for public comment,'' noting that preamble language is not subject to comment or judicial review. Courts have held that preambles are not law and considered as ''only an advisory opinion,'' O'Reilly said.

Second Line of Attack. A second line of attack mentioned by opponents of the preemption language focuses on the fact that the agencies failed to follow the requirements of a presidential executive order. As part of any rulemaking proceeding that involves preemption of state law, Executive Order No. 13132 issued in 1999 by President Clinton requires federal agencies ''to con-

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sult'' with state authorities and provide them ''notice and an opportunity for appropriate participation in the proceedings.''

In the case of the recent NHTSA and FDA rules, state officials were shut out of the process, said Frederick with the NCSL. ''This administration has violated the federal executive order repeatedly,'' she said.

The preemption language in the FDA rule only appeared when the final rule was published in January, she noted. ''The executive order requires agencies to contact state stakeholders as early as possible to try and minimize the rule's preemptive effect,'' she said. ''That never happened.''

While NHTSA did refer to preemption in its notice of proposed rulemaking, ''they would not consult with us,'' Frederick said. ''We forced them to meet but the process was completely wrong,'' she said.

GWU law professor Pierce expressed doubt that the courts will find merit in the executive order procedural argument. Calling the argument ''a perfectly valid politically-based argument,'' he pointed out that the order, like most executive orders, states that ''it is not enforceable at law by a party against the United States.''

As for including terms in a final rule that were not contained in a proposed rule, Pierce said, ''It's only a procedural error.'' A court can strike down the rule on that basis, he said, ''but the agency can come back and propose it again.''

BY RALPH LINDEMAN