

Preemption On The Mind: Recent High Court Rulings

Wednesday, Mar 12, 2008 --- Preemption is on the Supreme Court's mind. On Feb. 20, 2008, the Court issued two significant federal preemption decisions, *Riegel v. Medtronic* (8-1) and *Rowe v. New Hampshire Motor Transportation Association* (9-0)[1], holding that express preemption applies under a medical devices law and a motor carrier law.

Do these decisions manifest the Court's willingness to define preemption as one tool in their arsenal for tort reform? We think so.

And other federally regulated product manufacturers are lining up.

This term, the Supreme Court has already heard *Warner-Lambert Co. v. Kent* (argued Feb. 25), raising the issue of whether Michigan's pharmaceutical tort reform statute is preempted. The Michigan law protects manufacturers from liability if the FDA approved their drugs, except if the manufacturer obtained approval by misleading or bribing the FDA.

The Court will hear *Wyeth v. Levine*, another pharmaceutical preemption case, in October. Aviation tort claims against aerospace manufacturers are also ripe for review. Given the current circuit split on whether federal aviation regulations impliedly preempt the field of aviation safety—especially in light of the latest Ninth Circuit decision weighing in on that split—the Supreme Court may be the next preemption battleground for aviation defendants.

Riegel v. Medtronic

The Medical Device Amendments of 1976 express preemption clause prohibits states from imposing on medical devices “any requirement which is different from, or in addition to, any requirement applicable under” the MDA and which “relates to the safety or effectiveness of the device[.]”

In *Riegel v. Medtronic*, the Court held that this preemption clause bars common-law claims challenging the safety or effectiveness of a medical device that received premarket approval from the FDA, such as the Medtronic catheter at issue.

The Court found that New York's common-law tort duties constitute preempted “requirements” under the MDA, analogizing to the Court's similar holdings under the Federal Insecticide, Fungicide, and Rodenticide Act and the Public Health Cigarette Smoking Act.

The Court explained: “State tort law that requires a manufacturer's catheters to be safer, but hence less effective, than the model the FDA has approved

disrupts the federal scheme no less than state regulatory law to the same effect.”

The Court further intimated that it was more likely to find preemption of state common law claims than state statutes or regulations, as the latter “could at least be expected to apply cost-benefit analysis similar to that applied by experts at” the federal agency, in this case the FDA.

In describing the premarket approval process, the Court provided a blue print for the degree of federal regulation necessary for preemption to apply. The Court detailed the “rigorous” premarket approval process, during which the FDA spends on average 1,200 hours reviewing each application.

The FDA grants approval only if it finds that there is a “reasonable assurance” of the device’s “safety and effectiveness.” After premarket approval, the manufacturer is forbidden “to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness.”

The devices are also continually subject to FDA reporting requirements. The Court explained that premarket approval for an individual device “is in no sense an exemption from federal safety review—it is federal safety review.”

The Court clarified that “[s]tate requirements are pre-empted under the MDA only to the extent that they are ‘different from, or in addition to’ the requirements imposed by federal law.”

Thus, a State may provide a damages remedy “for claims premised on a violation of FDA regulations; the state duties in such a case ‘parallel,’ rather than add to, federal requirements.” However, since the Riegels failed to raise parallel claims below, the Court declined to address them.

In a post-Riegel world, the new focus in medical device claims will shift to noncompliance with FDA requirements. This will raise new issues about the degree of deference to be given to federal agency approval in deciding whether the defendant complied with federal standards.

Rowe v. New Hampshire Motor Transportation Association

The FAA Authorization Act of 1994 forbids States to “enact or enforce a law ... related to a price, route, or service of any motor carrier.”

In *Rowe v. New Hampshire Motor Transportation Association*, the Court held that this express preemption clause bars two provisions of a Maine tobacco law: (1) the requirement that tobacco licensees use a delivery service that promises to make delivery in a prescribed manner and (2) a provision imputing knowledge that a package contains tobacco if it is shipped by someone on a list or is marked as containing tobacco.

The *Rowe* Court followed its decision in *Morales v. Trans World Airlines, Inc.*,

504 U.S. 374 (1992), which addressed the nearly identical preemption clause in the Airline Deregulation Act.

Indeed, Congress “borrowed” language from the ADA. The Morales factors, which now apply to at least two fields of federal regulation, may provide insight into the Court’s future preemption analyses.

These factors include: (1) that state enforcement actions “having a connection with, or reference to” the preempted area are preempted; (2) that such preemption may occur even if the state’s effect on the preempted area “is only indirect”; (3) that preemption may take effect regardless of whether a state law is “consistent” or “inconsistent” with federal regulation; and (4) that preemption occurs at least where state laws have a “significant impact” related to Congress’ deregulatory and preemption-related objectives. However, state laws that affect the preempted area in only a “tenuous, remote, or peripheral ... manner” might not be preempted.

Rowe, finding preemption of a state statute, is an interesting compliment to Riegel, finding preemption of state common-law. Maine argued for an exception to preemption on the ground that its law helped to prevent minors from obtaining cigarettes.

The Court decided not to defer to Maine’s “cost-benefit” analysis: “Despite the importance of the public health objective, we cannot agree with Maine that the federal law creates an exception on that basis, exempting state laws that it would otherwise pre-empt.”

The Next Battlefield: Federal preemption in Field of Aviation Safety

Federal preemption in the field of aviation safety has long been hotly contested, and may be the next preemption issue on the Supreme Court’s mind.

Just as the FDA heavily regulates medical devices, so does the FAA enforce a comprehensive scheme of aviation safety regulations.

According to a recent Ninth Circuit decision, the Federal Aviation Act of 1958, and regulations promulgated pursuant to it, “establish complete and thorough safety standards for air travel, which are not subject to supplementation by, or variation among, state laws.” *Montalvo v. Spirit Airlines*, 508 F.3d 464, 468 (9th Cir. 2007).

The majority of other circuits considering this issue have also found standard of care preemption in aviation safety. *Greene v. B.F. Goodrich Avionics Sys., Inc.*, 409 F.3d 784, 795 (6th Cir. 2005); *Witty v. Delta Air Lines, Inc.*, 366 F.3d 380, 385 (5th Cir. 2004); *Abdullah v. American Airlines*, 181 F.3d 363, 367 (3d Cir. 1999); *French v. Pan Am Express, Inc.*, 869 F.2d 1, 4 (1st Cir. 1989).

However, two circuits have found there is no implied preemption in the field

of aviation safety. See *Cleveland v. Piper Aircraft Corp.*, 985 F.2d 1438 (10th Cir. 1993); *Public Health Trust of Dade County, Fla. v. Lake Aircraft, Inc.*, 992 F.2d 291 (11th Cir. 1993).

Given the Supreme Court's recent receptiveness to preemption arguments in *Riegel and Rowe*, the issue of aviation preemption is a prime candidate for Supreme Court review. Whether it will be *Montalvo* or another aviation case remains to be seen.

For now, the Ninth Circuit has remanded *Montalvo* to the district court for factual development on an Airline Deregulation Action claim, thus making it currently ineligible for certiorari.

Will Congress Take preemption Back?

The 2008 congressional elections could determine whether the trend of broadening federal preemption is here to stay. Congressional intent is the cornerstone of federal preemption.

A new, more liberal Congress may choose to pass laws overruling the Supreme Court's and the circuit courts' application of express and implied federal preemption; or, a new, more conservative Congress may choose to broaden further the fields to which federal preemption applies and thus to forward the goals of tort reform.

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[1] Morrison & Foerster LLP represented the three trade associations arguing in favor of preemption in *Rowe* — the New Hampshire Motor Transport Association, the Massachusetts Motor Transportation Association, and the Vermont Truck & Bus Association.