FEATURE ARTICLE

# The Recent Success of "Silent Tort Reform"

by Shaun Blake and John T. Lay, Jr.

As the Bush Administration draws to a close, the debate over whether the Administration has engaged in "silent tort reform," tort reform achieved without Congressional action, continues to rage in academic circles.[1] Policy concerns about silent tort reform have been at the center of these conversations. Regardless of your political views, however, a review of recent case law and regulations exposes efforts of the Administration to urge the courts to find common law actions for product liability preempted by federal authority. As practitioners, this intervention by federal agencies and the regulations propounded by them under the Bush Administration may have a significant impact on the defenses that we pursue before the courts on behalf of our clients in product liability cases.

A recent example of the importance of federal agency intervention is found in the Supreme Court's affirmation of the Second Circuit's decision in *Riegel v. Medtronic, Inc.*, - U.S. -, 128 S.Ct. 999, 169 L.Ed.2d 892 (2008), a controversial decision granting summary judgment in a product liability case based on the doctrine of preemption. In *Riegel*, a cardiac patient sued the manufacturer of a balloon catheter used in his angioplasty, asserting state-law claims including strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, sale and manufacture. The trial court granted summary judgment to Medtronic on all of these claims because of the preemption clause enacted in the Medical Devise Amendments of 1976 (MDA). Under the MDA, where the federal government has established requirements applicable to a medical devise, no state can alter these requirements.[2]

The Court utilized a two-step analysis in *Riegel* to find that the state causes of action were preempted by federal law. First, the Court found that the catheter balloon had undergone pre-market approval by the FDA. Importantly, the Court held that pre-market approval was prima-facie evidence that the Federal Government has established "requirements" sufficient to satisfy the first prong of the MDA. Second, the Court looked to New York common law to see if the state causes of action altered the "requirements." Relying on earlier authority, the Court determined that common law duties imposed by the state causes of action constituted "requirements."

Notably, the Court chose to iterate a broad conclusion of statutory construction for the benefit of Congress. The Court noted that "[a]bsent other indication, reference to a State's "requirements" includes its common-law duties." *Riegel*, 128 S.Ct a 1008. Following the Court's analysis in *Riegel*, in any product liability case involving medical devises subject to the MDA, so long as the product has undergone pre-market approval, any state product liability cause of action is preempted by federal law and is subject to summary judgment.

As evidence of the administration's pursuit of "Silent Tort Reform," the U.S. Justice Department weighed in as amicus curiae urging the Court to find that the state causes of action were preempted in *Riegel*. This effort by the administration played a role in the Court's decision. Specifically, the Court noted that where the preemptive scope of federal law is in some way affected by a federal agency's regulations, then the "agency's reading of its own rule is entitled to substantial deference." In *Reigel*, agency regulations played a lesser role, since the MDA itself included a preemption clause that the Court ultimately found unambiguous. However, the Court specifically refused to state that FDA regulations could not be used to interpret the preemptive scope of congressional action.

The Court's refusal to state that agency regulations cannot guide the Court on the issue of preemption in *Riegel* is significant because of recently adopted federal regulations. Often cited as glaring evidence of "Silent Tort Reform" by the Administration, federal agencies have gone beyond intervening in court cases to urge for preemption. More recently, federal agencies are placing preemptive language in the preambles to the regulations governing various products. Whether these preambles can effectuate preemption of state law claims is a controversial topic, and it requires a brief consideration of basic preemption principles.

Recall that preemption stems from the Supremacy Clause found in Article VI of the United States Constitution. According to the Supremacy Clause, the laws of the United States are the supreme law of the land; therefore federal law and regulations may preempt any state law which conflicts with federal authority. Preemption can result when Congress

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expressly states that it intends to do so, as evidenced by the *Riegel* decision. However, preemption normally occurs in one of the two following ways: 1) field preemption, where Congress has occupied the entire field, or 2) conflict preemption, where preemption is implied because of actual conflicts between state and federal law.[3]

The application of these principles of preemption has had a meaningful impact in product liability litigation. Since 2000, for instance, the FDA has intervened in pharmaceutical cases to argue that the Supremacy Clause bars state tort liability for failure to include a warning in a drug label that is in conflict with, or contrary to, warnings approved by the FDA.[4] Now, in the wake of the highly publicized Vioxx litigation, the FDA has placed express preemption language in the preamble to its January 2006 prescription drug labeling rule, causing quite a stir amongst legal academics.[5] In April of this year, the United States Court of Appeals for the Third Circuit weighed in squarely on the preamble's preemptive effect as the first federal court of appeals with an opportunity to do so since the FDA issued the preamble. *See (Colacicco v. Apotex*, 2008 WL 927848 (3rd Cir. April 8, 2008)).

Two district courts in the Third Circuit reached opposite conclusions as to whether a pair of drug manufacturers, Pfizer and Apotex, was entitled to judgment as a matter of law against state product liability claims for failure to warn of suicide risks. In *Colacicco v. Apotex, Inc.*, 432 F. Supp. 2d 514 (E.D. Pa. 2006), the plaintiff asserted that the label on a generic version of Paxil was insufficient to warn the deceased patient of a risk of suicide due to the anti-depressant. The Pennsylvania trial court dismissed the plaintiff's claim as conflict-preempted by FDA regulations.

In *McNellis ex rel. DeAngelis v. Pfizer, Inc.*, No. Civ. 05-1286(JBS), 2006 WL 281904 (D.N.J. Sept.29, 2006), the New Jersey trial court was faced with an identical claim based on Pfizer's antidepressant Zoloft. The court denied Pfizer's motion for summary judgment, but after the Pennsylvania court reached the opposite conclusion, the New Jersey court vacated its opinion and certified the question of conflict preemption to the Third Circuit. The Third Circuit consolidated the actions and agreed with the Pennsylvania trial court that the product liability claims were conflict-preempted.

In reaching its conclusion in *Colacicco*, the Third Circuit first discussed the presumption against preemption that federal courts regularly apply. According to this doctrine, courts are to rule against preemption absent a "clear and manifest intent by Congress." In its analysis, the court discussed the tension that exists between Supreme Court authority in this area, as the Court has both been willing to apply a presumption against preemption in some product liability cases and to denounce the presumption in others.[6] This tension arises in conflict preemption cases because inherently no explicit statement by Congress manifesting the intent to preempt exists, arguably rendering the presumption inapplicable. In *Colacicco*, the Third Circuit reached a compromise holding by recognizing the presumption against preemption, but applying it with lesser force because these two cases involved implied conflict preemption.

The Third Circuit went on to discuss the problems that would arise if state tort actions could continue against pharmaceutical manufacturers for failure to warn. The court noted that preemption would avoid pharmaceutical companies being subject to varying standards from state to state. Like the Court in *Riegel*, the Third Circuit pointed to the pre-approval process of the FDA and the controls in place to ensure adequate labeling. The court undertook a detailed discussion of the FDA's position regarding the lack of a warning indicating that either Paxil or Zoloft could cause an adult to commit suicide. The court noted that, in addition

to preemption in terms of statutes and regulations, preemption can be effectuated by the actions taken by a federal agency pursuant to its statutory authority. Therefore, the FDA pre-approval of the labels, in conjunction with its prior determination on the precise issue of suicidal risks for Zoloft and Paxil, were sufficient to effectuate preemption of the state product liability claims.

Importantly, the Third Circuit directly discussed the FDA's preemption statement included in the preamble to the 2006 amendment to the drug labeling regulations. Although the court noted that it would normally be "leery" of an agency's own position on preemption, the Supreme Court afforded an agency's position on preemption "some weight." *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883, 120 S.Ct. 1913, 146 L.Ed.2d 914 (2000). Therefore, the Third Circuit found that the FDA's position on preemption was entitled to receive "*Skidmore*" deference, another compromise reached by the Third Circuit that affords the FDA's preemption statement in its preamble an intermediate level of deference.[7] Therefore, the Court affirmed the Pennsylvania court's dismissal and ordered that the New Jersey Court grant Pfizer's motion for summary judgment.

The importance of this decision will have affects on product liability cases beyond the realm of pharmaceuticals. Recently other agencies, including the National Highway Traffic Safety Administration and the Consumer Product Safety Commission, have passed regulations with preambles containing express preemption provisions that relate to rollover standards for motor vehicles and fire safety standards for mattresses.[8] These actions and others taken by federal agencies are reforming manufacturers' product liability in state and federal court by affording these defendants a meaningful preemption shield against a myriad of tort liability. Prudent practitioners will be sure to check any federal regulations that may govern their client's product, even those seemingly innocuous preambles, to see if federal preemption is a defense available to product liability claims.

## Footnotes

1 Margaret Gilhooey, *Addressing Potential Drug Risks: The Limits of Testing, Risk Signals, Preemption, and the Drug Reform Legislation*, 59 S.C. L. REV. 347-390 (2008); Catherine M. Sharkey, *Preemption by Preamble: Federal Agencies and the Federalization of Tort Law*, 56 DEPAUL L. REV. 227-259 (2007); Robert L. Rabin, *Poking Holes in the Fabric of Tort: A Comment*, 56 DEPAUL L. REV. 293-306 (2007).

2 21 U.S.C.A. § 360k(a)(1) (2007).

3 Jill D. Jacobson and Rebecca S. Herbig, *The Transformation of Preemption Law*, FOR THE DEFENSE, 40-44, 88 (December 2007).

4 Sharkey, *supra*, at n. 99.

5 Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products, 71 Fed. Reg. 3922 (Jan. 24, 2006) (effective June 30, 2006).

6 *Contrast Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996) (applying a presumption against preemption where the plaintiff alleged negligence against a manufacturer) *and Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 347-48, 121 S.Ct. 1012, 148 L.Ed.2d 854 (2001) (declining to apply a presumption against preemption where the plaintiff alleged fraud against a manufacturer).

7 *Skidmore v. Swift & Co.*, 323 U.S. 134, 65 S.Ct. 161, 89 L.Ed. 124 (1944) (holding that agency interpretations contained in statements that "lack the force of law" are "'entitled to respect'" only to the extent they have the "'power to persuade'").

8 Starkey, at 230-36.

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*This article was first published in the IADC (International Assoc. of Defense Counsel) Product Liability Committee Newsletter, Bonus 2nd Ed. (May 2008).*