

Analysis & Perspective

For more than two decades, Public Justice has been fighting against preemption of injured victims' claims. In this Analysis & Perspective, Public Justice staff attorney Leslie A. Brueckner recalls the history of the preemption cases and addresses the issues currently before the Supreme Court, including the recently argued *Wyeth v. Levine* case, which addresses preemption of prescription drug failure-to-warn claims.

This new spate of Supreme Court cases underscores the huge threat posed by federal preemption—and the importance of fighting it with every means at our disposal, Brueckner says.

In the Eye of the Storm: The United States Supreme Court Takes On Four Preemption Cases Affecting Consumers' Rights

BY LESLIE A. BRUECKNER

More than 25 years ago, the first brief that Public Justice (then Trial Lawyers for Public Justice) filed in the U.S. Supreme Court opposed federal preemption of an injury victim's claim. It urged the Supreme Court to hold that Karen Silkwood could seek punitive damages against the Kerr-McGee Corp. for contaminating her with plutonium even though the company had complied with the federal government's regulations governing the safety of nuclear power plants. The Supreme Court agreed, 5-4.

Since that time, Public Justice's Federal Preemption Project has preserved the rights of millions of Americans to hold corporate wrongdoers accountable for the injuries caused by their hazardous products. In recent years, however, companies seeking to avoid responsibility for their conduct are advancing the federal preemption defense with more vigor than ever.

Just this term, the United States Supreme Court shocked the legal world by granting review in four cases involving federal preemption of consumer products. One of these cases—*Riegel v. Medtronic*, which involves defective medical devices—has already been decided adversely to the plaintiffs. Another case, *Warner-Lambert v. Kent*, was also decided—in a very unusual way. The remaining two cases could have an equally dramatic impact on the ability of victims of inadequately labeled prescription drugs and so-called "light" cigarettes to seek compensation for their injuries. Public Justice has participated as or on behalf of amicus curiae in all of these cases, urging the Court to

reject the unwarranted and overbroad preemption arguments that are being advanced by corporate America.

This new spate of Supreme Court cases underscores the huge threat posed by federal preemption—and the importance of fighting it with every means at our disposal.

Riegel v. Medtronic:

In *Riegel v. Medtronic*, which was decided Feb. 20, manufacturers of defective medical devices succeeded in convincing the Court to immunize them from almost any liability for the often-horrific injuries caused by their dangerous products. We joined with the American Association for Justice in an amicus brief urging the Court to leave state law damage claims in place, just as Congress intended. Unfortunately, eight out of nine Justices turned a blind eye to victims' rights, thereby stripping many consumers of the right to seek any remedy at all for their injuries caused by defective medical devices. See 128 S. Ct. 999 (2008).

The question in *Riegel* was whether the Medical Device Amendments (MDA) to the Federal Food, Drug, and Cosmetic Act bars a couple's state law claims against the maker of a balloon catheter that burst during the husband's angioplasty. In the decision below, the Second Circuit joined the majority of other federal appeals courts and state high courts in holding that the Food and Drug Administration's (FDA's) pre-market approval (PMA) of a medical device creates a "device-specific requirement" sufficient to trigger federal preemption under the MDA. In past litigation, the federal government and the FDA had said that PMA does not preempt state law actions seeking compensation for damages arising from defective medical devices. But in *Riegel*, the federal government flipped its position and said that PMA is sufficient to preempt state-law claims. And, in an 8-1 decision, (in an opinion written by Justice Antonin Scalia, with Justice Ruth Bader Ginsberg dissenting), the U.S. Supreme Court agreed, wiping out

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the majority of claims relating to drugs that have obtained pre-market approval from the FDA.

In so doing, the Court gave mere lip service to the fact that federal preemption analysis revolves around one all-important question: What did Congress intend? Our amicus brief in the case explained that Congress never intended to preempt state law tort claims involving hazardous medical devices. That's clear both from the history and the language of the statute that regulates medical devices, which was passed in the wake of the Dalkon Shield scandal to protect consumers from dangerous devices—not to immunize manufacturers from liability. The brief further explained the complementary roles played by the tort system and federal regulations in making the world a safer place for consumers of medical devices and other potentially dangerous products. The Court rejected all these arguments, finding that Congress must have intended to wipe out state law claims relating to PMA devices—even though it never said so and all evidence indicates to the contrary.

One of the many ironies of *Riegel* is that, in the past, the United States agreed that Congress never intended to preempt state law claims involving medical devices that had received pre-market approval. But, in *Riegel*, the Bush administration reversed the government's position and said there is preemption. The Supreme Court agreed, and now millions of Americans will be left without any remedy at all.

Warner-Lambert v. Kent

Public Justice also appeared before the U.S. Supreme Court in *Warner-Lambert v. Kent*, fighting to prevent pharmaceutical companies from avoiding liability based on the doctrine of federal preemption. In an amicus brief filed in January, we urged the Court to affirm a Second Circuit ruling that a drug manufacturer that failed to warn the public about the dangers of its product—and may have hidden key information from the federal government regarding the risks of the drug—cannot hide behind a Michigan state law that provides immunity to prescription drug manufacturers. See *Desiano v. Warner-Lambert*, 467 F.3d 85 (2d Cir. 2006). On March 3, the judgment below was affirmed because the Court was evenly divided 4-4. (The Chief Justice “took no part in the decision.” See 128 S. Ct. 1168 (2008).)

Kent involved injuries caused by the diabetes drug Rezulin, which was ordered off the market in March 2000 by the FDA after it was linked to nearly 400 deaths and hundreds of cases of liver failure. The plaintiffs in *Kent* were trying to get Warner-Lambert to compensate them for injuries caused by their ingestion of the drug. They argued that Michigan's state law immunity for drug manufacturers did not apply to their claims because it contains an exception for cases where the drug manufacturer withheld or misrepresented information that would have altered the federal FDA's decision to approve the drug. Warner-Lambert countered that the fraud exception is preempted by federal law because it conflicts with the FDA's authority to regulate prescription drugs.

Public Justice joined the fight in order to rebut one of the most radical—and dangerous—arguments in favor of federal preemption that we've ever seen. In an amicus brief filed in support of the drug company, the U.S. Chamber of Commerce—which seeks to increase corporate profits by filing amicus briefs in favor of

preemption—argued that there should be no presumption against preemption in implied conflict preemption cases. If the Court had adopted this argument, it could have tipped the scales in favor of preemption in a huge number of cases involving hazardous consumer products.

Our brief argued that the Chamber's argument—if adopted—would overturn more than a century of Supreme Court jurisprudence. It would also undermine the basic federalism principles upon which this country is based—principles preserving the historic importance of state tort law in protecting the health and safety of all Americans. Fortunately, due to the 4-4 split among the Justices, the Court never reached this issue and the Second Circuit's favorable decision remains good law.

Altria v. Good

Third on the roster is *Altria v. Good*, which involves federal preemption of consumer-fraud litigation over light cigarettes. This case arose when a class of smokers in Maine sued the maker of Marlboro Lights and Cambridge Lights—Philip Morris USA—under Maine's Unfair Trade Practices Act. The smokers alleged that Philip Morris' marketing, which describes the cigarettes as “light” and having “lowered tar and nicotine,” was deceptive because smokers may compensate for the reduced tar and nicotine by altering their smoking habits, making the products as unhealthy as “non-light” cigarettes at the end of the day. The plaintiffs sought economic damages for having been fooled into buying so-called “light” cigarettes.

The federal district court had found that the class claims were preempted by federal law because the Federal Labeling Act of 1965 gives the Federal Trade Commission (FTC) the authority to regulate all cigarette labeling and advertising that touches on the health impact of smoking. The First Circuit reversed this decision, finding that the state law claims were not preempted, emphasizing that the FTC has never adopted a formal rule governing the way companies described their cigarettes' tar and nicotine content. The First Circuit openly observed, however, that its opinion was in conflict with a Fifth Circuit opinion holding the opposite.

Philip Morris' parent company persuaded the U.S. Supreme Court to grant review, arguing that federal law preempts the rights of consumers to seek any damages relating to their inadequate labeling of light cigarettes. See *Good v. Altria*, 501 F.3d 29 (1st Cir. 2007).

Our brief, which we filed along with the Tobacco Control Legal Consortium and AARP, emphasized, among other things, the absence of any statutory basis for concluding that Congress actually intended to preempt these sorts of claims. The brief also emphasized what is always a central theme in our efforts to battle federal preemption: that, in light of the strong presumption against preemption, a court can only find preemption where Congress plainly intended it. This is especially true given that the Federal Labeling Act of 1965—like the statutes at issue in *Riegel*, *Wyeth*, and *Kent*—does not provide any mechanism for compensating the victims of defective and/or inadequately labeled products.

Wyeth v. Levine

Finally, there is the 800-pound gorilla known as *Wyeth v. Levine*, which will decide whether the federal

government's approval of a prescription drug's label preempts a claim that the label failed to warn of a drug's significant risks. At issue is an October 2006 ruling by the Vermont Supreme Court that federal law does not preempt a claim that the manufacturer of "Phenergan" should have warned against a method of administering the drug, called "IV push," directly into a vein.

The plaintiff Diana Levine, a guitar player, was given the drug to combat nausea associated with migraine headaches. Her arm developed gangrene and had to be amputated after the drug was inadvertently injected into an artery. A Vermont state court jury ultimately returned a verdict for the plaintiff of \$6.7 million.

On appeal to the Vermont Supreme Court, the drug's manufacturer (Wyeth) argued that her failure-to-warn claim is preempted because the drug's label was approved by the FDA. The Vermont Supreme Court rejected this argument, holding that the jury's verdict did not conflict with the FDA's labeling requirements because, under the FDA's "changes being effected" regulation, Wyeth could have warned against IV-push administration without prior FDA approval. The court wrote: "The litigation at issue here does not pose a direct and positive conflict with federal law, and, thus, there is no basis for federal preemption."

Wyeth sought U.S. Supreme Court review in March 2007. Most Court watchers expected that the petition would be denied, given that the Vermont Supreme Court's ruling did not conflict with the decisions of any federal Court of Appeals or state high court. (The U.S. Supreme Court ordinarily does not take a case absent such conflict.) Even the United States Solicitor General's office, which has switched the government's long-held position to favor FDA preemption, urged the Court to deny review given this lack of a split. But the Court read out and took the case anyway, in an ominous move that sent shudders through the plaintiffs' bar.

Public Justice filed an amicus brief on behalf of 10 current and former editors and contributing authors of the *New England Journal of Medicine* in their first-ever legal brief, urging the Court to reject Wyeth's attempt to immunize itself from liability for inadequately labeled drug. As a *Wall Street Journal* article highlighting the brief noted, the medical editors and writers—who have never before banded together to address a legal decision—"plunged into an escalating legal battle" with enormous national implications.

Our brief explained that the FDA is simply unable to ensure the adequacy of prescription drug labels. Among other suits, the agency, when deciding whether to approve drug label, is limited to the information submitted by the drug manufacturers themselves. Then, when

new risks become known after a drug's label has been approved, the agency has only limited authority to force a manufacturer to change its label to reflect the newly discovered risks. The upshot is that, in many, many cases, drugs are left on the market with inadequate labels, even as the casualty statistics climb ever higher. As proof of the pudding, the brief includes case studies of three drugs—Pondimin/Redux, Vioxx, and Trasylol—whose manufacturers withheld key information from the FDA while lobbying against stricter label warnings and while continuing to market their unsafe drugs to an unsuspecting public.

Our brief further explains that litigation is often the only way to dig up information regarding inadequacy of drug labels. This information can, in turn, spur the agency to put pressure on the manufacturers to improve the labels. But without this critical "feedback loop" generated by prescription drug litigation, the agency will not have the information that it needs to pressure drug manufacturers to improve their labels. And, without litigation, the manufacturers will neither compensate victims nor have any financial incentive to correct their labels and provide consumers with adequate warnings.

The upshot of an adverse ruling in *Wyeth* could be a disaster for public health. The scariest thing about the case is that, depending on how the Supreme Court rules, it could wipe out all failure-to-warn litigation regarding prescription drugs in this country. Victims of inadequately labeled drugs would have absolutely no recourse to seek compensation for their injuries. The FDA would be stripped of the invaluable information that is often unearthed during the course of litigation. The only winners in this scenario would be drug manufacturers, who could continue to increase their profit margins unrestrained by the risk of litigation, at the direct expense of the hapless victims of inadequately labeled drugs.

Altria and *Wyeth* should be decided by early next year. Meanwhile, it is worthwhile to note that Public Justice has already been at the forefront of the fight against preemption in a host of areas. Among other victories, we won a unanimous United States Supreme Court ruling upholding an injury victim's right to sue a manufacturer for failing to install propeller guards on its recreational motor boat engines. See *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002). We have also fought preemption for years in cases involving medical devices, prescription drugs, motor vehicle safety, flammable fabrics, and mandatory arbitration, to name but a few. In short, this is a battle that we have already joined, and we believe that it is of utmost importance that we continue to fight for the right outcome.