

# OPINION

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### ■ FEDERAL PRE-EMPTION

## Ignoring Congress' intent

By Arthur H. Bryant SPECIAL TO THE NATIONAL LAW JOURNAL

**E**ARLIER THIS year, in *Riegel v. Medtronic*, the U.S. Supreme Court held that the 1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act pre-empt injured consumers' rights and immunize medical device manufacturers from liability. Now, in *Altria v. Good* and *Wyeth v. Levine*, the court will decide whether to expand federal pre-emption and grant tobacco and drug companies immunity by judicial fiat, too. If it does, it will be making the same fatal mistake it made in *Riegel*—ignoring Congress' intent.

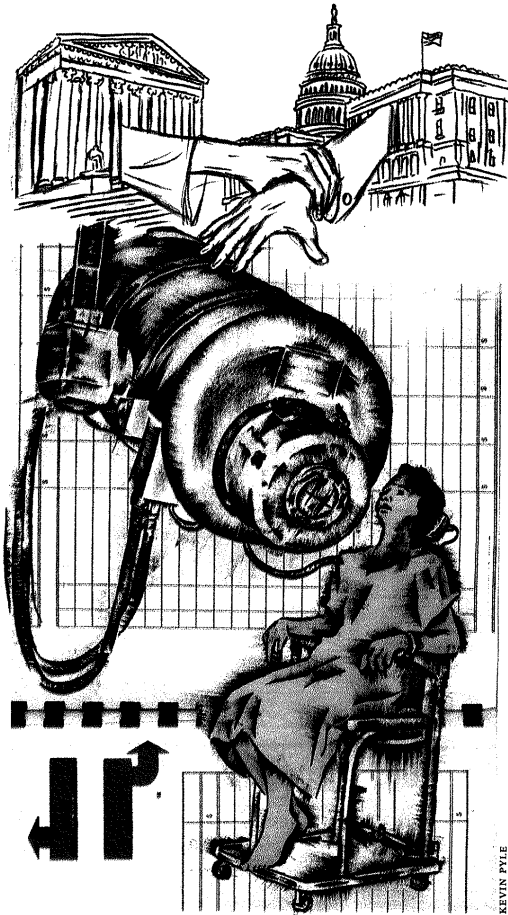
The court has repeatedly reaffirmed three principles of federal pre-emption: Congressional intent is the "ultimate touchstone" of pre-emption analysis; pre-emption analysis starts with a strong presumption that Congress did not intend to displace state law in areas, like injury compensation, traditionally governed by the states; and the court will not find pre-emption unless that was Congress' "clear" and "unequivocal" intent.

In *Riegel*, the court violated all three principles. Before 1976, the federal government did not regulate medical devices. Then the Dalkon Shield, an intrauterine birth control device, maimed and killed hundreds of thousands of women. Suits were filed, resulting in a \$2.5 billion trust, but Congress recognized that market forces—including potential liability costs—were not adequately protecting consumers. When California moved toward aggressive regulation, Congress authorized federal regulation by passing the Medical Device Amendments. To ensure that state regulations did not conflict with federal regulations, the amendments pre-empted state law "requirements with respect to a device" that were "different from or in addition to" federal requirements.

Those words had nothing to do with state laws requiring manufacturers of defective devices to compensate people they injured. Injured consumers were already being compensated; Congress left that to state law. As a result, no one thought—indeed, for the next decade, no medical device manufacturer argued—that the 1976 amendments affected compensation for injury victims.

In *Riegel*, however, the court said, "Congress is entitled to know what meaning this Court will assign to terms regularly used in its enactments," and held that "reference to a State's 'requirements' includes its common law duties," and simply eliminated injury victims' rights, as if Congress did this more than 30 years ago with

*Arthur H. Bryant is the executive director of Public Justice, which filed an amici brief opposing pre-emption in Wyeth on behalf of the New England Journal of Medicine's editors and authors.*



*Altria* involves 1960s legislation requiring warning labels on cigarette packages. In 1992, the high court held in *Cipollone v. Liggett Group* that tobacco companies could be sued for injuring consumers by making false and fraudulent statements. Precisely such statements are at issue in *Altria*: The companies marketed "light" cigarettes as having "lowered tar and nicotine" when they knew neither was true. But the court decided to hear their plea for immunity through pre-emption.

In *Wyeth*, Congress first passed legislation regulating drugs in 1906, overhauled it in 1938 and repeatedly amended it, but never said one word about pre-empting state law. Yet the drug companies claim that Congress implicitly intended FDA approval to pre-empt suits against them for inadequately labeling drugs. Juries, they insist, should not be allowed to second-guess federal regulatory agencies' decisions. But Congress never said that, and that's

not what's happening. That was sophistry. The question was what Congress meant by those words in 1976, not what the court says they mean now.

Then, as now, Congress saw a crucial distinction between creating federal regulation to decrease consumers' injuries and eliminating state liability law that compensates consumers' injuries. Congress has repeatedly done the former and almost never done the latter. In the rare instances when Congress displaced state liability law (for example, for children's vaccines and the Sept. 11 victims), it created alternative systems for compensating the injured. *Riegel*, however, leaves them with no remedy at all. The U.S. Food and Drug Administration is immune from suit whether its workers were bribed, overwhelmed or they simply erred, and once the FDA gives premarket approval, the manufacturer never has to compensate the injured—no matter how many people die or what it knew or does.

That is not what Congress intended. And things could get even worse.

not what's happening.

### Losing protection

Federal agencies, looking forward and reviewing information submitted by the manufacturer, decide whether it can market the product. Juries and judges, looking backward and reviewing all relevant information, decide whether the manufacturer must compensate a consumer allegedly injured by the product. Market forces determine if the manufacturer makes any other changes. Congress intended to give consumers more protection than market forces were providing, not less.

Finding pre-emption eliminates the protection consumers had before Congress acted and the incentives for product safety that the risk and cost of liability create. That's the mistake the court made in *Riegel*, which gives manufacturers a license to kill. If the court compounds it in *Altria* and *Wyeth*, more consumers will die. Ignoring Congress' intent in these cases is truly a fatal mistake. **NLJ**

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