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Supreme Court Revisits Pre-emption Pertaining to Pharmaceuticals

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The U.S. Supreme Court is presently considering whether federal law pre-empts state design-defect claims targeting generic pharmaceutical products. Just two years ago, the court insulated generic-drug manufacturers from state-law failure-to-warn claims. It seems doubtful that any of the justices in that majority will treat this case differently, and, thus, generic drugmakers may soon enjoy a new immunity.

Background

A complex federal regulatory scheme creates uniform guidelines for the manufacturing, marketing and sale of prescription drugs. To promote safety in the prescription drug market, Congress enacted the federal Food, Drug and Cosmetic Act (FDCA) and, years later, the Drug Price Competition and Patent Term Restoration Act of 1984 (part of the Hatch-Waxman amendments to the FDCA). While these pieces of legislation contain a Byzantine series of express directives, they are also silent on important questions.

Consequently, the Supreme Court has been forced over the past few years to interpret the meaning — namely, the pre-emptive scope — of those express directives and silences. In *Wyeth v. Levine*, 555 U.S. 555 (2009), a citizen of Vermont sued Wyeth Pharmaceuticals for failing to warn of certain side effects of a sedative called Phenergan. The justices held that the product's label inadequately warned of the potential risks accompanying this method. In particular, the court concluded by a vote of 6-3 that the U.S. Food and Drug Administration requirements merely provided a floor, not a ceiling, for state regulation. The *Wyeth* court endorsed a general "presumption against pre-emption" when state tort law and federal drug regulation collide.

Two years after *Wyeth*, the justices created a significant exception to that presumption for generic-drug manufacturers. In *Pliva v. Mensing*, 131 S.Ct. 2567 (2011), two plaintiffs contracted a neurological disorder from protracted use of a generic version of a drug called metoclopramide. Both individuals brought failure-to-warn claims under state tort law. The generic drugmakers asserted that federal statutes and FDA regulations obligated them to employ the same safety and efficacy labeling as the brand-name producers. They argued that it was impossible to simultaneously comply with both federal and state law when they imposed separate labeling obligations.

In a 5-4 decision, the court agreed that these generic-drug manufacturers were faced with the impossible decision to either: (1) disobey federal regulations in order to comply with state laws requiring manufacturers to provide more explicit warnings; or (2) follow federal law as required, which inevitably

leads to packaging that provides less-than-comprehensive warning to consumers. The court held that federal law must prevail when such a catch-22 exists. The court therefore created an exception to its holding in *Wyeth*, concluding that pre-emption rules are relaxed in their application to generic-drug manufacturers.

Facts of Bartlett

It is against this backdrop that the Supreme Court is revisiting the interplay between federal drug regulation and state tort law this term in *Mutual Pharmaceutical v. Bartlett*. In 2004, plaintiff Karen Bartlett was prescribed an anti-inflammatory drug called sulindac. She received a generic version of this drug from her pharmacist. Shortly thereafter, she was diagnosed with Stevens-Johnson syndrome and, eventually, toxic epidermal necrolysis, two life-threatening conditions that affect the skin and mucous membranes. Bartlett underwent months of recovery, which included a two-month, medically-induced coma. She ultimately suffered permanent injuries for which she sought redress from Mutual Pharmaceutical, the generic drug's manufacturer. Bartlett's complaint asserted a number of state-law claims, including strict products liability for defective design.

Mutual invoked *Mensing* and argued that federal law pre-empted the state design-defect claim. Specifically, Mutual asserted that, having obtained FDA approval for its generic version of sulindac, it would have been impossible to alter the drug's design without contravening federal law. This is the same catch-22 identified by the court in *Mensing* with respect to warning labels. Furthermore, Mutual advanced the policy argument that, even if the FDA permitted it to make changes, the tremendous expense it would incur in doing so would frustrate Hatch-Waxman's goal of making prescription drugs more affordable for consumers; the same would be true if Mutual stopped making the allegedly defective drug entirely. And, from a legal standpoint, if Mutual completely ceased production in order to comply with state law, it would make state law the "de facto supreme law of the land." Despite these arguments, both the district court in New Hampshire and the U.S. Court of Appeals for the First Circuit upheld the federal jury's award to Bartlett of $21 million based on her strict products liability claim for defective design of an "unreasonably dangerous" product.

Based on the justices' reactions at oral argument March 19, it appears that the court will reverse the lower courts and extend the protections afforded to generic manufacturers. The toughest questions for the drugmakers' attorney, Jay Lefkowitz — the same defense attorney from *Mensing* — came from *Mensing* dissenters like Justices Elena Kagan, Sonia Sotomayor and Ruth Bader Ginsburg, who pressed him on the distinction between generic and brand-name manufacturers. Why, these justices inquired, should a branded pharmaceutical maker shoulder all of the liability for design-defect claims while their generic counterparts escape liability? Furthermore, Ginsburg probed, is it really fair to consumers to be foreclosed from recovery when the only reason Bartlett did not take "the brand-name drug [was] because the pharmacist gave her the generic [version]"? Wherever possible, Lefkowitz drew a parallel between the dispositive catch-22 in *Mensing* and the dilemma faced by generic drugmakers threatened with design-defect claims. In particular, Lefkowitz effectively focused his responses on the *Mensing* majority's statements about the inseparable link between design-defect and failure-to-warn claims.

Respondent's counsel, David Frederick, faced predictable opposition from members of the *Mensing* majority. Justice Antonin Scalia expressed skepticism about turning juries into ad hoc regulators of drug manufacturers: "The jury decides all of this, right? ... That's wonderful. Twelve ... men ... decide for the whole state what the ... cost-benefit analysis is for a very novel drug that unquestionably has some deleterious effects, but also can save some lives." Chief Justice John Roberts echoed the sentiment that a state's ability to determine whether the risks of a product outweigh the benefits is at odds with a federal regime that has already approved the product. Frederick may have sealed his fate when Justice Anthony Kennedy persuaded him to admit that a drug's warning label — the subject of *Mensing* — was relevant to the determination of liability in a design-defect case.

While both counsel endured tough questioning, the oral argument suggests that the court will extend *Mensing* to provide additional protections for generic-drug manufacturers. This holding may convince "Big Pharma" to turn to lobbyists over lawyers in the future. It appears that Congress will be the only institution

on Capitol Hill that will force generic-drug manufacturers to share failure-to-warn and design-defect liability with the Big Pharma companies.

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