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TOP STORY

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Supreme Court grapples with generic drugs and design defects

Alyssa E. Lambert

The Supreme Court heard oral arguments on Tuesday in a case that could change how generic drug manufacturers can be held liable to injured consumers. The justices considered whether federal law preempts state products liability claims that allege a generic drug was unreasonably dangerous and defective, and they wavered between recognizing that the decision could be limited to the facts of the case and issuing a broad ruling that could significantly affect both generic and brand-name drug companies.

In a case that could reshape the generic drug industry and how manufacturers are held accountable to injured consumers, the Supreme Court heard oral arguments earlier this week about whether federal law preempts state products liability claims that allege a generic drug was unreasonably dangerous and defective. The justices wavered between recognizing that the decision could be limited to the facts of the case and issuing a broad ruling that could significantly affect both generic and brand-name drug companies. (***Mutual Pharm. Co., Inc. v. Bartlett***, No. 12-142 (U.S. oral arg. Mar. 19, 2013).)

Mutual Pharmaceutical Co., Inc., asked the Court to overturn a jury award to Karen Bartlett, a New Hampshire woman who was seriously injured when she used the generic anti-inflammatory drug sulindac for shoulder pain in 2004. Bartlett developed Stevens-Johnson syndrome (SJS)—a rare drug reaction and a life-threatening skin condition. She also developed a more severe form of SJS, known as toxic epidermal necrolysis, which resulted in burn-like lesions on almost two-thirds of her body and permanent near-blindness.

Bartlett sued Mutual in New Hampshire state court in 2008, alleging products liability claims, including design defect. New Hampshire law imposes strict liability against manufacturers for any injuries caused by selling products in an unreasonably dangerous and defective condition. The case was removed to federal district court, where a jury awarded Bartlett $21 million in compensatory damages. Mutual appealed.

The First Circuit upheld the verdict in May 2012, concluding that Bartlett's design defect claim was not preempted because federal law does not render compliance with state law impossible, as previously reported in ***Trial News***.

But at the Supreme Court, Mutual's attorney, Jay Lefkowitz, argued that this was a classic case of impossibility preemption and that the Court should apply its 2011 ruling in *Pliva, Inc. v. Mensing* to state law design defect claims. In *Mensing*, the Court held that FDA regulations bar failure-to-warn suits against generic drug manufacturers because it is impossible for them to comply with both federal law—which requires generic drugs to have the same labeling as their brand-name equivalents—and state laws, which may require stronger warnings.

Washington, D.C., lawyer David Frederick, arguing on Bartlett's behalf, disagreed. He said that the New Hampshire statute was seeking to "impose liability where there is proof of an unreasonably dangerous product. That unreasonable danger entails evidence of a risk-benefit analysis that looks at the overall risks to the population against the overall benefits that are provided for the drug."

Justice Antonin Scalia asked if this risk-benefit analysis was a jury question, and Frederick confirmed it was. Scalia shot back: "That's wonderful" and continued to chide the fact that 12 jurors would evaluate the cost-benefit analysis for a "very novel drug" for the entire state.

Dallas attorney Bill Curtis was frustrated by Scalia's and other justices' comments on the role of juries. "The implicit underpinning of the Seventh Amendment is that we trust juries," said Curtis, who represents plaintiffs in brand-name and generic drug litigation. "Those same 12 people might be deciding whether someone is put to death or not. That's why we have such faith in them."

Several justices recognized that a broad decision in this case could impact both generic and brand-name manufacturers. Both Lefkowitz and Frederick acknowledged that it was not possible to distinguish between the two for purposes of design defect claims.

Justices Elena Kagan, Sonia Sotomayor, and Ruth Bader Ginsburg were skeptical that impossibility preemption should apply and seemed reluctant to make the FDA's drug approval the ceiling of what manufacturers can do.

"I think what you are arguing now is that no truly bad drug, that shouldn't be on the market—would there ever be a tort claim that anybody could bring because the FDA approved it?" said Sotomayor.

Kagan later added: "There are quite a number of cases where we've really held when a federal law permits something, typically, a state can do more if it wants to."

But Dallas lawyer Keith Jensen, who represents Bartlett, was pleased by one aspect of Lefkowitz's argument. "I found it very agreeable that he conceded to Justice Alito that if there is a strict liability state, which solely requires compensatory damages, that state law duty would not result in impossibility preemption," he said. "*Wyeth* obviously established that federal regulation is the floor. Impossibility preemption does not exist in this case."

Assistant Solicitor General Anthony Yang, who argued on the U.S. government's behalf, told the Court that when a state imposes a safety obligation, it constitutes second-guessing the FDA and should be preempted.

Sotomayor immediately responded: "You're basically saying the minute the FDA gives you permission to sell, it's a right to sell. And it can't be altered by any state police power."

Yang disputed that contention, but he also said, "What we are trying to do is preserve the FDA's role here, not have juries second-guess on a case-by-case and state-by-state basis imposing different safety obligations on manufacturers—when Congress has established a regime for FDA to control this."

Andre Mura, litigation counsel at the Center for Constitutional Litigation in Washington, D.C., said the government's argument was troubling. "There were suggestions that the FDA shouldn't be second-guessed, but as the Court said in *Wyeth v. Levine*, the FDA approval process does not mean, and should not be taken to mean, that a drug is absolutely safe even for approved uses," said Mura, who wrote an amicus brief for AAJ in *Bartlett*. "Congress didn't intend the FDA to provide the sole level of consumer protection, and a broad preemption ruling here would ignore that clear congressional intent."

Jensen was also critical. "The Justice Department was arguing field preemption and was unable to confidently respond to the questions of Justice Kagan, Chief Justice Roberts, and Justice Sotomayor," he said. "It did not rebut claims both in [the plaintiff's] brief and made orally that its position about this case was in error."

Curtis said that ultimately, this decision could be disastrous for plaintiffs, but it depends on how narrowly or broadly the opinion is framed. "From the preemption standpoint it has the potential to be a dangerous opinion if FDA approval of the drug means you can never sue the company," he said. The justices "seem to suggest that they may think that if the FDA has approved a drug, it cannot be defectively designed, and you cannot sue the manufacturer for it. I would hope they would recognize that this has not been the jurisprudence for over 225 years." He added: "We're all holding our breath until June."