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Back to Article

Pre-emption of Generic Drug Suits Mulled by Superior Court

If all brand-name pharmaceutical manufacturers withdraw from the market and only generic drugmakers are left, does that mean "plaintiffs who are injured can sue no one"? a Superior Court judge asked Wednesday during an oral argument session in Philadelphia.

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If all brand-name pharmaceutical manufacturers withdraw from the market and only generic drugmakers are left, does that mean "plaintiffs who are injured can sue no one"? a Superior Court judge asked Wednesday during an oral argument session in Philadelphia.

The argument was held on what impact a U.S. Supreme Court holding that federal drug regulations pre-empt state lawsuits over the warning labels on generic drugs will have on over 2,300 Philadelphia Court of Common Pleas cases in which plaintiffs allege their use of generic versions of metoclopramide caused them to have an incurable neurological disorder called tardive dyskinesia.

Judge Mary Jane Bowes asked her question during arguments over whether generic drugmaker Morton Grove Pharmaceuticals/Wockhardt USA had greater duties to plaintiffs than other generic drugmakers, because Morton Grove's formulation of metoclopramide was designated by the federal Food and Drug Administration as the "reference listed drug" to which other manufacturers had to match their versions of the medication.

Robert L. Byer, the attorney for Morton Grove, said that there is indeed a gap in the law of torts under which plaintiffs would not have protection. "But that's a gap that Congress must fill," Byer said.

Bowes also asked if Morton Grove could have withdrawn its product from the market and why it did have to continue to sell.

Finding otherwise would upset the balance Congress struck between generic and brand-name drug

products, Byer said, and is turning each state into its own FDA to argue that there should be such liability.

Several other legal theories have been raised in the cases consolidated on appeal.

The U.S. Supreme Court ruled in *Pliva v. Mensing* that a plaintiff's claims that a generic drugmaker failed to warn adequately of the potential risks of taking a generic version of a drug are pre-empted by federal law because it would be impossible for generic drugmakers to comply both with a federal duty to keep their labels the same as brand-name labels and state-law duties to change their labels.

But Justice Sonia Sotomayor, dissenting in *Mensing*, said that the decision would affect 75 percent of the American prescription drug market involving generic versions of drugs and "a drug consumer's right to compensation for inadequate warnings now turns on the happenstance of whether her pharmacist filled her prescription with a brand-name drug or a generic."

Bowes was by far the most active questioner on the panel. President Judge Correale F. Stevens asked no questions during about an hour of oral argument and Senior Judge William H. Platt asked only one question at the very end of the argument.

Arguments also focused on whether the frontline appeals court has jurisdiction under the collateral order doctrine. The Superior Court rejected interlocutory review of the appeals, and the Supreme Court affirmed that decision.

Jay Lefkowitz, of Kirkland & Ellis and who argued the issue for around 25 generic drugmakers, said that the cases are "absolutely, unambiguously controlled by *Mensing*," but Bowes said she was struggling with Lefkowitz's argument that the cases involve the exact same issues.

It was Lefkowitz who argued the *Mensing* case to the U.S. Supreme Court.

Lefkowitz did acknowledge that *Mensing* would not control a claim that a drugmaker failed to update warning labeling, but Lefkowitz further argued that failure to update claims would actually be pre-empted because, he said, the plaintiffs ultimately claim the labeling updates would not have helped them and updated labeling for metoclopramide was false and misleading. Any labeling claim is pre-empted by *Mensing*, Lefkowitz said.

Howard Bashman, a Willow Grove, Pa., solo practitioner representing all of the plaintiffs, said that *Mensing* did not pre-empt two types of failure-to-warn claims: failing to update labeling, and failing to communicate the actual label to prescribers.

Mensing also did not pre-empt non-failure-to-warn claims, Bashman said. Bashman writes a column for *The Legal*.

While Bowes stated that many other courts have gone the other way, Bashman cited a U.S. Court of Appeals for the First Circuit decision, *Bartlett v. Mutual Pharmaceutical*, in which that court said the U.S. Supreme Court has not yet decided if it would extend *Mensing* to design defect claims regarding generic drugs and to claims that a drugmaker could have a duty under state law to withdraw generic drugs from the market. The U.S. Supreme Court is still considering whether to take that case.

In rebuttal, Lefkowitz said that Sotomayor said *Mensing* would affect 75 percent of the prescription drug market, and that U.S. Supreme Court precedent does indeed control the vast majority of lawsuits involving generic drugs.

Lefkowitz also rejected the argument that a generic drugmaker could seek through the FDA to effectuate a label change because he said "juries are not allowed to speculate" on what a federal agency would have done.

In another separate issue, Bowes asked if there was an issue of fact regarding Wyeth, which was the brand-name holder of the reference-listed drug until it withdrew from the metoclopramide market, and if Wyeth had any residual duties after it stopped making brand-name Reglan because of any contracts of sale and because drugs issued in 2001 had a shelf life of two years.

In terms of contracts, Wyeth's attorney, Robert C. Heim of Dechert, argued that "federal law would not permit the parties to contract away responsibility," and that the responsibility to warn users of Reglan of the risks and benefits of taking its products was lifted from Wyeth once it stopped making the drug.

In another separate issue, John A. McCauley, of Venable in Baltimore and arguing for generic drugmaker Hospira, said that his client made an injectable form of metoclopramide and it is an issue of law if *Mensing* pre-empts claims against a drugmaker who made a different form of the drug.

It's a "pure ... no static, no noise *Mensing* application," McCauley said.

But Bashman said that Philadelphia Court of Common Pleas Judge Sandra Mazer Moss rightly concluded that there were issues of fact if there were differences about labels provided for different forms of the same drug. Bowes said that she didn't see where that argument was going except into a failure-to-warn claim.

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