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REPORT FROM WASHINGTON

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The Supreme Court Considers Implied Preemption of Failure-to-Warn Claims Against Generic Drug Manufacturers

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INTRODUCTION

This week, the Supreme Court heard oral argument in three consolidated cases—*Pliva, Inc. v. Mensing*, No. 09-993, *Actavis Elizabeth, L.L.C. v. Mensing*, No. 09-1039, and *Actavis, Inc. v. Demahy*, No. 09-1501 (collectively, "*Mensing/Demahy*")—in which the Court is expected to address whether failure-to-warn claims against generic drug manufacturers are impliedly preempted by federal drug labeling law. The case specifically involves the Drug Price Competition and Patent Term Restoration Act (the "Hatch-Waxman Amendments"), which amended the Federal Food, Drug, and Cosmetic Act (the "FDCA") to simplify the process for generic drug approval and requires labels on generic drugs to be substantively identical to their brand-name counterparts.

Previously, the Court in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), held that the FDCA does not preempt state law failure-to-warn claims against manufacturers of brand-name drugs. *Mensing/Demahy* also follows two preemption decisions this Term, *Bruesewitz v. Wyeth*, No. 09-152, and *Williamson v. Mazda Motors of America*, Inc., No. 08-1314, both of which were covered in earlier *Reports from Washington* (click here for *Bruesewitz*; click here for *Williamson*). The Court in *Bruesewitz* held that the National Childhood Vaccine Injury Act of 1986 expressly preempts certain design defect claims. In *Williamson*, however, the Court held that the Motor Vehicle Safety Act does not impliedly preempt certain design defect claims.

BACKGROUND

The two plaintiffs-respondents in the consolidated cases, Gladys Mensing and Julie Demahy, were prescribed the brand-name prescription drug Reglan to treat gastrointestinal conditions. Both plaintiffs filled their prescription with the generic bioequivalent, metoclopramide, which they took for a number of years. The plaintiffs later developed tardive dyskinesia, a neurological movement disorder that allegedly was caused by long-term use of metoclopromide.

The plaintiffs separately filed suit against the metoclopramide manufacturers, including respondents Actavis, Inc., Actavis Elizabeth, L.L.C., and Pliva, Inc., claiming that the drug's label failed to warn them adequately about the risk of developing tardive dyskinesia from long-term use of metoclopramide. The defendants in both cases, various brand-name and generic drug manufacturers, moved to dismiss the plaintiffs' claims.

The district court deciding the action brought by Mensing granted the generic drug manufacturers' motion on preemption grounds, holding that Mensing's failure-to-warn claims would create an impermissible conflict with federal law because, if successful, it

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would require generic manufacturers to affix different labels on generic drugs than those placed on the name-brand equivalents when the FDCA requires a generic drug manufacturer to utilize the same label as the brand-name drug for which it is a bio-equivalent. By contrast, the district court in *Demahy* denied the generic manufacturers' motion to dismiss based on preemption of plaintiff's failure-to-warn claim. Both cases were appealed.

The Court of Appeals for the Eighth Circuit, deciding the case brought by Mensing, noted that the Supreme Court in *Wyeth v. Levine* held that failure-to-warn claims against brand name drug manufacturers are not preempted by the FDCA. The Eighth Circuit found that *Levine* "carries important implications for [the generic drug manufacturers'] situation as well" and stated that "[a]fter [*Levine*], we must view with a questioning mind the generic defendants' arguments that Congress silently intended to grant the manufacturers of most prescription drugs blanket immunity from state tort liability when they market inadequately labeled products."

The Eighth Circuit recognized that the FCDA, as amended by the Hatch-Waxman Amendments, and the regulations promulgated thereunder, requires generic drug manufacturers to include in their new drug applications a proposed label that is "in relevant part identical to the name brand drug label." Nevertheless, the Eighth Circuit rejected the defendants' arguments that it was impossible to comply with a state law requirement imposing a different label than those found on brand-name equivalents because, according the Court of Appeals, "defendants could have at least proposed a label change that the FDA could receive and impose uniformly on all metoclopramide manufacturers, if approved." The Eighth Circuit also rejected the defendants' argument that the state law claims, if allowed to proceed, would "obstruct the purposes and objectives of federal law."

The Court of Appeals for the Fifth Circuit, deciding the case brought by Demahy, also concluded that the state law failure-to-warn claims against a generic drug manufacturer were not preempted by the FDCA. The court also found that *Levine* "carr[ies] important implications for Actavis's situation," and that a conclusion of implied preemption "is not to be found lightly." Like the Eighth Circuit in *Mensing*, the Fifth Circuit found that it was possible for Actavis to comply with both federal labeling requirements and the duty purportedly imposed by state law to warn metoclopramide users adequately about the danger of developing tardive dyskinesia, and that the state law claims therefore did not obstruct the purposes or objectives of the FDCA.

The defendants appealed the respective circuit court decisions, and the United States Supreme Court granted certiorari and consolidated all three underlying cases.

"Well, [the defendants' argument] makes a lot of sense, but we do have our Wyeth *decision that seems to cut the other way."*

CHIEF JUSTICE ROBERTS

SUMMARY OF THE ARGUMENT

The defendants argued on Wednesday before the Court that it is impossible to comply with both (a) the Hatch-Waxman Amendments, which by their plain language require generic drug labels to be identical to brand name drug labels, and (b) state law requiring defendants unilaterally to change their labels to use different warnings.

Chief Justice Roberts noted: "Well, that makes a lot of sense, but we do have our *Wyeth* decision that seems to cut the other way." Justice Ginsberg also asserted that the defendants could discharge their state law obligations be proposing a revision to the label that included different warnings. Justice Sotomayor asked, "[B]ut if you also have a

Federal obligation to advise the FDA of . . . adverse results and of needs for change, why can't you then comply with a duty to warn obligation because you can go . . . to the FDA?"

The defendants, citing the Supreme Court decisions in *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2000), which held that state law "fraud-on-the FDA" claims were impliedly preempted by the FDCA, and *Arkansas La. Gas Co. v. Hall*, 453 U.S. 571 (1981), argued that "the relationship . . . between the Federal agency and its regulated party . . . are inherently Federal, and States simply don't have a business trying to enforce those obligations." Chief Justice Roberts observed that, in *Buckman,* the FDA was concerned about receiving a flood of proposals and warning revisions from manufacturers, and "that doesn't seem to me to be a concern here." Justice Ginsburg added: "The Federal agency says that these suits complement, they're not at odds with, the Federal regime, because they give the manufactures an incentive to come forward."

"Counsel, do you think Congress really intended to create a market in which consumers can only sue brand-named products? Because if that's the case, why would anybody ever take a [generic]?"

JUSTICE SOTOMAYOR

Justice Breyer then asked: "[W]hat are you supposed to do if your company happens by chance to come across a very, very high correlation between people who take your generic drug and who get seriously ill?" The defendants responded that they would be obligated by federal law to tell the FDA, but that state law should not be permitted to require generic drug manufacturers to propose different warning labels. The defendants also argued that "it wouldn't make any sense to go into a drugstore to buy Advil and to see 15 different generic ibuprophen and to have 15 different sets of warnings," to which Justice Sotomayor responded, "[c]ounsel, do you think Congress really intended to create a market in which consumers can only sue brand-named products? Because if that's the case, why would anybody ever take a [generic]?"

"What this Court said in *Wyeth v. Levine* is that State juries are a perfectly appropriate vehicle for assessing whether warnings in the past were adequately given," countered the plaintiffs. Justice Scalia responded: "I don't see how you can hold [the defendants] liable, so long as they continued to give the warnings that they had to give." Defendants should only be permitted to take advantage of the preemption defense if they can show that the FDA would have rejected the proposed label change proposal, the plaintiffs argued.

"I don't see how you can hold [the defendants] liable, so long as they continued to give the warnings that they had to give."

JUSTICE SCALIA

Justice Breyer stated that this case "sounds awfully familiar to *Buckman* . . . . And why isn't the same true here, that the FDA has to enforce their own legal requirement to tell us everything you know?" Similarly, Justice Kennedy questioned "why *Buckman* isn't applicable here." The plaintiffs argued that *Buckman* was "wholly distinguishable" because there, the defendant was a consultant to a medical device manufacturer and had no relationship to the injured party.

Justice Breyer pointed out that, in *Levine*, the brand-name manufacturer had the ability to change the warnings, whereas here the generic manufactures must copy the original drug maker's labels. The plaintiffs maintained that when the generic manufacturers are confronted with information that their drug label warnings are not adequate, they should tell the FDA and ask that labels be changed on both the generic and name-brand labels.

Justice Breyer wondered how imposing an obligation to ask for a label change adds anything given that the FDA already has the information about adverse incidents. Justice Alito likened the plaintiffs' theory to imposing on generic manufacturers "a duty to pursue an informal process that is nowhere provided for under the FDA rules."

"[I]t does seem to me that [imposing state law duties on the defendants] may significantly increase the costs for generic drug manufacturers, and therefore counteract one of the objectives of the statute, which was to provide generic drugs at a low cost."

JUSTICE ALITO

The United States, as Amicus Curiae, argued that the Hatch-Waxman Amendments "do not absolve a manufacturer of his responsibilities after entry onto the market to maintain the safety of the drug and the adequacy . . . of the label." Chief Justice Roberts expressed concern that: "Every time a generic manufacturer gets an adverse incident report, it will send that on to the FDA, and there will be a boilerplate sentence at the end of it saying, We think you should consider revising the labels because of this, and then, under your theory, that manufacturer is completely protected from State suits?" Justice Alito also asked whether the FDA had calculated the economic consequences of imposing a duty to ask for label changes, stating "it does seem to me that it may significantly increase the costs for generic drug manufacturers, and therefore counteract one of the objectives of the statute, which was to provide generic drugs at a low cost."

IMPLICATIONS

The Supreme Court's decision likely will have a significant impact on generic drug manufacturers' exposure to failure-to-warn claims, and may further define the scope of the Court's decision in *Levine*. If the Court were to rule for the plaintiffs, generic drug manufacturers would continue to face additional state law liability based on failure-to-warn allegations. On the other hand, if the Court were to rule for the defendants, it would represent a protection against state law suits against generic manufacturers that does not exist for the brand-name manufacturers of those identical drugs.

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