Greenblum & Bernstein, P.L.C.
CLIENT ADVISORY

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Supreme Court Rules That Generics Are Not Liable For Insufficient Warnings in Product Labeling

In a long-awaited decision, the United States Supreme Court ruled today in *Pliva v. Mensing* (Case No. 09-993), that generic drug manufacturers cannot be held liable for insufficient warnings in the labels of their generic products.

The case involved the drug metoclopramide, which is sold under brand name Reglan, and for which several generics are available. Some patients who had only taken generics of the product developed tardive dyskinesia after long-term use of the drug. Two such patients sued the generics in state court, alleging that the adverse effects they suffered from were known, or should have been known, and that the generics failed to include adequate warnings on the label. The generics argued that they should not be held liable because their labeling was dictated by the labeling of the brand product, and that federal labeling law pre-empts state laws requiring warning of known dangers.

In three lawsuits brought in two different states, the generics won at trial. The Courts of Appeals for the respective circuits reversed the trial decisions, holding the generics liable. The cases were consolidated for purposes of the appeal, and the present Supreme Court decision followed.

In its narrowly-decided (5-4) decision, the Supreme Court first acknowledged that state law apparently required the generic companies to provide adequate warning on the product labels, and that the generics had clearly not done so. However, where there is a conflict between state and federal law, the Court ruled, state law must yield. In this case, it would have been impossible for generics to unilaterally add warnings to the product labels (thereby complying with state law), yet maintain the "same-label" requirement (thereby complying with federal law). That the generics *might have* petitioned FDA to include warnings (as argued by the plaintiffs) was irrelevant since state law did not require generics to do so.

The majority opinion acknowledged the irony that had the plaintiffs taken the brand product, Reglan (which is what was actually prescribed), then their lawsuits would not have been pre-empted, and that it was the pharmacists' dispensing of generics pursuant to state law that led to pre-emption. However, given the significantly different statutory schemes for brand and generic drugs, the Court found this result unavoidable.

In a strongly-worded dissent, the minority argued that the majority took a simplistic view of the impossibility doctrine. In the minority's opinion, the generics had the duty to petition FDA to change the label, and the impossibility doctrine should only have been invoked if FDA refused the label change, or had not yet decided on it at the time of the plaintiffs' injuries.

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As a result of this ruling, it would appear that generic manufacturers cannot be held liable for failures to provide adequate warning of possible safety issues if such warnings are not included in the labeling of the brand product.

Should you have any questions or comments, do not hesitate to contact us.

Best regards,
GREENBLUM & BERNSTEIN, P.L.C.