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FDA ALERT

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Generic Drug Company Liability: What the *Bartlett* Decision Means to Your Company

Generic drug makers may take comfort from the reasoning contained in the June 24, 2013, U.S. Supreme Court ruling in ***Mutual Pharmaceutical Co. v. Bartlett*** (Docket No. 12-0142). The decision eliminates virtually all lawsuits by injured patients against generic drug makers, with the 5-4 majority following closely on a parallel decision against such lawsuits in the ***Pliva Inc. v. Mensing***, 131 S.Ct. 2567 (2011) decision.

Why should you care if you are not making generic drugs in your facility? Whereas branded or "pioneer" drug companies market innovative products for which they select claims of benefits, cautions, etc., generic drugs are locked into the same set of cautions that the original pioneer company's drug carried when the U.S. Food & Drug Administration (FDA) approved the generic version. Because the generic company cannot change the cautions without prior FDA approval – a change that pioneer companies are allowed to make when risk issues arise – the Supreme Court decision bars the product liability civil jury from deciding under state law that the generic drug should have had a stronger warning. Conflicts of state and federal powers like this are subject to the U.S. Constitution's Supremacy Clause, which deems state laws that conflict with federal law as "preempted" and without effect.

One aspect of the decision that applies broadly beyond generic drugs is the effect of the majority Justices' views on "risk utility analysis," a theory of product liability law that is often applied in a wide range of product categories. It says that if the risk from this product, e.g. a "widget," was greater than the benefit to widget consumers, the widget should have been redesigned or relabeled to make it safer, and damages can be awarded for the injured user. After ***Mutual***, a court will have to consider whether the regulatory controls on the wording of the product's label had been sufficient. If so, there may be a defense argument that this 2013 decision bars a state product liability verdict against the product maker. The jury could not indirectly force the changes or relabeling of the product by imposing a liability verdict for "defectiveness."

As companies evaluate their liability insurance needs and loss reserves for potential exposure to liability verdicts, it is advisable to have an attorney review the label and the federal rules that cover that product category. If immunity is available under the ***Mutual*** precedent, it may be timely to save money on these product insurance coverage costs. Roetzel & Andress attorneys specialized in pharmaceutical, medical device, consumer product, pesticide and chemical labeling issues can assist your review of product labels and scope of potential liability in light of the Supreme Court's ***Mutual*** ruling.

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