Generic Drug Company Should Not Be Allowed To Use Federal Preemption To Defeat Lawsuits

U. S. Supreme Court Will Hear Oral Arguments On This Legal Issue In Drug Injury Lawsuit Involving Gladys Mensing

(Posted by Tom Lamb at www.DrugInjuryWatch.com on March 3, 2011; see http://bit.ly/fRJIKX).

On March 30, 2011 the U.S. Supreme Court will hear oral arguments in a drug injury case which presents this important legal issue: Whether federal law preempts a tort claim under state law that a generic drug approved by the Food and Drug Administration was inadequately labeled.

This generic drug case involves a woman, Gladys Mensing, who developed a severe neurological disorder called tardive dyskinesia (TD) -- which is generally characterized by involuntary movements of the mouth, tongue, lips, and extremities -- after taking the generic version of a prescription drug called Reglan (metoclopramide).

In her lawsuit, Ms. Mensing alleges that the Prescribing Information, or label, for this generic Reglan drug understated the risk of developing tardive dyskinesia to Mensing and to her doctor who prescribed it to her.

The generic drug manufacturers named as the defendants in this drug injury lawsuit, Actavis Elizabeth and Pliva, essentially take the position that adequacy or sufficiency of their drug label warnings does not matter -- by asserting that they should be shielded altogether from legal liability in this *Mensing* case by operation of what is commonly called the "federal preemption doctrine".

As background, in March 2009 the Supreme Court held in *Wyeth v. Levine* that federal law does not preempt, *i.e.*, bar or eliminate, personal injury lawsuits against name brand drug manufacturers for failing to adequately warn about the serious side effects of their drug.

Now, however, Actavis and Pliva are arguing that federal law does preempt lawsuits for failing to warn of the dangers which involve **generic drugs**, and thereby immunizes those generic drug companies from any legal liability for the drug side effect which Ms. Mensing has suffered.

This *Mensing* Supreme Court case is especially significant given the somewhat remarkable fact that over 70 percent of prescription drugs sold today are generic drugs.

Moreover, several months ago the U.S. Solicitor General told the Supreme Court a federal appeals court which heard the *Mensing* case last year was correct in its ruling that the generic drug companies can be found liable for not providing sufficient warnings of about side effect risks -- even if such warnings are not found on the brand product's labeling -- and had urged the Supreme Court ***not*** to take up the drug company's appeal of the lower court's ruling in this *Mensing* case.

As for the plaintiff's position on this issue of federal preemption in generic drug cases, here are the first few paragraphs of the 96-page legal brief filed on behalf of Ms. Mensing:

> [In *Wyeth v. Levine*, the U.S. Supreme Court] held that the manufacturer, not the Food and Drug Administration (FDA), bears primary responsibility for ensuring that labeling for its drug adequately warns of the product's risks. This conclusion applies equally to the manufacturers of generic drugs. Under the federal regulatory scheme, the manufacturer of a generic drug shares responsibility with the manufacturer of its brand-name counterpart to ensure that the labeling for both products adequately warns prescribers and protects consumers.
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> Defendants seek a special immunity from state tort liability for generic drug companies, an immunity that would create an arbitrary and irrational distinction between classes of

> patients based on the vagaries of pharmacy practice: those whose prescriptions were filled with brand-name products would retain their right to sue, while those whose pharmacies substituted generic drugs would lose that right. Not only would such a regime make no sense, but it would also create a disincentive for consumers to take generic drugs, which is precisely the opposite of what Congress intended when it passed the Hatch-Waxman Amendments to the Food, Drug, and Cosmetic Act (FDCA) in 1984. Try as they might, Defendants cannot muster any evidence that Congress ever intended such a bizarre result.
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> Today, seventy percent of prescriptions in this country are filled with generic drugs. And, contrary to Defendants' claims, the fact that a drug has "gone generic" does not mean that it is safe. In reality, as the facts of this case demonstrate, drug risks frequently do not become clear until years after a drug has been on the market. The drug that injured Gladys Mensing and Julie Demahy, for example, had been available as a generic for more than fifteen years at the time it was first prescribed to them, and it was just two years ago that FDA finally mandated a "black box" warning of the risks of long-term use. If generic drug companies are granted immunity for failing to warn of known risks of their drugs, they will have very little incentive to strengthen their warning labels as new risks emerge, even though federal law mandates that they do so....

As regards the Reglan black-box warning mentioned above, see "FDA Requires Boxed Warning and Risk Mitigation Strategy for Metoclopramide-Containing Drugs -- Agency warns against chronic use of these products to treat gastrointestinal disorders", which was issued in February 2009.

For our prior coverage of the *Levine v. Wyeth* case and the issue of federal preemption in the context of drug injury lawsuits, see the Federal Preemption of Drug Injury Lawsuits page at our Drug Injury Law web site.

Of course, we will continue to monitor this *Mensing* case and report what the Supreme Court ultimately decides about whether the federal preemption doctrine should be available to generic drug companies so as to shield them from legal liability, or accountability, for serious side effects caused by their products.

Attorney Tom Lamb represents people in personal injury and wrongful death cases involving unsafe prescription drugs or medication errors. The above article was posted originally on his blog, **Drug Injury Watch** – with live links and readers' Comments.
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