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Federal Pre-emption and Generic Drug Labeling

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In recent years, drug manufacturers have attempted to reconcile their respective federal drug labeling duties with those that state tort laws impose. Manufacturers have argued that federal law pre-empts state failure-to-warn claims where the Food and Drug Administration has granted prior approval of a drug's label. In *Wyeth v. Levine*, a landmark pharmaceutical decision, the U.S. Supreme Court seemingly clarified these duties once and for all. 129 S.Ct. 1187 (2009). However, recent appellate decisions have once again brought federal preemption in prescription drug labeling to center stage.

In *Wyeth*, patient Diana Levine visited the doctor in April 2007 to receive treatment for headaches and nausea. When her initial treatment with the drug Phenergan failed to relieve her symptoms, Levine was treated with a second dose, this time intravenously via an "IV-push" method. Unknown to Levine, administering the drug in this manner carried substantial risks. Within weeks, Levine's right arm developed gangrene and doctors were forced to amputate. Levine subsequently filed suit against Wyeth under state common law negligence and failure-to-warn claims. Rejecting Wyeth's automatic preemption arguments, the Supreme Court held that it was possible for a name-brand drug manufacturer to comply with both state and federal FDA labeling duties. The Court added that requiring such compliance would not frustrate the purpose of FDA labeling regulations.

On the heels of this landmark decision, a new controversy over the Court's ruling has emerged. Are generic drug manufacturers held to those same preemption standards where unique FDA regulations require generic drug labels to mirror their name-brand counterparts? At the heart of generic manufacturers' arguments for preemption is the fact that they are governed by an entirely different set of statutes and regulations than name-brand manufacturers. They argue that compliance with heightened state laws would be impossible without running afoul of FDA regulations requiring generic drug labels to be identical to name-brand drug labels.

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Surprisingly, despite the lack of a circuit court conflict and against the urging of the U.S. solicitor general, the Supreme Court will now address this issue. Specifically, it has granted review to consolidated appeals from the 5th U.S. Circuit Court of Appeals and the 8th U.S. Circuit Court of Appeals. In *Mensing v. Wyeth*, the 8th Circuit ruled against blanket preemption, stating that generic manufacturers could have proposed a label change to the FDA, or alternatively, suggested that the FDA send out warning letters. In *Demahy v. Actavis*, the 5th Circuit reached the same outcome, albeit for slightly different reasons. 593 F.3d 428 (5th Cir. 2010). Recently, the 9th U.S. Circuit Court of Appeals also addressed this issue. In a unanimous ruling, the court joined the 5th and the 8th Circuits in extending drug labeling duties under *Levine* to generic drug manufacturers.

Given that over 70 percent of prescriptions are filled with generic drugs in the U.S., the stakes are high. The Court's ruling will have huge implications for consumers and class action attorneys alike. For instance, if the Court rules that FDA regulations categorically pre-empt state tort laws, name-brand manufacturers and the FDA will ultimately be responsible for appropriate warning labels. This would shield generic manufacturers from failure-to-warn liability and place no duty on them to update their drug warning labels or inform the FDA of new risks associated with their drugs. Some would argue that this unfairly favors generic manufacturers over innovator manufacturers, although both are ultimately placing a product into the stream of commerce.

Additionally, a finding of preemption would necessarily strip generic drug consumers of potential remedies that would be available to them under state law. The court in *Demahy* recognized that state law preemption would "foreclose a remedy that was traditionally available and for which federal law provides no substitute." Meanwhile, under *Wyeth*, consumers of name-brand drugs still have state tort law remedies available to them. Thus, preemption would make a different class of remedies available to consumers who are harmed from the effects of a generic drug versus those harmed by name-brand drugs. This distinction appears arbitrary and inequitable.

On the other end of the spectrum are the potential consequences should the Court rule against preemption and require compliance with both state and federal warning label laws. Such a ruling would charge generic manufacturers with the duty to keep the FDA, the medical community, and consumers continually informed of risks associated with their drugs. Generic manufacturers argue that such a duty would impose on them a severe economic burden. They claim that requiring label proposal changes would require them to conduct expensive clinical trials on the adverse effects of their drugs. Thus, some argue, the steep costs associated with this new business model could force many generic manufacturers out of business and would result in drug costs to rise. Additionally, others contend that requiring generic drug manufacturers to update their warning labels would frustrate the fundamental purpose of amendments to

the Hatch-Waxman Act, the 1984 law that governs the approval process for generic drugs. According to the amicus brief filed by the solicitor general in *Mensing*, "[p]etitioners contend that Congress' 'primary purpose' in enacting the Hatch-Waxman Amendments was to bring low-cost generic drugs quickly to market; they argue that state law duties to warn would obstruct that purpose because generic manufacturers would be forced, at great expense, to acquire and maintain extensive scientific data on their drugs."

However, as noted in *Mensing*, generic manufacturers already are obligated to report adverse drug reactions. Further, since name-brand and generic manufacturers are both ultimately liable for their drug labels, this could lead to the two entities collaborating on additional research efforts and sharing related costs.

Beyond these concerns lie additional practical considerations. For example, requiring generic drug manufacturers to include increased risks in their updated labels could result in lowered consumer faith in generic products. Consumers may attribute differences in labeling to differences in product safety and quality in a field where generic drug ingredients are assumed to be the same or substantially similar to name-brand drugs. Moreover, the lack of consistency between generic and name-brand drug labels is a concern. Consumers faced with different warning labels may not clearly understand the risks associated with the drugs they take, contravening the primary purpose of warning labels. And that is to keep consumers informed at all times. Other concerns include the method by which generic and name-brand drug-makers would resolve potential disputes regarding the interpretation of safety data, as well as the manner and timing in which they must inform the FDA of new safety concerns.

While a generic manufacturer's current duties to warn are riddled with uncertainty, the field of pharmaceutical litigation is due for dramatic changes in the coming year. Consumers, public officials, manufacturers and class action attorneys alike will need to pay close attention to the Court's upcoming ruling on the matter. A preemption ruling one way or the other may potentially open the door to federal preemption in areas where the interplay between federal regulations and state law remain as murky as the law in pharmaceutical drug labeling.