

DRUG & DEVICE  
BULLETIN



JANUARY 12, 2010

Pharmaceutical & Medical Device

Shook, Hardy & Bacon has successfully defended pharmaceutical and medical device manufacturers in products liability and other high-stakes litigation for over 35 years. Today, SHB represents more than 30 pharmaceutical and medical device parent companies and their subsidiaries in products liability, antitrust, employment, environmental, commercial, and intellectual property litigation. With more than 100 attorneys dedicated to the unique needs and challenges of this industry, SHB has cultivated a reputation for dynamic, cost-effective solutions built on decades of experience.

For additional information on SHB's Pharmaceutical & Medical Device Litigation capabilities, please contact

**Harvey Kaplan**  
Division Chair  
816-559-2214  
hkaplan@shb.com



**Eric Anielak**  
Division Managing Partner  
816-559-2359  
eanielak@shb.com



**FIFTH CIRCUIT PREEMPTION DECISION  
STRENGTHENS REACH OF WYETH V. LEVINE TO  
GENERIC MANUFACTURERS**

Yet another circuit court has held that federal law does not preempt failure-to-warn claims brought against generic drug manufacturers. On Friday, the Fifth Circuit Court of Appeals joined the Eighth Circuit in holding that the federal regulatory regime governing prescription drug labeling does not preempt state-law failure-to-warn claims brought against generic manufacturers. *Demahy v. Actavis, Inc.*, No. 08-31204 (5th Cir. Jan. 8, 2010).

The Eighth Circuit recently issued a two-part opinion in *Mensing v. Wyeth*, No. 08-3850 (8th Cir. Nov. 27, 2009), holding that (1) name brand manufacturers are not liable for failure to warn when the plaintiff uses a generic version of the drug only, and (2) federal law does not preempt failure-to-warn claims against generic manufacturers.

Similar to *Mensing*, the plaintiff in *Demahy* ingested a generic version of Reglan® and alleged that her use of the drug caused tardive dyskinesia (a neurological movement disorder). Although the *Demahy* plaintiff originally sued both the name-brand and generic drug manufacturers, the district court dismissed her claim against the name-brand manufacturer and allowed her claim against Actavis, Inc., the generic manufacturer, to proceed.

*Demahy* did not appeal the dismissal of her claim against the name-brand manufacturer; thus, the Fifth Circuit was faced with one issue only: whether federal law preempts state-law failure-to-warn claims against generic manufacturers. Finding support in the U.S. Supreme Court's decision in *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), the Fifth Circuit affirmed the district court. In *Levine*, the U.S. Supreme Court held that "the federal regulatory regime governing pharmaceuticals does not preempt a state-law failure-to-warn claim against the manufacturer of a name brand drug."

Actavis contended that *Levine* should not apply to generic manufacturers because, although name-brand manufacturers may change a label in advance of FDA approval through the "changes being effected" (CBE) process, "federal law requires that [generic manufacturers] maintain at all times a label that is the 'same as' the name brand's, thus preventing simultaneous compliance with a state law requiring additional warnings." The Fifth Circuit disagreed, noting that although federal law

## DRUG & DEVICE BULLETIN

JANUARY 12, 2010

requires that the generic product contain labeling that is the “same as” that of the name-brand drug at the time of approval, plaintiff’s failure-to-warn claim was based on a failure to change the label *after* approval. “And, while Congress plainly intended for a generic drug manufacturer to submit labeling identical to—or, the ‘same as’—the brand name drug when seeking ANDA [abbreviated new drug application] approval, the statutory scheme is silent as to the manufacturer’s obligations after the ANDA is granted.”

The court also concluded that, just like name-brand manufacturers, generic manufacturers have at least three ways to update product labeling in response to new safety information. First, nothing in the “changes being effected” regulation, which allows manufacturers to revise labeling in advance of FDA approval in certain circumstances, distinguishes between name-brand and generic drug manufacturers. Second, no aspect of federal law explicitly forbids generic manufacturers from proposing a labeling change to FDA through the prior approval process. Finally, the court stated that generic manufacturers can suggest to FDA that “Dear Doctor” letters be sent on their behalf.

The court noted that, although “most courts . . . focus on the CBE process, the CBE regulation was not the exclusive, or even the primary, basis for rejecting preemption in *Levine*.” Rather, there was a “fundamental misunderstanding” that “FDA, rather than the manufacturer, bears primary responsibility for drug labeling.” The Fifth Circuit stated that it was immaterial whether or not FDA regulations impose a duty on generic manufacturers to change their drug labels. Rather, the question is whether state law imposes duties that make compliance with federal law impossible.

Although the Fifth Circuit was not called on to address whether name-brand manufacturers can be held liable for the use of generic products, the court did contemplate and reject this possibility in reaching its preemption conclusion. “Here, if preemption is to be found, two additional conclusions necessarily follow: first, that Congress intended the name brand drug manufacturer to bear the sole burden of coping with incipient risks, even when it has ceased manufacturing the drug and left the market to generics; and two, that Congress intended either that the name brand manufacturer be liable for all failure-to-warn claims—even those arising out of the use of generic substitutes—or, that the injured plaintiff be left with no remedy.”

Rejecting preemption, the court concluded that it was avoiding the “bizarre” result of treating plaintiffs’ ability to recover differently depending on whether a plaintiff took a name-brand or generic product. In the future, name-brand manufacturers may use this opinion and those like it to assert that a plaintiff who used a generic product has a remedy—and therefore has no need to sue the name-brand manufacturer as well.

The Sixth Circuit will likely be the next circuit court to address whether federal law preempts state-law failure-to-warn claims against generic manufacturers. See *Smith v. Wyeth*, No. 09-5460; *Wilson v. Pliva*, No. 09-5466; and *Morris v. Wyeth*, No. 09-5509. ■

This analysis was prepared by SHB Associate [Ann Peper Havelka](#).

