

PRODUCT LIABILITY

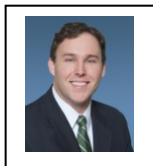
November 2011

IN THIS ISSUE

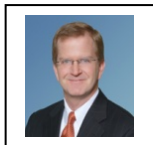
The authors discuss the Supreme Court decision that limited the application of the Court's 2009 decision in Wyeth v. Levine.

Supreme Court Decision in *Pliva v. Mensing* Breathes New Life into "Impossibility" Preemption of Prescription Drug Failure to Warn Claims

ABOUT THE AUTHORS



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On June 23, 2011 the U.S. Supreme Court issued its highly-anticipated opinion in *Pliva v. Mensing*, 131 S. Ct. 2567 (2011), *reh'g denied*, No. 09-993, 2011 U.S. LEXIS 5136 (Aug. 15, 2011). In so doing, the Court breathed new life into “impossibility” preemption for prescription drug failure to warn claims and limited the application of the Court’s 2009 decision in *Wyeth v. Levine*, 555 U.S. 555, 129 S. Ct. 1187 (2009). Although *Mensing* deals with preemption in the context of generic drugs, the opinion could also benefit brand-name drug manufacturers.

Recap of *Wyeth v. Levine*

From the defense perspective, *Wyeth v. Levine* proved the adage that bad facts make bad law. In *Levine*, the plaintiff was injured as a result of allegedly inadequate warnings associated with Wyeth’s anti-nausea medication Phenergan. Wyeth argued that the plaintiff’s claim was preempted because it was impossible for Wyeth to comply with both the FDA’s labeling regulations and the duties plaintiff sought to impose by way of her failure to warn claim. The Supreme Court rejected Wyeth’s argument, holding that it was not impossible for Wyeth to comply with both requirements because the FDA’s “Changes Being Effected” (CBE) regulations specifically allowed Wyeth to strengthen the language in its label without prior FDA approval. The Court held that in order to prove that a prescription drug failure to warn claim was preempted based on the “impossibility” of simultaneous compliance with both federal regulations and state-law tort duties, the manufacturer had to provide “clear evidence” that the FDA would not have approved the labeling change the plaintiff argued for if the manufacturer tried to institute the change using the CBE process. 129 S. Ct. at 1198. The 5-4 opinion, authored by Justice Stevens, also included several quotable passages that the plaintiffs’ bar has

since seized upon, particularly the Court’s statement that “the manufacturer bears responsibility for the content of its label at all times.” *Id.* at 1197-98.

In the wake of *Levine*, many proclaimed that the Supreme Court had set the bar for implied preemption of prescription drug failure to warn claims so high that the defense was effectively eliminated. Because the manufacturer bore ultimate responsibility for the content of its label, many argued, a manufacturer could not point to FDA regulations as a legitimate reason for failing to include a particular warning in its label. Indeed, in the two years since *Levine*, the “clear evidence” standard has proved to be a formidable hurdle. The Court’s recent decision in *Mensing*, however, appears to limit *Levine* to its unfortunate facts and to the specific FDA regulations at issue in that case.

Pliva v. Mensing

In *Mensing*, the plaintiffs claimed to have developed tardive dyskinesia following use of metoclopramide, (the generic version of the brand-name drug “Reglan”), and alleged that the generic manufacturers negligently failed to warn of that risk in their product labels. 131 S. Ct. at 2573. The generic manufacturers argued that the plaintiffs’ claims were preempted because the FDA’s labeling regulations “required them to use the same safety and efficacy labeling as their brand-name counterparts,” thus making it impossible for them “to simultaneously comply with both federal law and any state tort-law duty that required them to use a different label.” *Id.* Thus, they argued, *Levine* did not apply, because the CBE regulations that were available to Wyeth in that case were not available to generic manufacturers. The Fifth and Eighth Circuits rejected this argument, but the Supreme Court reversed.

In a 5-4 decision authored by Justice Thomas and joined by Roberts, Scalia, Alito, and Kennedy (who sided with the majority in *Levine*), the Court relied on the fact that in seeking approval to market a generic drug, FDA regulations require generic manufacturers to use a label that is identical to the brand-name label, and held that the duty to maintain “sameness” between the generic and brand-name label was ongoing (*i.e.*, it did not just exist at the time the drug was first marketed). *Id.* at 2574-75. The Court thus concluded that, unlike *Levine*, “the CBE process was not open to the Manufacturers for the sort of change required by state law.” *Id.* at 2575-76.

Importantly, the Court also rejected the argument that generic manufacturers at least had a duty to ask the FDA to change the corresponding brand-name label. “The question for ‘impossibility,’” the Court held, “is whether the private party could independently do under federal law what state law requires of it.” *Id.* at 2579 (emphasis added). While it was possible that the generic manufacturers could have convinced the FDA to have ordered a change to the brand-name label, adoption of such a standard would essentially eliminate conflict preemption altogether. *Id.*

Impact of *Mensing* for Generic and Brand-Name Manufacturers

Mensing is obviously very good news for generic manufacturers, which for the moment appear to be immune from failure to warn claims in cases where the generic label matches the brand-name label with respect to the warnings at issue. In this regard, generic manufacturers can expect the plaintiffs’ bar to more closely scrutinize generic labels to ensure that those labels in fact match the brand-name label with respect to all material warnings. *See, e.g., Fisher v. Pelstring*, No.

4:09cv252, Slip Op. at 7 (D.S.C. Sept. 30, 2011) (denying motion to dismiss based on *Mensing* because of a “possible deviation in PLIVA’s label for generic metoclopramide” from the branded label). Generic manufacturers can also expect a strong push by consumer protection groups and the plaintiffs’ for changes to FDA regulations making the CBE process equally available to generic manufacturers.

The impact of *Mensing* for brand-name manufacturers is decidedly less certain. On the one hand, *Mensing* establishes that *Levine* did not abrogate FDA authority over labeling or hold that manufacturers should simply ignore FDA regulations when a labeling change is necessary. Rather, *Mensing* simply reinforced that manufacturers have a duty to use the FDA procedures that are available. Arguably, if an FDA regulation prohibits a brand-name manufacturer from taking certain action with respect to its label – such as unilaterally changing the sequencing of information, adding a boxed warning, or otherwise altering the “Highlights” section without prior FDA approval – a failure to warn claim based on the manufacturer’s failure to take such action would be preempted. *See, e.g., In re: Avandia Mktg., Sales Practices and Prods. Liab. Litig.*, MDL No. 1871, 2011 U.S. Dist. LEXIS 101945, at *51 n.97 (E.D. Pa. Sept. 7, 2011) (noting that “[t]he FDA’s regulations mandate the order in which labeling information must appear” and that “boxed warnings can be added only with prior FDA approval”).

On the other hand, *Mensing* may actually lead to more litigation for brand-name manufacturers. Faced with the inability to sue generic manufacturers, plaintiffs injured by a generic drug may sue the manufacturer of the brand-name equivalent for “misrepresentation.” That is exactly what happened in *Conte v. Wyeth, Inc.*, 85 Cal.

Rptr. 3d 299, 313 (Cal. Ct. App. 2008) (“[W]e have no difficulty concluding that [the name-brand defendant] should reasonably perceive that there could be injurious reliance on its product information by a patient taking generic metoclopramide”). Fortunately, *Conte* has been heavily criticized and has not started a trend of imposing liability on brand-name manufacturers for injuries caused by a generic competitor’s drug. *But cf. Weeks v. Wyeth, Inc.*, No. 1:10cv602, 2011 WL 1216501, Slip Copy at *6 (M.D. Ala. Mar. 31, 2011) (denying motion to dismiss fraud-based claim against Reglan manufacturer for failing to provide prescribing physician adequate information about Reglan, even though the plaintiff’s injuries were caused by use of the generic equivalent, and noting that the manufacturer failed to “establish that a relationship between the [plaintiffs] and the brand name defendants is required when the plaintiff’s claims are based on fraud perpetrated against the prescribing physician”). Whether this will hold true post-*Mensing* is yet to be seen, though preliminary indications are that *Conte* will remain an exception to the rule. *See, e.g., Smith v. Wyeth, Inc.*, ___ F.3d ___, 2011 U.S. App. LEXIS 19393, at *9 (6th Cir. Sept. 22, 2011) (applying *Mensing* and “reject[ing] the argument that a brand-name manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company”).

Conclusion

Following *Mensing*, neither generic nor brand-name manufacturers should be quick to dismiss the possibility of a preemption defense in a failure to warn case. Although the availability of such a defense to brand-name manufacturers remains limited, at the very least brand-name manufacturers should ensure that a plaintiff’s failure to warn theory is not in any way based on the manufacturer’s failure to do what FDA regulations prohibit. In this regard, even if a dispositive preemption defense is not available, manufacturers should strongly consider whether a motion *in limine* is warranted to prevent plaintiff’s counsel from interjecting preempted theories into the case at trial.



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