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productsliability@joneswalker.com

STATE LAW FAILURE TO WARN CLAIMS GO *MENSING* AGAINST GENERIC DRUG MANUFACTURERS

On June 23, 2011, the Supreme Court released its highly anticipated ruling in *Pliva, Inc. v. Mensing*. 564 U.S. ____ (2011). In a 5-4 opinion, it held that state law claims against generic drug manufacturers are preempted by federal law.

The plaintiffs in the underlying cases were prescribed metoclopramide, a generic form of the brand name drug Reglan. At the time the plaintiffs were initially prescribed metoclopramide, the warning label stated that "tardive dyskinesia… may develop in patients treated with metoclopramide," and the drug's package insert added that "[t]herapy for longer than 12 weeks has not been evaluated and cannot be recommended." In 2004, the warning label was changed to read "[t]herapy should not exceed 12 weeks in duration." The label was once again strengthened in 2009 when the United States Food and Drug Administration ("FDA") ordered a black box warning stating that "[t]reatment with metoclopramide can cause tardive dyskinesia, a serious movement disorder that is often irreversible… Treatment with metoclopramide for longer than 12 weeks should be avoided in all but rare cases." After taking the drug as prescribed for several years, the plaintiffs developed tardive dyskinesia. The plaintiffs subsequently filed lawsuits against the generic manufacturers and the manufacturers of the brand name equivalents alleging that the manufacturers failed to warn them of the effects of long-term use of metoclopramide.

The manufacturers moved to dismiss the plaintiffs' claims arguing that federal statutes and FDA regulations preempted the plaintiffs' state law claims. The generic manufacturers argued that they are required to label the metcolopramide they produce with the same warnings that are required for Reglan, the brand name form of the drug. The brand name manufacturers argued that they owed no duty to warn consumers of the risks associated with taking the generic forms of their drugs. The district court agreed and dismissed the case. On appeal, the Eighth Circuit Court affirmed the district court's dismissal of the brand name manufacturers but reversed the dismissal of the generic manufacturers. The Eighth Circuit found that the FDA regulations provided mechanisms by which the generic manufacturers could propose changes for their labels. The generic manufacturers appealed the Eight Circuit Court's ruling.

On appeal, the U.S. Supreme Court noted that a conflict between state and federal law exists where it is impossible for a private party to comply with both state and federal law requirements. In such situations state law must give way. The Supreme Court found that a conflict exists between state law failure to warn claims asserted in the *Mensing* cases and the Hatch-Waxman Amendments to Federal Food, Drug, and Cosmetics Act. Specifically, the Court found that, under the Hatch-Waxman Amendments, a generic manufacturer seeking approval to produce a generic form for a brand name drug must show that the drug it wishes to produce is equivalent to an already-produced brand name drug *and* that the safety and efficacy labeling it proposes is the same as that already approved for the brand name drug. Therefore, the Court reasoned, the generic drug manufacturers could not comply with the Hatch-Waxman Amendments and provide the strengthened warnings that the plaintiffs contended were required because the generic manufacturers had no ability to change their labels.

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In so holding, the Court specifically rejected the Eighth Circuit Court's reasoning that the generic manufacturers could have satisfied the state law warning requirements by proposing label changes to the FDA. The Court explained that state law demanded a safer label, not communication between the manufacturer and the FDA. Therefore, even if the generic manufacturers had proposed label changes to the FDA, they could not have compelled the FDA to approve such changes. In such a circumstance, if the generic manufacturers' suggested label changes had not been approved the generic manufacturers would still be in violation of state law.

In closing, the Supreme Court noted that had the plaintiffs taken Reglan rather than metoclopramide, their claims would not have been preempted and acknowledged that, from the plaintiffs' perspective, the finding of preemption in this case, but not in *Wyeth* makes little sense. However, the Court noted that Congress enacted meaningfully different statutory schemes to govern generic manufacturers than those enacted to govern brand name manufacturers. The Court concluded that different statutes and regulations lead to different preemption results and noted that Congress and the FDA have the authority to change the law and regulations, if they so desire. Until Congress or the FDA adopts such changes, plaintiffs will not be able to maintain state law failure to warn claims against the manufacturers of generic drugs.

—*Steven F. Casey* and *David A. Lester*

Steven F. Casey is a partner in the firm's Business & Commercial Litigation Practice Group and enjoys a diverse practice involving product liability, mass tort, insurance, business and real estate disputes. He has extensive experience in pharmaceutical, toxic tort, electrical contact, environmental, and aviation cases, having completed over 55 jury trials. Mr. Casey recently successfully defended a generic pharmaceutical manufacturer in the first failure to warn claim to go to trial in the U.S. involving the drug metoclopramide (Reglan®), the drug at issue in the *Mensing* case discussed above.

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Remember that these legal principles may change and vary widely in their application to specific factual circumstances. You should consult with counsel about your individual circumstances. For further information regarding these issues, contact:

Steven F. Casey
Jones Walker
One Federal Place, Suite 1100
Birmingham, AL 35203
205.244.5282 tel
205.244.5482 fax
scasey@joneswalker.com

Products Liability Practice Group

Ainsworth, Kevin O.
Anseman, III, Norman E.
Balart, L. Etienne
Bonds, Emily Sides
Campbell, Melissa A.
Casey, Steven F.
Casey, Jr., Thomas A.
Chance, Rachal Dene
Crosby, Michele W.
Curtis, Tracy P.
Duvieilh, John L.
Fischer, Madeleine
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Lester, David A.
Liddick, Eric M.
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Windhorst, Judith V.
Winters, Amy M.
Wynne, William P.

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