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A Narrow Exception To The *Mensing* Preemption Defense

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Article

Law360, New York (April 04, 2013, 12:57 PM ET) -- The Sixth Circuit recently held that a failure-to-warn claim could proceed against a generic manufacturer that had failed to timely follow the brand-name label. Fulgenzi v. Pliva Inc., Case No. 12-3504 (6th Cir. March 13, 2013). In doing so, the court created a narrow exception to the preemption defense established by Pliva Inc. v. Mensing, 131 S. Ct. 2567 (2011).

Liability for Generic Manufacturers After Mensing

In Mensing, the U.S. Supreme Court held that failure-to-warn claims against generic drug manufacturers were preempted because it was impossible to comply with both state and federal law. The court reasoned that, because federal law requires generic manufacturers to maintain the "same" labels as that of the branded drug, it is impossible for generic manufacturers to independently change their drugs' labels to avoid liability for failure-to-warn claims under state law.

After Mensing, numerous courts have dismissed failure-to-warn claims against generic manufacturers, finding that federal law preempted the claims. See, e.g., Smith v. Wyeth, 657 F.3d 420, 423 (6th Cir. 2011); Gross v. Pfizer Inc., 825 F. Supp. 2d 654, 659 (D. Md. 2011); Bowdrie v. Sun Pharm. Indus., No. 12-CV-853, 2012 U.S. Dist. LEXIS 161239, at **14-18 (E.D.N.Y. Nov. 9, 2012).

However, recent appellate court decisions have identified potential avenues for users of generic drugs seeking relief in court. See Weeks v. Wyeth, No. 1101397, 2013 Ala. LEXIS 2 (Ala. Jan. 11, 2013) (brand-name manufacturer could be liable for failure to warn a patient who ingested the generic drug); Stengel v. Medtronic Inc., 704 F.3d 1224 (9th Cir. 2013) (manufacturer could be liable for failing to report adverse events to the U.S. Food and Drug Administration). Fulgenzi provides yet another path for plaintiffs claiming injury from a generic drug.

Fulgenzi's Claims

Plaintiff Eleanor Fulgenzi took metoclopramide, a generic equivalent of Reglan, from September to November 2004 and again in 2006 and 2007. She alleged that metoclopramide caused her to develop tardive dyskinesia.

In July 2004, the FDA approved a change to the brand-name labeling for Reglan: "Therapy should not exceed 12 weeks in duration." Pliva, a manufacturer of generic metoclopramide, did not update its own label. In February 2009, after Fulgenzi stopped taking metoclopramide, the FDA ordered Reglan's manufacturer to include "black-box warning," the strongest type of warning that can be placed on a drug label. Fulgenzi sued Pliva, alleging that any warning short of the FDA's 2009 "black-box" warning was unreasonable. Applying Mensing, the district court dismissed Fulgenzi's failure-to-warn claims. Fulgenzi appealed.

Impossibility Preemption Does Not Apply

The Sixth Circuit found that Pliva could not invoke preemption under this set of facts. The court emphasized that Mensing had relied on the impossibility of a generic drug manufacturer to comply simultaneously with its duty of sameness to the branded label and an alleged duty to strengthen its warning. In Fulgenzi, no such impossibility existed because the brand-name drug label had already been updated. Therefore Pliva could have, and should have, updated its label without violating its federal duty of sameness.

However, according to the boundary set by Mensing, liability would be found only to the extent a generic manufacturer's actions would be permitted under federal law. The Sixth Circuit cautioned that Fulgenzi is only "free to argue that any label lacking Reglan's 2004 updated warning was inadequate." The court further admonished that plaintiff's "allegation that any warning short of the FDA's 2009 'black-box' warning was unreasonable is preempted."

Thus, a generic manufacturer may be liable for failure to warn only to the extent its label did not mirror the brand label at the time plaintiff took the drug. Any allegation that the warning should have been stronger than — or different from — the brand label is foreclosed by Mensing.

The court did recognize that it may "be more difficult to prove proximate causation in a case where the warning that the defendant failed to provide was also legally inadequate." But this was a "matter for further proceedings." In order to survive a motion to dismiss, plaintiff only had to plead that the 2004 Reglan warning would have prevented plaintiff's injury had Pliva updated its generic label accordingly.

No Private Enforcement of FDCA

The court rejected the notion that Fulgenzi was simply attempting to enforce a federal law violation even though the Federal Food, Drug and Cosmetic Act excludes a private cause of action. The court carefully noted that "PLIVA's violation of the federal duty of sameness is essential to [Fulgenzi's] case — but only to avoid preemption under Mensing." In effect, the court used two federal concepts to offset each other. The duty of sameness, a federal duty under the FDCA, is germane only to whether preemption applies. As a result, "whether PLIVA has violated its federal duties is irrelevant to the adequacy of its warnings."

Instead, Fulgenzi was asserting a failure-to-warn claim grounded firmly in state law. Where a traditional, pre-existing independent state law tort was brought parallel to federal safety requirements, the state law claim would be allowed to continue.

Claims Not Preempted by Buckman

The Sixth Circuit did concede that evidence of federal law violations might be excluded under Buckman Co. v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001) (holding that fraud-on-the-FDA claims are preempted), but noted there is a "gap" between Mensing and Buckman through which a plaintiff may pass. Under Buckman, state tort suits premised solely on violations of the FDCA may be impliedly preempted as the federal government has exclusive authority to enforce the FDCA. This reasoning applies only where an element of the claim or link in the causal chain is premised on a violation of the FDCA.

Here, Fulgenzi alleged a state-law failure-to-warn claim, not a violation of federal law. Therefore, Buckman did not bar Fulgenzi's claim. However, because violation of federal law could not stand alone as a cause of action, "unless federal law bears on the state duty of care, evidence of such [federal] law is inadmissible."

In theory, it is questionable whether Buckman preemption would have any effect on the ultimate outcome of Fulgenzi's claim, which will hinge on causation. Fulgenzi will still have to argue that the 2004 Reglan warning would have changed her outcome; the reason defendant failed to use the 2004 Reglan warning (either failure to comply with federal law or failure to warn under state law) seems immaterial. To the extent evidence of federal law violations may bias a jury against a defendant, however, exclusion of such evidence under Buckman may provide a small benefit.

Mind the "Gap": Implications and Recommendations

Generic drug manufacturers should note the "gap" of liability described in Fulgenzi and take steps to minimize their exposure. Under Fulgenzi, manufacturers cannot simply cite Mensing and rely on a preemption defense, but must

show diligence and timeliness in keeping their labels up to date. Delay may be enough to defeat a motion to dismiss. Where a failure-to-warn claim survives a motion to dismiss, the Fulgenzi court's limiting language supports making an effort to exclude evidence of the federal duty of sameness. Because the court noted that the duty is only relevant to the extent it defeats preemption, it should not be used during trial to bias a jury against the defendant generic drug manufacturer.

In addition, any defense to a claim that falls within the "gap" should include a focus on causation and whether the physician actually relied on the manufacturer's label. Even if the prescribing physician testifies that he "would have" changed his prescribing habits if the warning had changed, many physicians rely on information other than the manufacturer's warning. In "gap" cases, causation could be defeated by demonstrating that the treating physician relied on the brand drug label. Where the physician relies on the updated brand label, a change to the generic label would not have made a difference.

Because preemption of claims based on generic pharmaceutical labels is not certain, generic manufacturers should be careful to mind the "gap" in the future so they are not caught outside the protection of Mensing, and keep their labels the "same" as the branded drugs.

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