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Poking Holes in *Pliva v. Mensing*: Are Failure to Timely Update Label Claims Cognizable?

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In *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567 (2011), the United States Supreme Court held that state law failure to warn claims against manufacturers of generic pharmaceutical products were impliedly pre-empted by federal law because FDA regulations preclude generic manufacturers from including additional or stronger warnings on their products without prior FDA approval. The Court's holding was premised on the view that FDA regulations only impose a "duty of sameness" on generic manufacturers, which requires that their warnings be the same as those included in the label for the corresponding brand name product. For the most part, the *Mensing* decision has resulted in the dismissal of many failure to warn claims against generic pharmaceutical manufacturers.

In the wake of *Mensing*, many plaintiffs have attempted to avoid federal pre-emption by alleging that the generic manufacturer violated this duty of sameness by failing to timely update the warnings on its product to incorporate changes made to the warnings of the brand name product. Over the last few years, the validity of these "failure to update" claims has been analyzed by several federal and state courts with varying results.

Whether Failure to Update Claims are Pre-empted by Federal Law

Some generic manufacturers have argued that a failure to update claim is just another


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version of a failure to warn claim that is pre-empted, noting that the *Mensing* Court did not expressly carve out claims for failing to update warnings. Most federal and state courts have rejected this argument, holding that *Mensing*, by acknowledging that generic manufacturers have a duty of sameness under federal law, implicitly recognized that failure to update claims do not impose obligations on generic manufacturers that conflict with federal law. *See, e.g., Fulgenzi v. Pliva, Inc.*, 711 F.3d 578, 584 (6th Cir. 2013) (holding that plaintiff's claim that the defendant's warning was inadequate to the extent that it did not include the language contained in the updated 2004 Reglan label was not pre-empted by *Mensing*); *In re Reglan Litig.*, No. A-2014-13T4, 2014 N.J. Super. Unpub. LEXIS 2664, at *12 (N.J. App. Div. Nov. 12, 2014) (holding that "the trial court correctly determined that plaintiffs' claims based on the Generic Defendants' failure to update their warnings to conform to changes made to the brand-name warnings are not pre-empted by federal law"); *In re Reglan/Metoclopramide Litig.*, 81 A.3d 80, 95 (Pa. Sup. Ct. 2013) (same); *Teva Pharmaceuticals USA, Inc. v. Superior Court*, 217 Cal. App. 4th 96, 107 (Cal. Ct. App. 2013) (same).

Generic manufacturers have also argued that failure to update claims are precluded by federal law because the Food, Drug and Cosmetic Act ("FDCA") specifically excludes private causes of action for alleged violations of the FDCA and FDA regulations. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001) (holding that the FDCA pre-empts plaintiffs' claims alleging "fraud on the FDA"). State laws generally do not specifically authorize failure to update claims, and generic manufacturers have argued that plaintiffs are just attempting to privately enforce FDCA and FDA requirements. Courts, however, have generally held that failure to update claims are premised on traditional state product liability laws rather than federal law, and therefore, are not pre-empted under *Buckman*. *See Fulgenzi*, 711 F.3d at 578; *In re Reglan*, 2014 N.J. Super. Unpub. LEXIS 2664 at * 16-17 (holding that plaintiffs' failure to update claims were "grounded in state law and are not based solely upon a federal violation"). *In re Fosamax Prods. Liab. Litig.*, 965 F. Supp. 2d 413, 418 (S.D.N.Y. 2013) (holding that "failure to update claims are not premised on federal law, but rather on an independent state duty"); *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 369 (Iowa 2014) (plaintiff's failure to update claims against generic metoclopramide manufacturer were not pre-empted by *Buckman* because plaintiff was "suing for conduct that violates the FDCA, but she [was] not suing because the conduct violates the FDCA"). *But see Morris v. Pliva, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013) (holding that plaintiff's failure to update claim was premised "exclusively in federal (not state) law, and is pre-empted" under *Buckman*).

Whether Failure to Update Claims Are Precluded Because Plaintiff Alleges That the Updated Brand Name Product's Warnings Were Inadequate

In many pharmaceutical failure to warn cases, plaintiffs have asserted claims against both the brand name manufacturer and one or more generic manufacturers. In such cases, plaintiff may allege that the generic manufacturers failed to timely update their warnings to match those of the brand name product's while also alleging that the brand name manufacturer's updated warnings were defective or inadequate. Generic

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manufacturers have argued, with some degree of success, that a failure to update claim is not cognizable where plaintiff has alleged that the brand name manufacturer's updated warnings, which the generic manufacturer failed to timely implement, were also defective or inadequate. In *Morris*, for example, the court upheld the dismissal of plaintiff's failure to update claim against a generic metoclopramide manufacturer because it was "logically incoherent" to assert that the generic manufacturer should be liable for failing to timely add warnings that were implemented by the brand name manufacturer which plaintiff also contended were inadequate. 713 F.3d at 777 ("Tort liability does not arise for failure to attach an inadequate label."). *See also Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 612 (5th Cir. 2014) (same). Similarly, in *Wagner v. Pfizer, Inc.*, No. 13-cv-497 (JDP), 2014 U.S. Dist. LEXIS 94281, at *11-12 (W.D. Wis. Jul. 11, 2014), the court held that the generic manufacturer's failure to update its warnings could not be a cause of plaintiff's injuries where the plaintiff alleged that the updated warnings would not have adequately warned her. *But see Fulgenzi*, 711 F.3d at 587 (rejecting this argument because there is "nothing in the Ohio product-liability law inconsistent with a claim that a defendant failed to warn, even inadequately").

Challenges to Failure to Update Claims Based on Lack of Proximate Cause

Generic manufacturers have achieved the greatest degree of success with challenges to failure to update claims based on lack of proximate cause. Proximate cause challenges can take several forms. The most common challenge involves the learned intermediary doctrine. In almost all states, pharmaceutical companies satisfy their duty to warn with respect to prescription medications by providing warnings to prescribing physicians (the learned intermediary), who are then responsible for conveying any material risks associated with the medication to their patients. In many generic pharmaceutical cases, plaintiff's prescribing physician actually prescribed the plaintiff the brand name medication which the pharmacy then filled with the generic form of the medication. In addition, irrespective of whether the prescriber prescribed the brand name or generic product, the prescribing physician likely will have reviewed and relied on the warnings in the package insert and/or Physician's Desk Reference ("PDR") for the brand name product.

In cases where the prescribing physician has relied on the warnings for the brand name product in prescribing the medication to plaintiff, courts have generally held that plaintiff's failure to update claim must be dismissed for lack of proximate cause. Courts have held that proximate cause is lacking for two reasons. First, under the learned intermediary doctrine, the manufacturer cannot be held liable where the prescribing physician was aware of the alleged risk that the manufacturer allegedly failed to warn about. Where the prescriber relied on the updated warnings for the brand name product, which the plaintiff alleges the generic manufacturer failed to timely incorporate in its labeling, there can be no proximate cause because the prescriber was aware of the warnings from the brand name product. *See Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1097-98 (8th Cir. 2013) (upholding the dismissal of plaintiff's failure to update claim against a generic metoclopramide manufacturer because plaintiff's prescriber had independent knowledge of the risks from reviewing the Reglan package insert and PDR). Second, because the prescribing physician did not review or rely on the labeling accompanying the generic product, the absence of a warning in the generic manufacturer's labeling could not have been the proximate cause of plaintiffs' injuries. *See Brinkley v. Pfizer, Inc.*, No. 13-3663, 2014 U.S. App. LEXIS 22742, at *7-8 (8th Cir. Dec. 2, 2014) (upholding the dismissal of plaintiff's failure to update claim because the "prescribing physicians' exclusive reliance on information from the brand-name manufacturers broke any causal link between Pliva's failure to incorporate the label change and the plaintiffs' injuries."). *See also Fullington v. Pfizer, Inc.*, 720 F.3d 739, 747 (8th Cir. 2013) (upholding dismissal of plaintiff's failure to update claim based on learned intermediary doctrine and lack of proximate cause because plaintiff admitted that her physician relied on warnings of brand name product in prescribing brand name product to plaintiff).

Depending on the facts of any given case, the generic manufacturer may have other potential challenges to proximate cause as it relates to plaintiffs' failure to update claims. For example, in *Johnson v. Teva Pharm. USA, Inc.*, 758 F.3d 605, 612 and n.1 (5th Cir. 2014), the plaintiff continued to take generic metoclopramide for almost four years after the generic manufacturer updated its warnings to match those of the brand name product's. Given plaintiff's continued use of the generic product after the warnings were updated, the court held that Teva's one-year delay in updating the warnings could not have been a proximate cause of plaintiff's injuries. *Id*.

Conclusion

The Supreme Court's broad holding in *Mensing* has left very few avenues for plaintiffs to sue generic pharmaceutical manufacturers for injuries allegedly caused by their products. Therefore, it is not surprising that plaintiffs are seeking to poke holes in *Mensing*'s pre-emption principles through the assertion of failure to update claims against generic manufacturers. The likelihood of broad, long-term success with failure to update claims remains to be seen.