Legal Opinion Letter

Vol. 25 No. 28 December 2, 2016

Washington Legal Foundation
Advocate for Freedom and Justice®
2009 Massachusetts Avenue, NW
Washington, DC 20036
202.588.0302 wlf.org

New Jersey High Court Rejects Generic Preemption Defense When Label Updates "Unreasonably" Delayed

by Linda Pissott Reig and Alexandre H. Gapihan

In re Reglan Litigation, 226 N.J. 315 (2016), decided by the New Jersey Supreme Court on August 22, 2016, held that federal law did not preempt state-law failure-to-warn claims against generic drug makers because the defendants were not reasonably diligent in updating their product labels to match those of their reference-listed branded drugs. The decision exacerbates a split in federal and state appellate courts over whether generic defendants can dismiss product-liability lawsuits on preemption grounds.

Nearly 1,000 plaintiffs filed individual lawsuits against over 50 brand and generic companies in New Jersey state courts, alleging inadequate warnings for Reglan (metoclopramide), a drug used to treat gastroesophageal reflux disease. The plaintiffs' complaints alleged that the defendants' failure to timely update their labeling violated New Jersey's Product Liability Act (PLA). The New Jersey Supreme Court ordered the individual lawsuits consolidated. The trial court denied the defendants' motions to dismiss and for summary judgment, and the Appellate Division affirmed, after which the state high court granted the defendants' motion for leave to appeal.

Federal regulations require generic drug manufacturers to maintain labeling consistent with their branded counterparts, 21 C.F.R. § 314.150(b)(1). Several label updates have been made since Reglan was first marketed in 1980. A 2004 update advised that "(t)herapy should not exceed 12 weeks in duration." In 2009 a black-box warning was added stating that the drug can cause tardive dyskinesia. The plaintiff in *In re Reglan* presented evidence to the trial court that a minimum of six months and a maximum of four-and-a-half years passed between these labeling updates and the generic defendants' comparable updates.

New Jersey Supreme Court Holding. The New Jersey Supreme Court upheld the lower court's refusal to bar all state-law failure-to-warn claims that are premised on a federal-law duty to match the brand label. The decision reflects the New Jersey high court's interpretation of *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). In *Mensing*, the US Supreme Court held that federal law preempted state-law failure-to-warn claims against generic drug manufacturers so long as the defendants complied with their federal-law obligation that generic product labels match those of their branded equivalents. *See* 21 U.S.C. § 355(j)(2)(A).

The *In re Reglan* court distinguished *Mensing*, explaining that decision did not "directly address the issue before us because, here, defendant generic manufacturers of metoclopramide tablets did not comply with the [Food, Drug and Cosmetic Act] requirement that their labeling mimic the brand-name labeling." 226 N.J. at 333. The court looked instead to the US Supreme Court's key precedent on federal preemption of state-law failure-to-warn suits against *branded* drug manufacturers, *Wyeth v. Levine*, 555 U.S. 555 (2009). The Court in *Levine* reasoned that because federal law authorized drug makers to print pre-approval warnings on their labels, it was not impossible for Wyeth to comply with both federal and state law. The decision also posited that in passing the Food, Drug and Cosmetic Act (FDCA), Congress did not intend to preempt relevant common-law tort suits, and that such suits can complement federal labeling regulation.

Linda Pissott Reig is a Shareholder with Buchanan Ingersoll & Rooney PC in the firm's Newark, NJ office, and **Alexandre H. Gapihan** is an Associate in the firm's Washington, DC office.

Following the lead of *Levine*, the *In re Reglan* court reasoned that under the New Jersey PLA, manufacturers must provide product warnings that apprise consumers of drug risks. That requirement does not conflict, the court continued, with the FDCA's "duty of sameness" with which generic drug makers must comply. 226 N.J. at 335-36. Rather, a PLA lawsuit alleging that the defendants' failing to update their labels harmed the plaintiffs complements federal law.

The New Jersey Supreme Court noted the prevailing split in state and federal courts over generic drug preemption. The court found a contrary US Court of Appeals for the Fifth Circuit ruling, *Morris v. PLIVA*, 713 F.3d 774 (5th Cir. 2013) "not persuasive," while it favorably cited a Sixth Circuit decision, *Fulgenzi v. PLIVA*, 711 F.3d 578 (6th Cir. 2013).

In re Reglan squarely places the burden of discovering branded drug label updates on generic drug manufacturers. The court did not consider this to be a significant burden, remarking on the "easy access to information about brand-name labeling changes" through the Food and Drug Administration's "Labeling Review Branch Homepage" or from "the FDA's Freedom of Information Staff." 226 N.J. at 342. It did acknowledge that "some lag time is inevitable" before a generic manufacturer will be able to match the brand-name label. A defendant could benefit from a "safe-harbor protection under the sameness doctrine" so long as it demonstrates "reasonable diligence to learn of updates to the brand name labeling" and those changes are made "at the very earliest time possible." *Ibid*. Defendants must make that case to the trial court, the Supreme Court held, dictating that "[w]hether preemption applies is a matter of law to be decided by the court, not a jury." *Id.*, citing *Fulgenzi*, 711 F.3d at 583.

***In re Reglan*'s Implications**. *In re Reglan* will alter some generic manufacturers' defense strategies in failure-to-warn lawsuits. If plaintiffs raise doubts about the timeliness of a label update, rather than pursuing a rapid preemption-driven dismissal at the pleading stage, a defendant will instead become mired in a fact-intensive, time-consuming, and costly debate over whether the generic label was updated "at the very earliest time possible." The court provided virtually no guidance to defendants or trial judges on how to determine the defendant's "reasonable diligence" in discovering the branded drug's labeling change, or whether the company took undue advantage of the "inevitable" lag time.

In re Reglan does not, however, eliminate generic drug makers' preemption safe harbor entirely. In situations where the defendant can demonstrate that it matched the branded-drug label updates to the point of "sameness," preemption under *Mensing* remains available. Also, as the New Jersey Supreme Court wrote in its decision, "plaintiffs may not contend that defendant generic manufacturers had a duty to provide warnings beyond those that the FDA approved for the brand name." *Id.* at 343.

In situations where the generic drug labels were not updated "at the very earliest time possible," plaintiffs suing under the New Jersey PLA must prove that the failure to warn was the proximate cause of their alleged injury. Some generic drug maker defendants may find that mounting an aggressive challenge to the plaintiff's proximate-cause argument is a more efficient, cost-effective approach early in failure-to-warn litigation than asserting a preemption defense. That was, in fact, the ultimate outcome in the favorably-cited Sixth Circuit *Fulgenzi* decision—PLIVA prevailed on remand when the plaintiff could not establish its failure to update the generic metoclopramide label as the proximate cause of her injuries. *See Fulgenzi v. PLIVA, Inc.*, 140 F. Supp. 3d 637 (N.D. Ohio Oct. 23, 2015).

Conclusion. Since the US Supreme Court's 2011 *Mensing* decision, the plaintiffs' bar has made a concerted effort to poke holes in the preemption shield that precedent provides to generic drug failure-to-warn defendants. *In re Reglan Litigation* is a notable achievement in that campaign, and it certainly creates incentives for more litigation against the many pharmaceutical companies located in New Jersey. That said, generic drug maker defendants can still rely on a stout preemption defense in many instances, and where they perhaps cannot, proving proximate cause before a jury presents another formidable hurdle for plaintiffs to overcome.

 ISBN 1056 3059