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Recent 'Reglan' Decision Chips Away at Preemption

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In August 2016, the New Jersey Supreme Court examined the doctrine of preemption, and ruled that state law failure-to-warn claims against generic-drug manufactures are not preempted when the generic-drug manufacturer fails to timely update its warning labels following a label change to the brand-name drug. *In re Reglan Litig.*, 226 N.J. 315, 336 (2016).

The court's ruling in *Reglan* expanded a New Jersey consumer's ability to recover against a generic-drug manufacturer under a state-law failure-to-warn claim—a claim that the manufacturers argued was preempted by federal law based on the U.S. Supreme Court's holding in *PLIVA v. Mensing*, 131 S.Ct. 2567 (2011). This article will provide a brief background on federal preemption pre-*Reglan*, an analysis of the court's decision, and future implications for consumers' product liability suits.

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Historical Supremacy Clause and Federal Preemption

In recent years, litigants have put the scope of the Supremacy Clause to the test. The Supremacy Clause of the U.S. Constitution, the basis for the

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doctrine of federal preemption, establishes that the "federal constitution, and federal law generally, take precedence over state laws, and even state constitutions." U.S. Const. art. IV, §2. For years, brand-name manufacturers argued that state law failure-to-warn claims were preempted by the Federal Food, Drug and Cosmetic Act (FDCA) and regulations of the Food and Drug Administration (FDA). But in *Wyeth v. Levine*, 129 S.Ct. 1187 (2009), the Supreme Court held that failure-to-warn claims filed against brand-name drug manufacturers are *not* preempted even if the labeling had been approved by the FDA. Pursuant to federal regulations, brand-name manufacturers are able to strengthen the drug's warning label prior to FDA approval, and therefore could comply with both federal and state law.

Nearly two years later, a divided Supreme Court decided *PLIVA v. Mensing*, 131 S.Ct. 2567 (2011), finding that failure-to-warn claims against generic-drug manufactures *are* preempted. *Mensing* held that all state law failure-to-warn claims against generic-drug manufactures are preempted because federal regulations require generic-drug manufacturers to comply with the "sameness" requirement under 21 U.S.C. §355(j)(2)(A)(v), which requires that the brand-name and generic drug be equivalently safe and effective. If the generic-drug manufacturer unilaterally changed the warning label without FDA approval, even to strengthen the warnings, it would be in violation of the federal statute. While the Supreme Court noted that the differing outcomes in *Wyeth* and *Mensing* "make[] little sense" to plaintiffs who could have brought suit if they had used the brand-name drug instead of the generic, the court deferred to Congress to change the federal labeling regulations. *Mensing*, 131 S.Ct. at 2571, 2581 ("Congress and the FDA retain authority to change the law … if they so desire").

Following the decision in *Mensing*, the FDA proposed a rule change that would allow generic manufacturers to independently strengthen warning labels in advance of any FDA approval. If passed, the new rule could undo *Mensing* and put generic-drug manufacturers on the same terms as brand-name manufacturers by eliminating the "sameness" requirement. Notwithstanding its initial effort, since 2013, the FDA has delayed publishing the rule and extended the comment period three times. To date, the FDA has received over 23,000 comments, including staunch opposition from the Generic Pharmaceutical Association. The final rule is currently scheduled for publication in April 2017 unless the FDA delays it further.

Plaintiffs Target Brand-Name Manufactures

As courts narrowed the ability to recover against generic-brand manufacturers, and regulatory relief proved elusive, plaintiffs refocused their attention on brand-name manufacturers. In fact, even when the consumers' alleged injuries were caused by a generic drug that the brand-name manufacturer did not sell, plaintiffs' lawyers would file suits against the brand-name manufacturers. This theory, known as "innovator liability," has almost unanimously been rejected by courts across the country. *See, e.g., Foster v. Am. Home Prod. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994); *In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig.*, 756 F.3d 917, 939 (6th Cir. 2014) (concluding that every federal circuit that has addressed the issue, and the highest courts in each of 22 implicated states, would not recognize claims against brand-name manufacturers by consumers who ingested generic drugs). The same is true in New Jersey. Under the New Jersey Products Liability Act (PLA) and New Jersey law, a plaintiff-consumer cannot recover against a brand-name manufacturer for alleged injuries caused by a generic drug. *See, e.g., Condouris v. Wyeth (In re Reglan Litig.)*, No. ATL-L-1940-10 (N.J. Sup. Ct. June 26, 2012) (unpublished opinion). The court's reasoning in *Condouris* is simple—a plaintiff cannot prove causation when the alleged injuries were not caused by the brand-name manufacturers' product.

Following *Mensing* and courts' rejection of innovator liability, plaintiffs with failure-to-warn claims against generic-drug manufacturers had no apparent avenue for recovery. However, plaintiffs have developed a new exception against generic-drug manufacturers who have not updated their labels in accordance with the "sameness" requirement. It is this exception that the plaintiffs raised in the *Reglan* litigation.

'Reglan' Puts Generic-Drug Manufacturers at Risk

In the *Reglan* decision, the New Jersey Supreme Court approved a narrow exception to *Mensing* preemption: claims against generic drug manufacturers are not preempted when the

innovator makes a label change and the generic manufacturer does not timely update its labels. *Reglan* involved failure-to-warn claims against manufacturers of generic versions of the name-brand drug Reglan (metoclopramide). *In re Reglan Litig.*, 226 N.J. 315, 336 (2016). In 2004, the FDA approved a label change requested by the brand-name manufacturer, which included new warnings about the dangers of long-term use of metoclopramide, and in 2009 the FDA strengthened the warnings yet again. The generic manufacturers did not immediately update their labels to include the 2004 warnings, taking anywhere from six months to several years to update their generic labels. The plaintiffs alleged that the generic manufacturers' labeling was inadequate because it lacked the strengthened warnings. The trial court denied the defendants' motions to dismiss and motions for summary judgment in part because it concluded that there were genuine issues of fact as to whether the defendants updated their warning labels in a reasonable amount of time. The Appellate Division affirmed.

The New Jersey Supreme Court affirmed as well. The court found that *Mensing* did not directly apply because, unlike in *Mensing*, the defendants' labels did not comply with the FDA requirement that generic labels match the name-brand label. Instead of it being impossible for the generic manufacturers to comply with both federal law and state tort law, the manufacturers were required under federal law to provide the stronger warnings approved by the FDA for the brand-name labels. Relying on *Wyeth*, the court found that the plaintiffs' state-law failure-to-warn claims under the PLA were complimentary of federal safety regulation and not preempted. The court also distinguished the plaintiffs' claims from those based on violations of federal law (which would be preempted under *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001)) because plaintiffs' state tort claims are based on the PLA and parallel federal law instead of relying on violations of federal law. While the generic defendants' violation of their federal duty to update their labels was important for the preemption analysis, the plaintiffs "could proceed on their failure-to-warn claims under the PLA even if" federal law on the subject did not exist. 226 N.J. at 337-38.

In finding no preemption, the court joined the majority position on this topic, which includes the Sixth Circuit as well as courts in California, Iowa and Missouri. In *Morris v. PLIVA*, another generic metoclopramide case, the Fifth Circuit took the opposite position. 713 F.3d 774, 777 (5th Cir. 2013) (per curium). The court reasoned that the plaintiff was alleging that all warning labels prior to a 2009 change were inadequate, including the 2004 label that the defendants failed to adopt, and that "[t]ort liability does not arise for failure to attach an inadequate label." *Id*. The Fifth Circuit also concluded that any claims based on the defendants' violation of their federal law duty to update the generic labels was preempted under *Buckman*. The New Jersey Supreme Court found *Morris* to be unpersuasive. 226 N.J. at 341. The court concluded that Congress could not have intended the "absurd result" of allowing a lawsuit against a name-branded manufacturer for FDA-approved labels while barring claims against generic manufacturers for labels that fell short of what the FDA had approved.

Though *Reglan* offers a way for plaintiffs to bring failure-to-warn claims against generic drug manufacturers, the practical impact may be limited. First, a generic drug manufacturer can still take advantage of *Mensing* if it exercises reasonable diligence in monitoring the FDA's label updates (such as through the FDA's website or Freedom of Information staff) and updates its labels "at the very earliest time possible." 226 N.J. at 342 (quoting an FDA guidance document). Second, a plaintiff will be limited to arguing that the generic manufacturer had a duty to provide a warning only as strong as the updated warning of the brand-name manufacturer; arguing that the generic manufacturer should have provided stronger warnings will trigger preemption. Finally, a plaintiff will still need to show that the generic manufacturer's failure to provide the updated warning proximately caused his or her injury. As the court in *Reglan* said, the plaintiffs' ability to actually prove their claims "is a matter for another day." *Id*. at 344.■