

Client Alert

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Generic Drug Manufacturers to Face Failure-to-Warn Claims in California

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On January 20, 2015, the Supreme Court declined to hear an appeal involving failure-to-warn claims against generic pharmaceutical manufacturers. *Teva Pharms. USA Inc. v. Super. Ct.*, No. 13-956, 2015 WL 231967 (U.S. Jan. 20, 2015). This leaves intact the California Court of Appeal's ruling and provides plaintiffs claiming injury from generic drugs with a trifecta of liability theories—failure to update, failure to communicate, and innovator liability.

PROCEDURAL HISTORY

The *Teva* case arose out of plaintiffs' use of the drug alendronate, the generic form of the branded drug Fosamax, a drug indicated for treating osteoporosis. Multiple plaintiffs alleged that they suffered femur fractures from prolonged use of the drug and filed suit against the manufacturers of the brand and generic drugs. After coordination of the cases in Orange County Superior Court, the parties agreed to a test case (brought by Olga Pikerie) to resolve whether claims against the generic manufacturers were preempted by federal law.

The trial court held that plaintiffs had adequately stated causes of action for failing to make timely label changes and failing to communicate safety information to healthcare providers via Dear Doctor letters. The generic defendants filed a petition for a writ of mandate and/or prohibition, which was denied by the California Court of Appeal. *Teva Pharms. USA, Inc. v. Super. Ct.*, 217 Cal. App. 4th 96 (2013), review denied (Sept. 25, 2013) ("*Pikerie*").

The California Supreme Court declined to hear the defendants' appeal, and they petitioned the Supreme Court for a writ of certiorari. The Court requested the views of the Solicitor General, who recommended in December 2014 that the Court deny defendants' petition.

THE COURT OF APPEAL'S OPINION

The California Court of Appeal's opinion held that plaintiffs properly pleaded claims against the generic defendants for (1) failure to update and (2) failure to communicate, and that neither of these claims were preempted under the reasoning set forth by the Supreme Court in *PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

1. Failure to Update

Since the Supreme Court decided *Mensing*, plaintiffs have sought new avenues of liability for injuries cause by generic drugs. In large part, generic manufacturers are immune from failure-to-warn claims because federal law prohibits them from unilaterally updating their labels, triggering impossibility preemption. 21 U.S.C. § 355(j)(2)(A)(v) (generic labels must be "the same as" those of their branded equivalents).

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However, some courts, including the *Pikerie* court, have held that the federal requirement of “sameness” that gives rise to impossibility preemption also gives rise to a federal standard of care for state-law failure-to-warn claims. Indeed, the *Pikerie* court adopted the reasoning of the Sixth Circuit, which was the first federal circuit court of appeals to hold that failure-to-update claims survived *Mensing* preemption. See *Fulgenzi v. PLIVA, Inc.*, 711 F.3d 578 (6th Cir. 2013). Quoting *Fulgenzi*, the *Pikerie* court noted that “not only could [generic defendants] have independently updated [their] labeling to match that of the branded manufacturer . . . , but [they] had a federal duty to do so.” 217 Cal. App. 4th at 108. Thus, impossibility preemption did not apply.

Defendants argued that failure-to-update claims could not be pled if plaintiff also alleged that label changes *after* her exposure were inadequate. But the court found that California’s pleading standards permitted plaintiff to plead inconsistent facts. *Id.* at 109-110. This is consistent with the reasoning of the *Fulgenzi* court, which also permitted plaintiff’s claim to proceed over defendants’ argument that “there is no such thing as a ‘failure-to-inadequately-warn’ claim. 711 F.3d at 587.

The *Pikerie* court also disagreed with defendants’ contention that the failure-to-update claims were preempted as either a fraud-on-the-FDA claim or a private attempt to enforce the Food, Drug & Cosmetic Act, under the reasoning of *Buckman Co. v. Plaintiffs’ Legal Comm.*, 531 U.S. 341 (2001). Instead, plaintiff’s claims were based on “state law tort principles of a drug manufacturer’s duty to the consumers of its product.” 217 Cal. App. 4th at 111.

2. Failure to Communicate

Similarly, the Court of Appeal held that failure-to-communicate claims were not preempted. The *Pikerie* court determined that “[i]t would not have been impossible for the [generic defendants] to send Dear Doctor letters advising health care professionals of the risks identified in the 2010 and 2011 Fosamax label changes. Therefore, the impossibility preemption doctrine does not bar such claims.” *Id.* at 113.

Interestingly, courts have vehemently disagreed on the meaning of federal regulations governing Dear Doctor letters, specifically as they were interpreted by FDA in the Solicitor General’s *amicus* brief in *Mensing*. Citing the Solicitor General’s brief, the Court stated: “A Dear Doctor letter that contained substantial new warning information would not be consistent with the drug’s approved labeling. Moreover, if generic drug manufacturers, but not the brand-name manufacturer, sent such letters, that would inaccurately imply a therapeutic difference between the brand and generic drugs and thus could be impermissibly ‘misleading.’” *Mensing*, 131 S. Ct. at 2576.

Several courts have interpreted this language to mean that generic drug manufacturers cannot send Dear Doctor letters **unless the brand manufacturer has already sent an identical letter**. See, e.g., *Morris v. PLIVA, Inc.*, 713 F.3d 774, 777 (5th Cir. 2013); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1249-50 (11th Cir. 2013); *In re Darvocet, Darvon, & Propoxyphene Products Liab. Litig.*, 756 F.3d 917, 932-33 (6th Cir. 2014).

But notably, in his invitation brief in *Pikerie*, the Solicitor General adopted the *Pikerie* plaintiff’s interpretation of the Dear Doctor regulations. See Brief for the United States as Amicus Curiae at 20-23, *Teva Pharms. USA, Inc. v. Super. Ct.*, No. 13-956 (U.S. Dec. 16, 2014). Specifically, he stated that once FDA has approved a generic manufacturer’s update, “the generic manufacturer may ‘unilaterally’ disseminate a [Dear Doctor] letter to

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communicate the new labeling warnings even if the brand-name manufacturer has not done so Such letters would not imply any difference between the generic and brand-name drugs or otherwise run afoul of FDA's regulatory requirements." *Id.* at 21-22.

IN LIGHT OF FDA'S PROPOSED RULE, DOES ANY OF THIS MATTER?

In recommending that the Court deny the generic defendants' petition, the Solicitor General counseled that "[r]eview of the preemption issues in this case would also be premature in light of pending FDA regulatory changes. FDA has proposed a regulation that would 'enable ANDA holders to update product labeling promptly . . . , irrespective of whether the revised labeling differs from that of the [brand-name drug].'" Brief for U.S. at 23 (quoting 78 Fed. Reg. 67,985, 67,986 (Nov. 13, 2013)).

The Solicitor General affirmatively quoted FDA's explanation that "these changes, if adopted, 'may eliminate the preemption of certain failure-to-warn claims with respect to generic drugs.'" *Id.* (quoting 78 Fed. Reg. at 67,989). But the proposed rule, which was supposed to be finalized in late 2014, faced vocal opposition and now the final rule is slated for publication in late 2015.¹ In light of the comments opposing the proposed rule, no one knows what form the final rule will take.

PIKERIE AND CONTE PUT CALIFORNIA AT THE END OF THE LIABILITY SPECTRUM

Until FDA resolves the regulatory uncertainty surrounding labeling updates for generic drugs, *Pikerie* is binding authority for some California courts and is likely to be found highly persuasive by many others. Therefore, we expect that in California many plaintiffs will survive challenges to pleadings alleging liability for failure to update and failure to communicate.

California is no stranger to expansive theories of liability for drug-related injuries. In 2008, a California Court of Appeals held that a brand drug manufacturer could be liable to a patient who took a generic drug made by a different manufacturer. *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008). There, the court allowed misrepresentation claims to proceed against the brand drug manufacturer because, due to the "sameness" requirement imposed on generic manufacturers, a brand manufacturer could "reasonably foresee" that doctors would rely on the brand label in prescribing its generic version. *Id.* at 111.

Between *Pikerie* and *Conte*, California now has one of the most permissive legal landscapes in the country with respect to providing relief to plaintiffs who claim injury from generic drugs. We anticipate heated litigation over these issues on several fronts as companies try to escape California's litigious atmosphere, whether by challenging personal jurisdiction in California or by attacking these claims on the merits and seeking review by the California Supreme Court in the hopes that the holdings in these opinions would be overturned. We will continue to monitor these developments as they unfold.

¹ See <http://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201410&RIN=0910-AG94>.

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