Client Alert.

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Weeks Defies Years of Jurisprudence, Allowing Innovator Liability for Generic Drugs

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Last week the Alabama Supreme Court adopted brand-name manufacturer liability for a generic drug sold by another company, becoming the first state supreme court to do so. *Wyeth, Inc. v. Weeks*, No. 1101397 (Ala. Jan. 11, 2013). The court held that a generic drug user could foreseeably rely on a brand-name drug warning and maintain a failure to warn claim against the brand-name manufacturer, even when the plaintiff did not ingest that manufacturer's drug.

CERTIFIED QUESTION FROM DISTRICT COURT

Danny and Vicki Weeks filed suit against four pharmaceutical companies in federal district court, alleging injury from long-term use of metoclopramide, the generic form of Reglan. They claimed that Mr. Weeks ingested generic metoclopramide manufactured by Teva and Actavis. Plaintiffs also named Wyeth and Schwarz, the manufacturers of brand-name Reglan, even though they never alleged that Mr. Weeks ingested the brand-name drug. Instead, they sued Wyeth and Schwarz on a theory that the brand-name manufacturers had a duty to warn *all* users of the drug based on federal requirements that all generic labels be identical to the brand-name label. Faced with this question and conflicting precedent, the district court certified the question to the Alabama Supreme Court, specifically:

> Under Alabama law, may a drug company be held liable for fraud or misrepresentation (by misstatement or omission), based on statements it made in connection with the manufacture or distribution of a brand-name drug, by a plaintiff claiming physical injury from a generic drug manufactured and distributed by a different company?

The Alabama Supreme Court answered in the affirmative, joining a small group of courts to do so. *Cf. Conte v. Wyeth*, 168 Cal. App. 4th 89 (2008); *Kellogg v. Wyeth*, 612 F. Supp. 2d 421 (D. Vt. 2008).

MENSING SETS THE STAGE

The court began its analysis with a discussion of *Wyeth v. Levine*, 555 U.S. 555 (2009), and *PLIVA v. Mensing*, 131 S.Ct. 2567, 564 U.S. __ (2011), highlighting "the seeming contradiction in preemption claims against a generic manufacturer in *PLIVA* but allowing state-law tort claims in *Wyeth*." The court also examined several federal court decisions applying Alabama law, which had found that brand drug manufacturers may *not* be held liable to a plaintiff who ingested a generic drug. *See Mosley v. Wyeth*, 719 F. Supp. 2d 1340 (S.D. Ala. 2010); *Overton v. Wyeth, Inc.*, No. CA 10-0491-KD-C (S.D. Ala. Mar. 15, 2011); *Simpson v. Wyeth, Inc.*, No. 7:10-cv-01771-HGD (N.D. Ala. Dec. 9, 2010).

Common to these federal court decisions was their holding that generic drug manufacturers were responsible for the content of their own labels. However, these cases preceded *Mensing*, which held that generic drug labels had to be the same as their branded counterparts. 131 S.Ct. at 2581. This "sameness" requirement was crucial to the Alabama Supreme Court's finding.

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FORESEEABILITY

The court recognized it was adopting the minority view and that the majority view followed *Foster v. American Homes Products Corp.*, 29 F.3d 165 (4th Cir. 1994). In *Foster*, the Fourth Circuit held that a brand-name manufacturer owed no duty to users of generic drugs. The *Foster* court began with the pre-*Mensing* premise that a generic manufacturer was responsible for the content of its own label and concluded that to impose a duty on the brand-name manufacturer for the content of generic labels would "stretch the concept of foreseeability too far."

The Alabama Supreme Court found that this logic should be limited to a strict liability claim arising out of a defect in production (i.e., not a failure to warn). Such a defect would only foreseeably harm a user of the manufacturer's product. Not so for a warning claim, particularly post-*Mensing*: "an omission or defect in the labeling for the brand-name drug would necessarily be repeated in the generic labeling, foreseeably causing harm to a patient who ingested the generic product." *Weeks*, slip op. at 41.

FOLLOWING *CONTE*

In finding that generic users foreseeably rely on brand-name labels, the *Weeks* court followed the reasoning first set forth by the California Court of Appeals in *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89. Though often derided by the defense bar and other courts as illogical, the *Conte* court provided ample bases in traditional tort principles for its then-novel finding that generic users would foreseeably rely on the brand-name drug's warnings. Because the generic and brand-name drugs were required to be identical, it was entirely foreseeable that a physician would rely on the brand-name drug's warning in prescribing a generic drug. It was also foreseeable that the pharmacist would substitute the generic as permitted or required by state law or insurance, even if the brand-name drug had originally been prescribed.

Similar logic was applied in Vermont in *Kellogg v. Wyeth*, 762 F. Supp. 2d 694, another case finding that a brand-name manufacturer could potentially be liable to a generic user. The *Kellogg* court denied defendant's motion for summary judgment in order to allow the trier of fact to determine whether the plaintiff's doctor had in fact relied on the brand-name label in prescribing the drug at issue.

What the *Weeks* court did not address was whether *Conte* still applies in California in light of the California Supreme Court's subsequent clarification that "the foreseeability of harm, standing alone, is not a sufficient basis for imposing strict liability" on a manufacturer for another company's product. *O'Neil v. Crane Co.*, 53 Cal. 4th 335, 362 (2012). However, a federal district court in Kentucky, applying California law, distinguished *O'Neil* from a *Conte*-like fact pattern involving innovator liability and found that the plaintiffs could pursue their claims against the brand-name manufacturer. *In re Darvocet, Darvon and Propoxyphone Prods. Liab. Litig.*, No. 2:11-md-2226-DCR, 2012 WL 3842271, at *6 (E.D. Ky. Sept. 5, 2012). Moreover, the Ninth Circuit recognized *Conte* as the law of the state, citing it for the proposition that "California's negligence law may impose on a manufacturer a duty to warn individuals who, while not users of its products, could foreseeably rely on its warnings." *Rosa v. TASER Int'l, Inc.*, 684 F.3d 941, 949 (9th Cir. 2012).

NOTIONS OF FUNDAMENTAL FAIRNESS

Given the state of pharmaceutical product liability law and the perceived injustice established by *Mensing*, it seemed only a matter of time before more courts began embracing *Conte*. While this logic is often criticized, tort law is replete with examples of defendants being held liable to plaintiffs with whom they had no relationship. This absence of privity is one of the hallmarks of tort law, which is defined instead by foreseeability and the "zone of danger."

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For example, construction companies have been held liable for injuries to children on their equipment when the children are mischievous trespassers. Courts that have not followed traditional tort analysis have found that innovator liability goes "too far." However, it is certainly possible that other courts will allow for innovator liability based on traditional tort theories.

In reality, courts are struggling to balance two perceived injustices. On the one hand, there is the unfairness of leaving patients who use generic drugs (often through no choice of their own through substitution at the pharmacy) without any remedy for their injuries. This unfortunate landscape was recognized by Justice Thomas, writing for the majority in *Mensing*, and ridiculed by Justice Sotomayor in her vehement dissent. On the other hand, courts are reluctant to hold a brand-name manufacturer liable when it had no role in making the drug in question.

Ultimately, the *Weeks* court concluded that "it is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce" where plaintiffs bring "misrepresentation theories based . . . on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated by the generic manufacturer."

RELIEF FOR GENERIC DRUG PLAINTIFFS?

The holding in *Weeks* remains the minority view, significantly outnumbered by the "traditional' products liability theory represented by *Foster*. However, *Weeks* is now the law of Alabama and constitutes binding precedent for any pharmaceutical product liability cases filed there. The possibility remains that more states will follow. Plaintiffs could potentially reap enormous benefits from this holding, particularly in situations involving multiple manufacturers where product identification has historically caused plaintiffs problems.

In California, where *Conte* remains the highest state court opinion on the issue, brand-name manufacturers can assert a number of *Rowland* factors to override foreseeability, the factor given the greatest weight by the *Conte* court. *See Rowland v. Christian*, 69 Cal. 2d 108, 113 (Cal. 1968). Other factors not considered in depth in *Conte* include the "moral blame" associated with defendant's conduct, burden to defendant, consequences to the community, and the availability and cost of insurance, all of which favor dismissal of the brand-name manufacturer.

Still, under *Conte* and *Weeks*, plaintiffs can survive a motion to dismiss and seek to hold the brand-name manufacturer liable for failure to warn even where product identification is impossible. This could significantly impact brand-name manufacturers, especially those with small market share who historically enjoyed an exit strategy based on product identification. Because of this there may be more filings against brand-name manufacturers, both in Alabama and nationwide, as plaintiffs try to make *Conte* and *Weeks* the law of every state.

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