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Sweet Home No More, Innovator Liability Leaves Alabama

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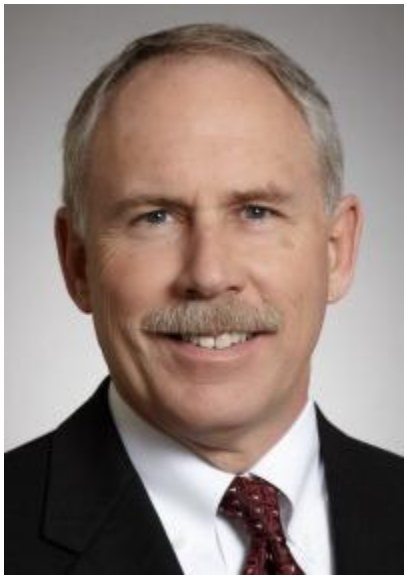

James W. Huston

On May 1, 2015, Alabama Gov. Robert Bentley signed into law a bill to "provide that a manufacturer is not liable ... for damages resulting from a product it did not design, manufacture, sell, or lease." Sponsored by state Sen. Cam Ward, the bill supersedes the Alabama Supreme Court's controversial holding in Wyeth Inc. v. Weeks, 159 So.3d 649 (2014).[1]

Backdrop of Weeks

The Weeks case was originally decided by the Alabama Supreme Court in January 2013, in response to a certified question from a federal district court. Danny and Vicki Weeks had filed suit in federal district court, alleging injury from long-term use of metoclopramide, the generic form of Reglan. In addition to suing two brand-name manufacturers, the Weeks sued two brand-name manufacturers even though they never alleged Danny Weeks ingested the brand-name drug. Instead, they sued 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. This theory is founded on the premise that the label designed by the brand-name manufacturer is the one health care practitioners would rely on in prescribing the drug, regardless of whether the brand-name or generic was prescribed.

To resolve this question in light of conflicting precedent, the district court certified the question to the Supreme Court of Alabama:

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. Wyeth Inc. v. Weeks, No. 1101397 (Ala. Jan. 11, 2013), reargument granted (June 13, 2013), opinion

withdrawn and superseded, 159 So. 3d 649 (Ala. 2014); cf. Conte v. Wyeth, 168 Cal. App. 4th 89 (2008); Kellogg v. Wyeth, 612 F. Supp. 2d 421 (D. Vt. 2008).

Weeks II Affirmed Innovator Liability

The Alabama Supreme Court agreed to reconsider, en banc, its original Weeks opinion, which had been issued on the papers. But even with the benefit of oral argument in September 2013, the court affirmed its original holding. In doing so, it highlighted Alabama law regarding misrepresentation and "the fact that two parties have had no contractual relationship or other dealings does not preclude the finding of a legal duty not to make a material misrepresentation or to suppress a material fact." The majority concluded its opinion by reiterating that the fraud or misrepresentation claim at issue in Weeks premised liability not on "a defect in the product itself but as a result of statements made by the brand-name manufacturer that Congress, through the [U.S. Food and Drug Administration], has mandated be the same on the generic version of the brand-name drug."

Weeks Set Alabama Apart

Weeks represented the only instance in which a state supreme court held that a brand-name drug manufacturer, or innovator, could be liable for injuries caused by a generic version of the drug that the innovator did not manufacture because of the innovator's primary labeling responsibilities. By so holding, the court set itself apart from the vast majority of jurisdictions, which have rejected innovator liability.

Alabama Legislature Reacts Swiftly

Less than one year after Weeks II was decided, the Alabama Legislature took matters into its own hands. On April 29, 2015, the Alabama Senate passed S.B. 80, which had been previously passed by the House (H.B. 110). The new bill attempts to abolish innovator liability. It also squarely places Alabama with the majority of jurisdictions, which is where many believed the state would fall when the Weeks question was first certified.

The text of the new bill reads as follows:

In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product. Designers, manufacturers, sellers, or lessors of products not identified as having been used, ingested, or encountered by an allegedly injured party may not be held liable for any alleged injury. A person, firm, corporation, association, partnership, or other legal or business entity whose design is copied or otherwise used by a manufacturer without the designer's express authorization is not subject to liability for personal injury, death, or property damage caused by the manufacturer's product, even if use of the design is foreseeable.

The new law thus limits liability to entities in the chain of commerce for the product that allegedly caused injury. Under this new statutory regime, the brand-name manufacturers in Weeks would likely have succeeded in moving to dismiss the plaintiffs' claims.

While the new legislation is welcome news for brand-name drug companies that might have otherwise faced liability for failure to warn regarding generic drugs, unfortunately it does not help companies currently defending such claims. The bill doesn't go into effect for six months and has no language that it can be applied retroactively.

The pharmaceutical industry will find this bill helpful in reducing liability exposure where the innovator drug company had no role in manufacturing the drug that caused the underlying injury. This strong action by the Alabama Legislature will also cut off a growing area of generic drug litigation, closing the door on one of the few viable causes of action for plaintiffs alleging injury from generic drugs. Plaintiffs' counsel have been exploring new theories of liability since the U.S. Supreme Court's landmark decision in PLIVA Inc. v. Mensing, 131 S. Ct. 2567 (2011), which completely changed the generic litigation landscape. There, the Supreme Court held that failure-to-warn claims against generic drug companies were preempted because it was impossible for generic drug companies to independently change their labels.

Three other states — California, Illinois and Vermont[2] — have had state or federal courts hold that innovator liability for generic cases is a viable cause of action. It is unlikely that any of these states' legislatures will follow Alabama's lead in passing similar legislation. For now, brand-name drug companies can take comfort in the Alabama Legislature's quick and decisive reaction to fix what many viewed as the wrong result in Weeks.

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[1] For our previous commentary on Weeks, see "Weeks II: Innovator Liability Finds a Sweet Home in Alabama," Morrison & Foerster Client Alert (Aug. 20, 2014); and "Weeks Defies Years of Jurisprudence, Allowing Innovator Liability for Generic Drugs," Morrison & Foerster Client Alert (Jan. 16, 2013).

[2] Conte v. Wyeth Inc., 168 Cal. App. 4th 89 (2008; Dolin v. SmithKline Beecham Corp., No. 12 C 6403 (N.D. Ill. Feb. 28, 2014); Kellogg v. Wyeth Inc., 762 F. Supp. 2d 694 (D. Vt. 2010).
