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Another Step Toward Reasonable Preemption Case Law

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Law360, New York (April 3, 2017, 1:05 PM EDT) -- Last month, the Sixth Circuit affirmed a complete defense verdict for Abbott Laboratories Inc. which was based in part on branded drug preemption. Rheinfrank v. Abbott Laboratories Inc., Case No. 16-3347, 2017 WL 680349 (6th Cir. Feb. 21, 2017).

This defense decision is another step toward limiting liability for manufacturers that could not prevent these types of claims even if they endeavored to.

Background

Rheinfrank arises out of alleged birth defects from in utero exposure to the anti-epileptic medication Depakote. Between 1988 and 2003, plaintiff Pamela Rheinfrank used a regimen of two antiepileptic drugs, one of them Abbott-manufactured Depakote, to treat her epilepsy.

In late 2003, while still on the antiepileptic medications, she became pregnant with her fifth child. That child was born in July 2004 and allegedly had physical and cognitive developmental disabilities.

The plaintiff sued Abbott individually and on her child's behalf, claiming that her own daily use of Depakote caused her child's development disabilities.

Regulatory History

Depakote was first approved by the U.S. Food and Drug Administration in 1983. In 1988, when the plaintiff first took the drug, the FDA had already designated Depakote a "Pregnancy Category D" drug. This classification is for drugs for which the potential benefits may outweigh the risks if used during pregnancy.[1]

Fast forward to 2003. By this time, Depakote's label included a "Black Box Warning" about risks to developing fetuses. The label warned that antiepilepsy drugs like Depakote "should be administered to women of

childbearing potential only if they are clearly shown to be essential in the management of their seizures."

The black box warning did not mention developmental delays. Between 2005 and 2011, Abbott repeatedly tried to add warnings about fetal development risks. At least twice the FDA denied these requests.

Abbott continued to submit new information, and in October 2011, based on new studies, the FDA finally approved Abbott's CBE ("changes being effected") labeling supplement (submitted in 2009) that added a warning about developmental delay risks for Depakote use during pregnancy.

2013 Lawsuit in Ohio Federal Court

In 2013, the plaintiff sued Abbott, asserting numerous Ohio statutory product liability claims, along with several state common-law claims. Id. at *5.

Abbott argued that its hands were tied with regard to the plaintiff's claims — the FDA's rejection of Abbott's proposed warning concerning developmental delay constituted "clear evidence" (a standard enunciated in Wyeth v. Levine, 555 U.S. 555 (2009)) that the FDA would not have approved such a warning before the conception and birth of the plaintiff's child.

The district court found that federal law preempted the specific claim that Abbott had failed to warn of the risk of developmental delay, but denied summary judgment on a broader failure-to-warn claim because questions of material fact remained.

The plaintiff's pared-down claims — strict liability under Ohio statutory law for failure to warn and failure to conform to representations, and common-law claims for negligent failure to warn and negligent design — were heard over the course of a two-week trial.

The final jury instructions — generally addressing "increased risks of harm to unborn children" rather than the specific developmental delays alleged — indicate that the claims considered by the jury may have been broader than should have been allowed.

Regardless, the jury returned a complete defense verdict for Abbott. The plaintiff's motion for a new trial was denied before she appealed to the Sixth Circuit Court of Appeals.

Appeal to the Sixth Circuit

The plaintiff appealed the jury verdict and the district court's determination that the failure-to-warn claim — to the extent it was based on failure to warn of the risk of developmental delays — was preempted.

Concerning the verdict, the plaintiff argued that the district court erred by excluding certain expert testimony and by refusing to provide certain jury instructions. The Sixth Circuit found no merit in these contentions, holding that the district court did not err, and even if it did, such error was harmless.

Of greater interest in this context, the plaintiff argued that the district court improperly granted summary judgment on Abbott's preemption defense because "genuine issues of material fact remained as to whether the FDA would have approved a developmental delay warning prior to [the minor plaintiff]'s suffering the injuries she did in utero." Id. at *13.

The Sixth Circuit did not agree. "Because the FDA twice refused Abbott's attempts to strengthen Depakote's

label, based on its own review of the evidence that the drug adversely affected the development of children exposed to it in utero, [the plaintiff]'s failure-to-warn claim is preempted by federal drug labeling law." Id.

The court noted that Abbott's evidence of the FDA's refusal to allow label changes was "precisely [the] kind of evidence" required to satisfy the "clear-evidence standard." Id. at *14. It further reasoned that documented FDA rejections of proposed label changes in 2005 and 2008 proved that "the FDA did not believe the state of the data supported a developmental delay warning," and stated that "it stands to reason that as of 2003, with even less data to go on, the FDA would similarly have rejected a developmental delay warning — even as a CBE." Id.

Accordingly, it would have "been impossible for Abbott, prior to [the minor plaintiff]'s injury in 2003-2004, to comply with Ohio's product liability law to provide warnings about developmental delay while respecting the FDA's apparent unwillingness — and their authority not — to accept them." Id.

The plaintiff argued that the FDA rejections Abbott cited were "too informal to be binding." Citing the FDA's email response to Abbott's 2005 label-strengthening request, the plaintiff contended this was too little and too "fleeting" to constitute clear evidence that the FDA would have rejected a proposed label change in 2003.

Again, the Sixth Circuit disagreed: "the Court in Wyeth did not say that for evidence to be clear it must result from a formal procedure of approval or disapproval." Id. Accordingly, the court concluded that the clear evidence standard was satisfied by "the kind of informal communications from FDA higher-ups that Abbott provided." Id.

The Sixth Circuit further debunked the plaintiff's "too fleeting" argument, noting that "considerable evidence in the record showed that Abbott followed up on new data surrounding developmental delay and Depakote, that Abbott contacted the FDA multiple times to propose modifications to reflect that data, and that each time officials from the FDA unit responsible for reviewing these modifications unequivocally stated that they were inappropriate at the time." Id.

Additionally, the plaintiff claimed that Abbott either misrepresented the state of the evidence in its communications with the FDA or should have known but failed to obtain additional relevant evidence. This, according to the plaintiff, should preclude a clear-evidence finding on the FDA's decision not to approve a label change.

The Sixth Circuit rejected this argument, too. The FDA undertook its own review of relevant empirical literature apart from what Abbott provided before clearly determining that the proposed warning was not yet warranted. Id. at *15.

Finally, the plaintiff argued that Abbott should have performed additional tests or undertaken more studies related to developmental delay and Depakote use. The court summarily rejected this final argument as "too conjectural to defeat preemption." Id.

Quoting Mensing, the Sixth Circuit stated that "speculation as to what 'a third party or the Federal Government might do' that would make 'it lawful for a private party to accomplish under federal law what state law requires of it' cannot thwart a claim of preemption." Id. Evidence of that kind, the court held, would make most conflicts between state and federal law illusory, rendering conflict preemption "all but meaningless." Id.

Shifting Jurisprudence

The Rheinfrank decision represents a step in the right direction in preemption jurisprudence. While preemption in branded pharmaceutical cases is not yet par for the course, these types of cases are no longer outliers.

However, any optimism for branded drug manufacturers should be tempered with caution — preemption decisions are case-specific and have generally been limited to situations involving a robust regulatory history evidencing FDA rejection(s) of the exact warning plaintiff alleges was missing.

Even so, this decision should be applauded and viewed as progress for manufacturers facing failure-to-warn claims — claims that the manufacturer could not have remedied even if it wanted to.

—By Erin Bosman, Julie Park and Austin Marsh, Morrison & Foerster LLP

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[1] In 2015, the FDA replaced pregnancy risk letter categories with a new labeling system. See FDA/CDER SBIA Chronicles, Drugs in Pregnancy and Lactation: Improved Benefit-Risk Information, Jan. 22, 2015, available at https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/SmallBusinessAssistance/UCM431132.pdf.
