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An FDA Petition Denial Preempts A Failure-To-Warn Claim

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Law360, New York (August 1, 2017, 12:30 PM EDT) -- The Tenth Circuit recently upheld a Utah district court's finding that a branded drug manufacturer could not be held liable for failing to warn consumers about alleged birth defect risks when the U.S. Food and Drug Administration had previously rejected a citizen's petition calling for the same warnings. Cerveny v. Aventis Inc., No. 16-4050 (10th Cir. May 2, 2017).

Factual Background

Plaintiffs (mother, father and their child) alleged that the fertility drug Clomid led to the child's birth defects due to the mother's use of the drug before becoming pregnant. They sued under Utah tort claims, including failure to warn, breach of implied warranty, negligent misrepresentation and fraud.

Relying on the doctrine of impossibility preemption, the district court granted the defendant's motion for summary judgment, holding that, because the FDA "would not have approved the drug warnings that the Cervenys allege are required under Utah law," it was impossible for Aventis to comply with both FDA regulations and state law.

On appeal, the plaintiffs relied on a 1987 proposed FDA warning that "Clomid may cause fetal harm when administered to pregnant women." Although Aventis did not adopt the FDA's proposed warning, and even though it only applied to those who took the drug while pregnant (unlike the plaintiff in this case), the Cervenys contended that (1) the proposed warning demonstrated the FDA's willingness to approve warnings for women taking Clomid before becoming pregnant, and (2) Ms. Cerveny would not have taken Clomid before her pregnancy if Aventis had used the proposed warning.

Impossibility Preemption

The Cerveny court began with a discussion of basic preemption principles.

The court explained that federal law will preempt a state law when (1) the

language of the federal law reveals an express congressional intent to preempt state law (express preemption); (2) federal regulation is so all-encompassing that Congress must have intended to leave no room for a state to supplement it (field preemption); or (3) compliance with both the federal and state laws is a physical impossibility (conflict preemption). When a state's regulations for drug labels conflict with the FDA's, preemption issues arise.

Impossibility preemption is at play when state law is preempted because compliance with both the federal and state laws is a physical impossibility — the laws are inapposite such that complying with state law necessarily results in a violation of federal law. In Cerveny, Aventis made that very argument: it only needed to comply with the FDA regulations and not Utah state law because complying with both would be impossible.

In Wyeth v. Levine, 555 U.S. 555 (2009), the U.S. Supreme Court established a loose framework for determining when federal law could preempt state law failure-to-warn claims against branded drug manufacturers. Specifically, the defendant must present "clear evidence" that the FDA would have rejected the desired label change in order to preempt a state law failure-to-warn claim. Id. at 571.

Wyeth did not define "clear evidence," but instead left the question to the lower courts. A recent Third Circuit case interpreted Wyeth's not-so-clear "clear evidence" language. According to In re Fosamax Alendronate Sodium Prods. Liab. Litig., 852 F.3d 268, 285 (3rd Cir. 2017), the phrase "clear evidence" sets forth a standard of proof synonymous with "clear and convincing evidence" and involves a question of fact rather than a question of law.

In order to preempt the state law failure-to-warn claim, a manufacturer needs to convince a factfinder that it was "highly probable" that the FDA would not have approved a change to the drug's label. The Cerveny court adopted this interpretation.

The Court's "Clear Evidence" Analysis

As clear evidence that the FDA would not have approved plaintiffs' suggested warnings, Aventis pointed to (1) the FDA's history of approving Clomid for use by women before becoming pregnant, and (2) the FDA's rejection of a citizen's petition.

Although the court determined that Clomid's regulatory history did not, in and of itself, constitute clear evidence, the FDA's rejection of a citizen's petition did provide the requisite evidence. In 2007, a citizen petition was filed demanding stronger Clomid warnings regarding the potential risks of fetal harm when a woman takes Clomid prior to becoming pregnant.

The FDA first denied the petition in 2009 and in 2012 declined to reconsider its original denial, reasoning that the original denial had "appropriately applied the standards in the [Federal Food, Drug, and Cosmetic Act] and FDA regulations regarding drug safety, warnings, and potential safety hazards."

The standard used by the FDA in rejecting the citizen's petition was the same standard the FDA would have applied in evaluating a proposed label change to Clomid. Because the FDA concluded in evaluating the citizen's petition that the requested additional warnings were unjustified as to risks related to taking Clomid prior to pregnancy, the court determined that, had Aventis sought FDA approval to include stronger pre-pregnancy warnings, the FDA would have denied the request, just as it did the citizen's petition.

The plaintiffs argued that when the FDA considers proposed label changes, it treats manufacturers more favorably than citizen's petitions, which "leads the FDA to accord greater deference to changes proposed" by manufacturers than those proposed in citizen petitions. In rejecting this argument, the court explained that the FDA standard for revising a warning label "does not discriminate" between proposals submitted by manufacturers and proposals submitted by citizens.

The Cervenys attempted to use the 1987 FDA proposed label change regarding use during pregnancy to argue that Ms. Cerveny would not have taken Clomid prior to becoming pregnant if Aventis had adopted the 1987 proposed label. They argued that the proposed label would have warned women more directly about the potential harm to a fetus when a woman takes Clomid during pregnancy.

The district court agreed with Aventis that, even if Aventis accepted the proposed label change, Ms. Cerveny took Clomid prior to her pregnancy and therefore the label would not have applied to her. Under Utah law, a plaintiff cannot allege as a defect in a label a warning that would not have applied to her.

Aventis moved for summary judgment based solely on preemption. While the Cervenys urged the district court to ignore Aventis's state-law argument, the district court granted Aventis' motion for summary judgment without explaining why or how a state law defense fell within the scope of the motion that was based solely on preemption.

The appellate court remanded the issue because the district court did not "consider whether it could rest on [state] law when deciding a summary judgment motion that had relied solely on federal preemption." This leaves open the possibility that this claim could similarly be rejected based on federal preemption at the district court level.

Looking Forward

This ruling clarifies a defendant's burden of proof in establishing a preemption defense. It establishes that the FDA's denial of a sufficiently similar citizen's petition satisfies the clear-evidence standard required to successfully preempt a failure-to-warn claim. Therefore, branded drug manufacturers have an additional evidentiary tool even when no other form of FDA decision-making exists to demonstrate that the FDA would have rejected a label change.

Ultimately, if other circuits follow the Tenth Circuit's lead, pharmaceutical companies may no longer need to demonstrate an attempt to provide the kind of warning allegedly required under state law. We anticipate that going forward parties will disagree on the issue of how similar a citizen's petition needs to be in order to have this preemptive effect. Identical? Virtually identical? Substantially similar?

In Cerveny, the Tenth Circuit acknowledged that the citizen's petition was "virtually identical" to the warnings the Cerveny's advocated; however, we anticipate that courts may still find a preemptive effect when a citizen's petition is substantially similar to proposed warnings. So long as the substance of the proposed warning is the same, as well as its effect on the consuming public, it is unlikely that a decision will turn on semantics.

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