Products Liability Law Daily Wrap Up, PREEMPTION—DRUGS—10th Cir.: State failure to warn claims not pre-empted where FDA had proposed same warnings, (May 3, 2017)

Products Liability Law Daily Wrap Up

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By Jeffrey H. Brochin, J.D.

In a husband and wife's product liability lawsuit against the manufacturer of the prescription infertility drug Clomid, the federal trial court in Utah erred in granting summary judgment favoring the drug maker based on federal preemption and an impossibility of compliance with both federal and state law where the U.S Food and Drug Administration previously had proposed the same warning regarding use of that drug during pregnancy, a federal appellate panel ruled. The trial court did not explain why a state law claim based on FDA's own proposed language would be preempted by federal law, the panel observed, adding that clear evidence established that the agency would not have approved of the plaintiffs' desired warnings regarding the pre-pregnancy use of the drug. As such, the panel reversed the lower court's ruling on the couple's failure to warn claims but upheld the preemption finding on their theory that the drug maker had a duty to warn of the risks of using the drug prior to pregnancy because the evidence showed that FDA would not have approved a warning about taking the drug before pregnancy (*Cerveny v. Aventis, Inc.*, May 2, 2017, *per curiam*).

Over twenty years ago the wife gave birth to a son with birth defects after having used (in 1992) the infertility drug, Clomid, manufactured by Aventis, Inc., prior to becoming pregnant. She and her husband sued Aventis asserting various state tort claims under Utah law, including failure to warn under theories of strict liability and negligence, breach of implied warranty, negligent misrepresentation, and fraud. The district court granted summary judgment to Aventis based on federal preemption, reasoning that the FDA would not have approved the drug warnings that the parents alleged were required under Utah law [see *Products Liability Law Daily*'s March 17, 2016 analysis]. The district court concluded that Aventis could not have complied with both federal and state law. Summary judgment was granted as to all claims, and the parents appealed.

Two failure to warn theories. The parents presented two theories pointing to two types of warning labels that Aventis had allegedly failed to provide: (1) a label that warned of risks to the fetus when a woman takes Clomid before becoming pregnant, and (2) a label that unmistakably warned about harm to the fetus when Clomid is taken during pregnancy. For both theories, they cited a warning that the FDA proposed in 1987, which stated that "Clomid may cause fetal harm when administered to pregnant women." For their first theory, they argued that this proposed warning demonstrated the FDA's willingness to approve warnings for women taking Clomid prior to pregnancy. For their second theory, they argued that (1) the warning clearly informed women of risks to the fetus if taken during pregnancy and (2) the mother would not have taken Clomid if Aventis had used the FDA's proposed wording. The district court rejected the claims based on preemption.

Tenth Circuit holding. The appeals court ruled that the district court's ruling of preemption was correct as to the first theory, because the undisputed evidence showed that the FDA would not have approved a warning about taking Clomid before pregnancy. As to the second theory, however, the Tenth Circuit found that the district court did not explain why a state claim based on the FDA's own proposed language would be preempted by federal law.

Clomid's regulatory history. The FDA requires brand-name manufacturers to obtain approval of their proposed drug labeling, and if the drug application is approved, the manufacturer is generally restricted from changing the label without advance permission from the FDA. Since Clomid entered the market in 1967, its labels have consistently warned about the risk of fetal harm if the mother takes Clomid while pregnant. However, in 1986, the FDA ordered Aventis to add a "Pregnancy Category X" designation to the label which would indicate that "the

risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit." The FDA recommended this designation on the ground that Clomid does not benefit pregnant women and that any risk to pregnant women would be unjustified. Aventis resisted the change, and the FDA acknowledged a dilemma: Aventis needed to warn about taking Clomid during pregnancy, but no woman who was already pregnant would have any reason to take Clomid. In light of this dilemma, the FDA suggested in 1987 that Aventis change the label to include the warning: "Since there is a reasonable likelihood of the patient becoming pregnant while receiving Clomid, the patient should be apprised of the potential hazard to the fetus." Aventis eventually added a similar warning, but only after the mother in the current case gave birth to her son with birth defects.

Three types of preemption. The court noted that there are three types of preemption: (1) express preemption, which occurs when the language of the federal statute reveals an express congressional intent to preempt state law; (2) field preemption, which occurs when the federal scheme of regulation is so pervasive that Congress must have intended to leave no room for a State to supplement it; and (3) conflict preemption, which occurs either when compliance with both the federal and state laws is a physical impossibility, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.

Aventis contended that a form of conflict preemption known as impossibility preemption applied because compliance with both the federal and state laws was a physical impossibility.

Preemption and the clear evidence standard. Although the parents argued that their state law claim as to labeling was not preempted, the court noted that a state tort claim was indeed preempted if a manufacturer presents clear evidence that the FDA would have rejected an effort to strengthen a label's warning, and the court applied the "clear evidence" test to the instant case. It is a question of fact as to whether the clear evidence test has been satisfied, and the court ruled that a state-law failure-to-warn claim will be preempted only if a finder of fact concludes that it is highly probable that the FDA would not have approved a label change. The court then considered the issues of: (1) whether Aventis presented clear evidence that the FDA would have disapproved of the warnings suggested by the parents, and (2) whether a reasonable juror could conclude that the FDA would have approved those warnings.

Regulatory history alone not determinative. The FDA's approval of Clomid's labels suggested only that the FDA knew about potential issues involving pre-pregnancy use of Clomid—not that the FDA would have rejected a stronger warning if one had been proposed. As a result, the court found that Clomid's regulatory history alone did not constitute clear evidence that the FDA would have rejected the warnings desired by the parents. The court looked outside of that history and considered the impact of a citizen's petition.

Consideration of a citizen's petition as clear evidence. Aventis pointed to the FDA's rejection of a citizen's petition as meeting the clear evidence standard. In his citizen's petition, a petitioner to the FDA presented arguments virtually identical to that of the parents, including that taking Clomid prior to pregnancy risks fetal harm because (1) Clomid has a long half-life and is still biologically active well into the second month of pregnancy when most organs are being formed and can accumulate with multiple courses of treatment, and (2) Clomid inhibits cholesterol, which may endanger the developing fetus. Accordingly, the petitioner urged stronger warnings for Clomid.

In 2009, the FDA denied the citizen's petition, and Aventis argued that the denial constituted their sought-after clear evidence that the FDA would not have approved of a warning in 1992 about the risks of taking Clomid prior to pregnancy. The parents noted a high rate of FDA denials for such petitions as reason to reject Aventis' contention; however, the court concluded that the FDA's denial of the citizen's petition constituted clear evidence that the FDA would not have approved the parents' desired warning of the risks of taking Clomid prior to pregnancy.

Reversal and remand. Based on the foregoing, the appellate court reversed the grant of summary judgment to Aventis as to the failure to warn claims, but upheld the ruling as to the parents' theory that Aventis had a duty to warn of the risks of using Clomid prior to pregnancy—the claims based on that theory were in fact preempted by federal law. On remand, the district court was directed to further address the claim based on the failure to use the FDA's own wording on the risk of harm to the fetus when Clomid is taken during pregnancy.

The case is No. 16-4050.

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