Products Liability Law Daily Wrap Up, TOP STORY—SUPREME COURT—U.S.: Merck gets another chance to assert federal preemption of MDL patients' state-law failure-to-warn claims on Fosamax®, (May 20, 2019)

Products Liability Law Daily Wrap Up

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By Georgia D. Koutouzos, J.D.

The "clear evidence" standard governing impossibility preemption—that the drug maker fully informed the U.S. Food and Drug Administration of the justifications for a warning required by state law and that agency responded that it would not approve such a label change—is a question for the judge and not the jury.

In a 9-0 ruling, the U.S. Supreme Court reversed and remanded a federal appeals court's decision that the manufacturer of the osteoporosis drug Fosamax® failed to carry its burden of proving that state-law failure-to-warn claims against the company by a class of patients who had sustained bone fractures while taking the drug were preempted as a matter of law. Noting that the appeals court's decision had been based on the rationale that there was sufficient evidence for a reasonable jury to conclude that the FDA would have approved a properly-worded warning about the risk of thigh-bone fractures related to the drug, the High Court instructed that its previously articulated "clear evidence" standard supporting federal preemption is a matter of law for the judge to decide (*Merck Sharp & Dohme Corp. v. Albrecht*, May 20, 2019, Breyer, S.).

More than 500 individuals who took the prescription bisphosphonate Fosamax for the treatment of postmenopausal osteoporosis and who suffered atypical femoral fractures between 1999 and 2010 sued the drug's manufacturer, Merck Sharp & Dohme Corp., seeking tort damages on the basis that state law imposed upon Merck a legal duty to warn respondents and their doctors about the risk of atypical femoral fractures associated with using Fosamax.

The cases were consolidated as a multidistrict litigation, and Merck argued that the patients' state-law failure-to-warn claims were preempted by federal law. The trial court agreed and granted summary judgment in Merck's favor, but the U.S. Court of Appeals for the Third Circuit reversed the trial court's decision, finding that the drug maker failed to carry its burden of proving that the patients' failure-to-warn claims were preempted as a matter of law [see *Products Liability Law Daily's* March 23, 2017 analysis].

The lower court's decision was based on U.S. Supreme Court precedent in *Wyeth v. Levine*, 555 U.S. 555 (2009), which holds that state-law failure-to-warn claims are preempted when there is "clear evidence" that the FDA would not have approved the warning that a plaintiff claimed was necessary—so-called impossibility preemption. The Third Circuit panel noted that the *Wyeth* "clear evidence" standard is demanding and fact-sensitive, requiring that a factfinder predict a highly probable outcome in a counterfactual world. The panel determined that the patients in the MDL had provided enough evidence for a reasonable jury to conclude that the FDA would have approved a properly-worded warning about the risk of thigh fractures, or, at minimum, to conclude that the odds of FDA rejection were less than highly probable, which was enough under *Wyeth* for the patients to defeat summary judgment and proceed to trial.

In its petition for certiorari from the Third Circuit's decision, Merck queried whether a state-law failure-to-warn claim is preempted when the FDA rejected the drug manufacturer's proposal to warn about the at-issue risk after having been provided with the relevant scientific data or whether such a case must go to a jury for conjecture as to why the FDA rejected the proposed warning. The High Court granted the drug maker's petition on June 28, 2018 [see *Products Liability Law Daily's* June 28, 2018 analysis].

"Clear evidence" is a question of law. While *Wyeth* established that there must be "clear evidence" that the FDA would not have approved a change to the drug's label in order to preempt a state-law claim that a

drug manufacturer failed to warn consumers of the change-related risks associated with using the drug, the preemption question is for a judge to decide, the High Court instructed, elucidating that "clear evidence" is evidence which shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the agency would not approve a change to the drug's label to include that warning.

While the majority elected not to further define "clear evidence" in terms of evidentiary standards, it explained that courts should treat the critical question not as a matter of fact for a jury to decide but as a matter of law for the judge to decide. The question often involves the use of legal skills to determine whether agency disapproval fits facts that are not in dispute. Moreover, judges, rather than lay juries, are better equipped to evaluate the nature and scope of an agency's determination. To understand the question as a legal question for judges makes sense given the fact that judges are normally familiar with principles of administrative law.

Doing so should produce greater uniformity among courts, and greater uniformity is normally a virtue when a question requires a determination concerning the scope and effect of federal agency action. And where that is so, the judge must simply ask himself or herself whether the relevant federal and state laws irreconcilably conflict. In that regard, however, the only agency actions that can determine the answer to the preemption question are agency actions taken pursuant to the FDA's congressionally delegated authority, the majority advised.

In a case like *Wyeth*, showing that federal law prohibited the drug manufacturer from adding a warning that would satisfy state law requires the drug manufacturer to show that it fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve changing the drug's label to include that warning. Because the Third Circuit in the instant case treated the preemption question as one of fact and not of law, its judgment was vacated and remanded for further proceedings.

Justice Thomas concurs. Writing separately to explain his understanding of the relevant preemption principles and how they applied to the case at bar, Justice Thomas said that while the High Court previously has articulated several theories of preemption, Merck's sole argument was that state law was preempted because it was impossible for the company to have complied with both federal and state law. While expressing his skepticism that "physical impossibility" is a proper test for deciding whether a direct conflict exists between federal and state law, Justice Thomas said that Merck's preemption defense failed even under the Court's precedents on impossibility.

The question for impossibility is whether it was lawful under federal law for Merck to do what state law required of it, he said. Noting that the patients here had claimed that state law obligated Merck to add a warning about atypical femur fractures to the Warnings and Precautions section of Fosamax's label, he opined that Merck's impossibility preemption defense failed because it did not identify any federal law that prohibited the company from adding any and all warnings that would satisfy state law. Merck's belief that the FDA eventually would have rejected a "changes being effected" (CBE) application did not make an earlier CBE change impossible. Therefore, because Merck pointed to no statute, regulation, or other agency action with the force of law that would have prohibited it from complying with its alleged state-law duties, its preemption defense should fail as a matter of law, Justice Thomas said.

Further concerns. Concurring in the judgment only, Justice Alito (joined by Chief Justice Roberts and Justice Kavanaugh) expressed concern that the majority opinion's discussion of the law and the facts might be misleading on remand. While the majority correctly noted that a drug manufacturer can prove impossibility preemption by showing that federal law (including appropriate FDA actions) prohibited the company from adding any and all warnings to the drug label that would satisfy state law, the majority opinion provided a "skewed summary" in expounding further on the preemption analysis.

Dwelling on the *Wyeth* decision, the majority barely noted a statutory provision enacted after the underlying events in that case that could have an important bearing on the ultimate preemption analysis in the case at bar, Justice Alito determined. In 2007, Congress imposed on the FDA a duty to initiate a label change "[i]f

the Secretary becomes aware of new information, including any new safety information … that the Secretary determines should be included in the labeling of the drug." Although the new provision does not relieve drug manufacturers of their own responsibility to maintain their drug labels, the FDA's actions taken pursuant to this duty arguably affect the preemption analysis because, if the agency declines to require a label change despite having received and considered information regarding a new risk, the logical conclusion is that it determined that a label change was unjustified.

The case is No. 17-290.

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Companies: Merck Sharp & Dohme Corp.

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