Sills Cummis & Gross P.C.

Client Alert **Product Liability Law**

Merck Sharp & Dohme Corp. v. Albrecht: The U .S. Supreme Court Weighs In On Preemption

In an eagerly anticipated preemption decision relating to Merck Sharp & Dohme Corp.'s ("Merck") Fosamax medication, the U.S. Supreme Court in *Merck Sharp & Dohme Corp. v. Albrecht*, 2019 U.S. LEXIS 3542 (May 20, 2019), unanimously determined that the issue of whether state law failure to warn claims were preempted by federal law is a question of law to be decided by the court, and not a question of fact to be decided by a jury. In addition, the Court clarified what it meant over ten years ago in *Wyeth v. Levine*, 555 U.S. 555 (2009), by the statement that "absent clear evidence that the FDA would not have approved a change to . . . [the] label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Id*. at 571. The *Albrecht* Court instructed that "clear evidence" was not an evidentiary standard like a "preponderance of the evidence" or "clear and convincing evidence". *Albrecht*, 2019 U.S. LEXIS 3542, at *25-26. Rather, the Court held that "clear evidence" is "evidence that 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 FDA would not approve a change to the drug's label to include that warning." *Id*. at *7.

The Court did not determine whether plaintiffs' state failure-to-warn claims were preempted as a matter of law and remanded to the Third Circuit for further proceedings. It remains to be seen whether Merck will prevail on its preemption defense, but drug manufacturers should be encouraged that courts, not juries, will

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resolve preemption motions in the future, and that the Court defined what it meant by "clear evidence" in *Wyeth v. Levine*.

Background

Fosamax is an FDA approved medicine prescribed to treat and prevent osteoporosis in postmenopausal women. Fosamax affects the bone remodeling process by slowing down the breakdown of old bone cells and helping postmenopausal women avoid osteoporotic fractures. *Id*. at *10. Fosamax, however, may increase the risk of atypical femoral fractures because it may cause certain stress factors, that typically heal on their own, to progress to complete fractures. *Id*. at *11.

At the time of Fosamax's approval in 1995, the label did not warn of the risk of atypical femoral fractures even though Merck was aware of the "theoretical risk" of such fractures as early as 1990 and 1991. *Id*. at *11. Merck informed the FDA about these theoretical risks, but the FDA did not require them to be mentioned in the approved Fosamax label. *Id*. at *11-12.

After receiving evidence connecting atypical femoral fractures with long term Fosamax use, Merck attempted to update the Fosamax label by submitting a Prior Approval Supplement ("PAS") to the FDA in 2008. *Id*. at *12-13. A PAS requires FDA approval before the label changes can be made. *Id*.; *see* 21 C.F.R. §314.70(b). Merck proposed to add information related to "low-energy femoral shaft fracture" in the Adverse Reactions section and additional information in the Precautions section focusing on the association between Fosamax and the risk of stress fractures. *Id*. at *13. The FDA approved the Adverse Reactions section changes, but determined that Merck's justification for changing the Precautions section was "inadequate." *Id*. FDA informed Merck that it could resubmit the PAS and address FDA's concerns. *Id*. Instead of resubmitting its PAS and addressing the issues identified by the FDA, Merck withdrew its application and made changes to the Adverse Reactions section through the Changes Being Effected ("CBE") process, which permits a label change without FDA approval where there is "newly acquired information" about the "evidence of a causal association" that will "add or strengthen a . . . warning". *Id*. at *9-10, *13; *see* 21 C.F.R. §314.70(c)(6)(iii)(A).

Fosamax Litigation

Respondents include more than 500 women who alleged that Merck failed to warn about the risk of atypical femoral fractures between 1999 and 2010. *Albrecht,* 2019 U.S. LEXIS 3542, at *14. While Merck conceded that it could have tried to change the

label before 2010 to add such a warning, Merck argued before the U.S. District Court of New Jersey that the FDA would have rejected the change and that because federal law prevented it from complying with any state-law duty to warn of the association between Fosamax and atypical femoral fractures, respondents claims were preempted. *Id*. at *15-16. In particular, Merck argued that the FDA's rejection of its 2008 PAS to the Fosamax label to warn of "stress fractures" prevented Merck from complying with any state law duty to warn of atypical femoral fractures associated with Fosamax. *Id*. at 16. The District Court agreed and granted Merck summary judgment. *Id*.

The Third Circuit vacated and remanded. *Id*. The Third Circuit explained that under *Wyeth v. Levine*, a state law failure to warn claim would only be pre-empted if there was "clear evidence that the FDA would not have approved a change to the . . . label." *Id*. (quoting *Wyeth v. Levine*, 555 U.S. at 571). Noting that lower courts had interpreted this language differently and that it would be helpful for the U.S. Supreme Court to clarify what it meant, the Third Circuit determined that "[t]he term 'clear evidence' . . . does not refer directly to the type of facts that a manufacturer must show, or to the circumstances in which preemption will be appropriate", but "[i]t specifies how difficult it will be for the manufacturer to convince the factfinder that the FDA would have rejected a proposed label change." *Id*. at *16-17 (quoting *In re Fosamax Alendronate Sodium Prods. Liab. Litig.*, 852 F.3d 268, 285-86 (3d Cir. 2017)). The Third Circuit further held that "whether the FDA would have rejected a proposed label change is a question of fact that must be answered by a jury.'" *Id*. at *17 (quoting *In re Fosamax Alendronate Sodium Prods. Liab. Litig.*, 852 F.3d at 286).

Preemption Determinations Are Matters Of Law For the Court To Decide

The U.S. Supreme Court described the "determinative question" before the Court as follows: "Is the question of agency disapproval [FDA rejection of the proposed label] primarily one of fact, normally for juries to decide, or is it a question of law, normally for a judge to decide without a jury?" *Id*. at *27. In holding that this was a question of law, the Court stated:

> 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. Judges are experienced in "[t]he construction of written instruments," such as those normally produced by a federal agency to memorialize its considered judgments. And judges are better suited than are juries to understand and to interpret agency decisions in

> light of the governing statutory and regulatory context. 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.

Id. at *27-28 (citations omitted). Moreover, the Court held that any factual disputes relevant to the judges' determination of this legal issue were "subsumed" in the judge's legal analysis, and not to be submitted to a jury. *Id*. at *29.

Unanswered Questions in *Wyeth v. Levine*

In *Wyeth v. Levine*, the Court held that state law failure-to-warn claims were pre-empted by federal law and regulations "when there is 'clear evidence' that the FDA would not have approved the warning that state law requires." *Id*. at *18 (citing *Wyeth v. Levine*, 555 U.S. at 571). Plaintiff in *Wyeth* developed gangrene after a physician's assistant improperly injected her with Penergan, an anti-nausea medication. *Id*. Plaintiff alleged that Wyeth failed to warn of the significant risk of catastrophic consequences if Phenergan was directly injected into a person's vein ("IV-push"), which risks could be avoided by administering the medication through a saline solution intravenous drip method ("IV-drip"). *Id*. at *19. After a jury determined that Wyeth's warning label was inadequate as a matter of state law, Wyeth appealed and argued that the plaintiff's state law failure-to-warn claim was pre-empted "because it was impossible for Wyeth to comply with both state law duties and federal labeling obligations." *Id*.

Both the Vermont Supreme Court and the U.S. Supreme Court rejected Wyeth's pre-emption argument. In particular, the Court determined that Wyeth had a duty under state law to update its label and provide an adequate warning while the drug was on the market, and that the federal CBE process permitted Wyeth to provide such a warning before FDA approval. *Id*. at *21-22. In so holding, the *Wyeth* Court had noted that "the FDA retains authority to reject labeling changes pursuant to the CBE regulation in its review of the manufacturer's supplemental application, just as it retains such authority in reviewing all supplement applications." *Id*. at *22 (quoting *Wyeth v. Levine*, 555 U.S. at 571). But without defining what it meant, the *Wyeth* Court also noted that "absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements." *Id*.

In rejecting Wyeth's pre-emption defense, the *Wyeth* Court determined that the record did not show that Wyeth "supplied the FDA with an evaluation or analysis concerning the specific dangers" to support the warning or that "either the FDA or the manufacturer gave more than passing attention to the issue of IV-push versus IV-drip administration." *Id*. at *22-23 (citing *Wyeth v. Levine*, 555 U.S. at 572-73). As a result, the *Wyeth* Court could not conclude that it "was impossible for Wyeth to comply with both federal and state requirements." *Id*. at *23 (quoting *Wyeth v. Levine*, 555 U.S. at 573).

Meaning of "Clear Evidence" Clarified

The *Albrecht* Court clarified that "clear evidence" was not, as some courts had postulated, an evidentiary standard, such as "preponderance of the evidence" or "clear and convincing evidence". *Id*. at *25. The Court instructed that when faced with preemption defenses, the trial court must determine whether there is "evidence that shows . . . 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 FDA would not approve a change to the drug's label to include that warning." *Id*. at *7.

Further, the Court noted that only agency actions within the FDA's congressionally delegated authority can be used to determine whether federal law prohibited a manufacturer from adding warnings to comply with state law. *Id*. at *26. These include: 1) FDA communicating its disapproval of a warning through a "notice-and-comment rulemaking setting forth labeling standards"; 2) "by [FDA] formally rejecting a warning that would have been adequate under state law"; or 3) "with other agency action carrying the force of law." *Id*. at *26-27 (citing 21 U.S.C. §355(d), 21 C.F.R. §§201.57, 314.105; 21 C.F.R. §§314.110(a), 314.125(b)(6); 21 U.S.C. §§355(o)(4)(A)).

Concurring Opinion: Justice Thomas

Justice Thomas wrote separately to explain that in his view, Merck's preemption defense should fail as a matter of law because Merck failed to identify any federal law or FDA disapproval prohibiting it from adding a warning that would satisfy state law. *Id*. at *34-35. Justice Thomas rejected Merck's argument that the FDA would have rejected a CBE labeling change because "neither agency musings nor hypothetical future rejections constitute pre-emptive 'Laws" under the Supremacy Clause." *Id*. Justice Thomas noted that Merck acknowledged that "it could have resubmitted its PAS application, sought a hearing, or changed its label at any time through the CBE process." *Id*. at *36. If Merck had re-submitted its PAS application, sought a hearing, or utilized the CBE process, in Justice Thomas's view, "it could have satisfied its federal and alleged state-law duties – meaning it was possible for Merck to independently satisfy both sets of duties." *Id*. at *37.

Concurring Opinion: Justice Alito

Justice Alito, joined by Chief Justice Roberts and Justice Kavanaugh, concurred in the judgment but did not join the Court's opinion "because [he was] concerned that its discussion of the law and the facts may be misleading on remand." *Id*. at *38. In particular, Justice Alito took issue with the Court's failure to address the following issues: 1) Under 21 U.S.C. §355(o)(4)(A), Congress imposed on the FDA a duty to initiate a label change where justified, which FDA did not do here until 2010; 2) despite receiving and considering information related to a new risk, FDA decided not to impose a label change, which demonstrates that FDA had determined that a label change was not justified; and 3) although a manufacturer may change a label through the CBE process, as Merck did here, a manufacturer "may (and, in many circumstances, must) submit a Prior Approval Supplement", which requires FDA approval, "where significant questions exist on whether to revise or how to modify existing drug labeling." *Id*. at *38-41.

Justice Alito also took exception with the Court's omission of balancing facts that demonstrated that Merck and the FDA had "extensive communications" during the relevant time period, which support the position that the "FDA's decision not to require a label change prior to October 2010 reflected the FDA's 'determin[ation]' that a new warning 'should [not] be included in the labeling of the drug." *Id*. at *45. (citations omitted). Justice Alito explained that while the FDA was considering Merck's 2008 proposed label changes, Merck and the FDA continued discussing the issue. *Id*. at *42-43. Indeed, there were several communications between Merck and the FDA, in which FDA expressed the need for more time to analyze the data and determine whether a precaution was warranted. *Id*. at *43. Justice Alito noted that several months after rejecting Merck's labeling proposal, FDA issued a Safety Announcement concerning its safety review of this class of drugs (bisphosphonates) and atypical femoral fractures, and its plan to further study the issue along with a task force. *Id*. The FDA also announced that the data at that time did not show a "clear connection" to the risk of atypical femoral fractures, and that healthcare professionals should continue to follow the current label. *Id*. The task force published its report in September 2010, and concluded that the risk of atypical femoral fractures rose with long term use of bisphosphonates even though a causal association had not been established. *Id*. at *44. In response, the FDA issued a statement that committed to considering a label change and a month later, in October 2010, issued another Safety Announcement, stating that it would be making changes to the Precautions section of bisphosphonate labels. Shortly thereafter, FDA instructed Merck to include a warning of atypical femoral fractures in the Fosamax label. *Id*.

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Conclusion

The Court's decision is significant, but narrow. On the one hand, the Court made clear that questions of impossibility preemption are questions of law to be decided by judges not juries. The Court also clarified what it mean by "clear evidence" in *Wyeth v. Levine*. On the other hand, the Court did not offer an opinion on whether respondents' claims were pre-empted by federal law. It will be interesting to see how the Third Circuit responds to the Court's ruling. We will continue to monitor this issue as it makes its way through the Third Circuit on remand and will advise of any important updates.

If you would like additional information, please contact:

Beth S. Rose, Esq.
Chair, Product Liability Practice Group
brose@sillscummis.com | (973) 643-5877

Charles J. Falletta, Esq.
Member, Product Liability Practice Group
cfalletta@sillscummis.com | (973) 643-5926