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BLOG

Petition for Certiorari Seeks Clarification of Preemption Analysis in Pharmaceutical Failure-to-Warn Cases

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On June 26, 2020, GlaxoSmithKline LLC (GSK) filed a Petition for Writ of Certiorari regarding "the first—and, to date, only—appellate decision interpreting" the "fully informed" prong of the pharmaceutical preemption analysis in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). Pet. 2.

In *Wyeth v. Levine*, the Supreme Court "held that federal law preempts state-law failure-to-warn claims against a brand-name drug manufacturer only where the manufacturer can provide '**clear evidence** that the FDA would not have approved a change to [the drug's] label' had the manufacturer attempted unilaterally to make one." Pet. 1 (citing *Wyeth*, 555 U.S. 555, 571, 573 (2009)) (emphasis added). The Court then defined the "clear evidence" standard in *Merck* as "evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning [allegedly] 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." Pet. 1 (quoting *Merck*, 139 S. Ct. at 1672).

In its Petition, GSK now challenges the Third Circuit's application of *Merck* in reversing summary judgment granted on preemption grounds in failure-to-warn cases regarding its drug Avandia. Pet. 13-14. GSK argued below that it could show clear evidence that the FDA would not approve a label change. *See* Pet. 13. In August 2006 GSK submitted a Prior Approval Statement (PAS), an avenue by which a manufacturer can request a label change, asking the FDA's permission to add a warning about myocardial ischemia to Avandia's label. Pet. 4, 7. But in June 2007, the FDA rejected the PAS through a "not approvable" letter, explaining that "it was rejecting a myocardial-ischemia warning because 'the information presented is inadequate' to justify it." Pet. 8. The FDA then instructed GSK to provide the agency with additional data, including from ongoing clinical trials. Pet. 9. "In other words, until [ongoing clinical trial] data emerged, the FDA would not approve any changes to Avandia's label." Pet. 10.

According to the Petition, the Third Circuit acknowledged that the information requested by the FDA did not come through until after it issued the not approvable letter, but still "concluded that to rely upon a not approvable letter 'as proof that the FDA rejected its proposed label change, [GSK] must also demonstrate that the FDA possessed all the information it deemed necessary to decide whether to approve or reject the proposed warning *at the time it issued the Letter*.'" Pet. 14. Therefore, given its decision on the fully informed prong, the Third Circuit concluded that "the FDA's not approvable letter could not qualify as a rejection of GSK's proposed warning because the letter—and the record itself—indicated that the warning might become justified in the future, if enough new information later came to light." Pet. 15.

GSK now argues that preemption was entirely appropriate because it "sought to add a stronger cardiovascular warning to Avandia's label and provided to the FDA all the information in its possession that justified the warning and that the FDA regulations instructed it to provide, but the FDA nevertheless rejected the warning as unsupported by that comprehensive body of information." Pet. 16. By contrast, under the Third Circuit's interpretation, "to 'fully inform' the FDA, a manufacturer must provide the FDA with information (1) that did not exist at the time of the FDA's decision or (2) that the FDA regulations instruct manufacturers *not* to provide and which the FDA in fact did not rely on." Pet. 16.

The Supreme Court's treatment of the Petition could, therefore, have a significant impact on the availability of preemption based on the "fully informed" prong in failure-to-warn cases. For any questions, please contact Bryce Cooper, or your Winston relationship attorney.

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