17-290 MERCK SHARP & DOHME CORP. V. ALBRECHT

DECISION BELOW: 852 F.3d 268

LOWER COURT CASE NUMBER: 14-1900

QUESTION PRESENTED:

In *Wyeth v. Levine*, 555 U.S. 555 (2009), this Court held that the FDA's approval of a drug label does not, standing alone, insulate the manufacturer from failure-to-warn liability under state tort law. At the same time, the Court recognized that if "the FDA would not have approved" the label demanded by state law, then the manufacturer could invoke an "impossibility'' preemption defense. *Id*. at 571.

In this case, it was "undisputed" that (i) "the FDA was aware of the possible link" between petitioner's drug and the risk at issue; (ii) petitioner "submitted a comprehensive safety update to the FDA reporting . . . numerous studies" finding "such an association"; (iii) petitioner "proposed warning language" about this risk, but the FDA "rejected" it; (iv) the FDA stated that the "conflicting nature of the literature d[id] not provide a clear path forward" and that it needed "more time" to consider "the issue of a precaution"; and (v) only later, after a report from a task force, did the FDA become "confident" that an association "potentially'' existed. Pet.App.59a-60a.

The Third Circuit nonetheless held that a jury could find that petitioner had not shown by "clear and convincing evidence" that the FDA would have rejected a warning label of the type that respondents claim state law required. See Pet.App.37a, 56a-57a.

The question presented is: Is a state-law failure-to-warn claim preempted when the FDA rejected the drug manufacturer's proposal to warn about the risk after being provided with the relevant scientific data; or must such a case go to a jury for conjecture as to *why* the FDA rejected the proposed warning?

JUSTICE ALITO TOOK NO PART.
October 26, 2018 JUSTICE ALITO IS NO LONGER RECUSED.

CERT. GRANTED 6/28/2018