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Merck, Sharpe & Dohme v. Albrecht: The Supreme Court's Chance to Re-Open a Preemption Door the Third Circuit Tried to Close Forever

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**Ed. Note: This is Mr. Hollingsworth's inaugural post as the WLF Legal Pulse's newest Featured Expert Contributor. He is a nationally renowned courtroom advocate who specializes in trials and appeals and leads a practice group of seventy-five attorneys.*

No one ever said preemption should be easy. But then there's the U.S. Court of Appeals for the Third Circuit's preemption decision last year in *Merck, Sharpe & Dohme v. Albrecht*, 852 F.3d 268 (3d Cir. 2017).

The appellate court found a way to circumvent the fact record before it, directing that a jury must be allowed to "speculate"—the court's word—about how a federal agency might have responded to a hypothetical application by Merck to add to its Fosamax® label a warning about atypical femur fracture (AFF); even though Merck *in fact* had submitted an actual application to the Food and Drug Administration (FDA) to add an AFF label warning, and FDA refused to permit it. The Third Circuit effectively imposed an insurmountable hurdle to pharmaceutical defendants seeking summary judgment on preemption grounds (despite the court's protestations to the contrary).

There is hope. On June 28, 2018, the Supreme Court granted Merck's petition for certiorari to review the Third Circuit's preemption blockade. And the Solicitor General filed a strong *amicus* brief in support of the cert grant.

Fosamax® is in the bisphosphonate class of drugs. Bisphosphonates inhibit bone resorption to correct the imbalance between bone resorption and bone formation that characterizes osteoporosis, common among post-menopausal women and other patients. Bisphosphonates have been the subject of suits by thousands of plaintiffs in three separate MDLs in federal courts in New York, New Jersey, and Tennessee (the latter involving Aredia® and Zometa®, bisphosphonates with life-saving application in treating the effects of cancer that has metastasized to bone), in addition to several state mass tort proceedings in New Jersey and California.

Consider: One month before formally rejecting Merck's proposed AFF warning, FDA told Merck that it wanted to address the question of a warning as a class issue "from the [perspective] of all bisphosphonates;" that "the conflicting nature of the literature does not provide a clear path forward;" and that consequently, "more time will be need[ed] for FDA to formulate a formal opinion on the issue of a [warning] around these data." *Id*. Later that month, FDA asked Merck to "hold

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off on the [warnings] language at this time" to allow FDA to work on warning language, "if it is warranted." *Id*.

Nearly a year later, in a March 2010 Drug Safety Communication, FDA publicly announced that the causation data it had reviewed to date had "not shown a clear connection between bisphosphonate use and a risk of [AFFs]," and that the agency was working with a task force of experts (from the American Society of Bone and Mineral Research (ASBMR)) to gather additional information. *Id*. at 278. Finally, in September 2010, the ASBMR task force issued its report, recommending that a label warning be added to inform the medical community about the potential risk of AFFs, *id*., and the labeling change followed.

Judge Pisano's lower-court ruling that failure-to-warn claims against Merck were preempted by federal law flowed inexorably from this robust factual record and represents precisely the type of decisive management that the MDL rules are designed to encourage in appropriate cases, yet it is something that litigants in the U.S. see all too seldom; talk of substantive resolution rather than settlement machinations as an MDL management tool seems all but blasphemous. Supreme Court guidance on preemption (and *Daubert*, say—but we leave that for another day) suggest the view should be otherwise.

The Supreme Court in *Wyeth v. Levine*, 555 U.S. 555 (2009), held that because a pharmaceutical manufacturer can update the warnings on its product labels (based upon "newly acquired information") without first obtaining FDA approval under the FDA's "Changes Being Effected" (CBE) regulation, 21 C.F.R. § 314.70(c)(6)(iii), it is not impossible, as a general matter, for a pharmaceutical defendant to comply with both state law requirements (i.e., the alleged tort duty asserted by plaintiffs to add a particular label warning) and federal law requirements (i.e., FDA regulations). 555 U.S. at 568. But the Supreme Court noted that even under the CBE procedure, the FDA can subsequently reject a label change made unilaterally by the manufacturer. Accordingly, *state law tort claims are preempted if there is "clear evidence that FDA would not have approved a change" to the label that plaintiffs contend is required*. *Id*. at 571.

Apparently uncomfortable with the door even so slightly ajar, the Third Circuit seized Albrecht to forge a bottomless inquiry as to what constitutes "clear evidence" and how the inquiry should be conducted procedurally. Until Albrecht, FDA's rejection of an actual proposed warning had been considered the gold standard for determining whether there was "clear evidence" of preemption under *Wyeth*; the court did not have to speculate about what the FDA might have done, it need only look at what the FDA *actually did*. But the Third Circuit read "clear evidence" to require an extremely heightened burden—not simply whether the evidence plainly shows that FDA would have rejected a proposed warning, but whether the evidence shows it is "highly probable" that FDA would have done so.

Further, although the construction of the scope and import of regulatory actions traditionally is a question of law, the Third Circuit held that the speculation about whether it is "highly probable" that FDA would have rejected a hypothetical proposed warning is a question of fact for the jury. Summary judgment is precluded if a reasonable jury could conclude it is anything less than "highly probable" that FDA would have rejected a proposed warning.

The Solicitor General rejects this approach. The government argues that the scope and import of regulatory action is a question of law for the court, not a fact question for the jury; and

that where the manufacturer actually proposed to warn about the adverse event at issue and the FDA declined, that should end the inquiry. That approach is a sensible one that the Supreme Court should adopt, as forecast in *Wyeth*; even better, though we would have thought unnecessary at one time, the Supreme Court should clarify that its "clear evidence" language in *Wyeth* was not intended to establish an impossibly high evidentiary burden on defendants asserting preemption.

The Supreme Court's grant of certiorari is encouraging. But one word of caution: Justice Alito recused himself from consideration of Merck's petition, reportedly because he owns stock in Merck, and presumably he would do the same on the merits determination.