



MERCK V. ALBRECHT: VICTORIES, UNCERTAINTIES & OPPORTUNITIES FROM SUPREME COURT'S RETURN TO BRANDED-DRUG PREEMPTION

by Jonah M. Knobler

Last month, the Supreme Court issued its decision in *Merck Sharpe & Dohme Corp. v. Albrecht*, No. 17-290 (May 20, 2019), once again addressing preemption in the pharmaceutical context. *Merck* makes official what the Court first suggested a decade ago: when expert scientists at the Food and Drug Administration (FDA) actually conclude that a particular safety warning is unjustified, their view must prevail, and state-law tort claims based on a manufacturer's failure to issue that warning are preempted. In addition to unequivocally recognizing this principle, *Merck* sweeps away some lower-court misconceptions that had made it unduly difficult for defendants to invoke its protection. In these respects, *Merck* is a major win for pharmaceutical innovation. At the same time, some dicta in the Court's opinion are less clear than they could have been, and have the potential to sow unnecessary confusion.

Merck is a follow-up to *Wyeth v. Levine*, 555 U.S. 555 (2009). There, the Court considered the argument that the FDA's approval of a prescription drug's label—including its safety warnings—is necessarily preclusive of state-law tort claims challenging the adequacy of those warnings. A divided Court rejected this argument, holding that the plaintiff could bring her state-law failure-to-warn claim with respect to Wyeth's name-brand drug, Phenergan, even though the FDA had approved the drug's label and warnings. Importantly, however, the *Wyeth* majority opinion included a cursory comment suggesting that the result would have been different if there were "clear evidence that the FDA would not have approved [the label] change" that the plaintiff argued was necessary. In that scenario, the Court suggested, a state-law failure-to-warn claim *would* be preempted.

In the ensuing decade, lower courts read *Wyeth*'s "clear evidence" passage in inconsistent ways. Many courts viewed it as an extremely narrow exception to a general rule of non-preemption, and imposed such a high burden on defendants to invoke it that establishing preemption through this route was practically impossible. For example, in the *Merck* case itself, the Third Circuit held that even a formal letter from the FDA expressly rejecting the warning is insufficient to establish preemption as a matter of law, and that a jury of laypersons must decide—applying a "clear and convincing evidence" burden of proof, no less—whether the FDA *really* rejected the warning on its merits, or whether its decision might instead be attributable to other factors, such as a quibble with wording.

Although the Justices produced three separate opinions in *Merck*, each one rejected the Third Circuit's uncharitable gloss on *Wyeth*-style preemption. For starters, the Court held, "a judge, not the jury, must decide the pre-emption question." This is because judges "are better equipped" than lay jurors "to evaluate the nature and scope of an agency's determination" and to "understand and interpret agency decisions in light of the governing statutory and regulatory context." Importantly, this holding that the judge must decide extends beyond the

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ultimate *legal* question of whether the plaintiff's claim is preempted; it also encompasses any "subsidiary factual disputes" relevant to the preemption question, such as "what information the FDA had before it." As the Court recognized, removing the preemption question—including all facts bearing on that question—from juries should result in greater uniformity in decisions.

The Court also unanimously rejected the heightened burden—"clear and convincing evidence"—that the Third Circuit had placed on defendants to show preemption. Since preemption is a question of law, the Court explained, instead of holding the defendant to any particular evidentiary burden, "the judge must simply ask himself or herself whether the relevant federal and state laws 'irreconcilably conflic[t].'" As Justice Alito's concurrence in the judgment put it, "*Wyeth's* use of the phrase 'clear evidence' was merely a rhetorical flourish." Importantly, not one of the opinions in *Merck* mentioned the purported "presumption against preemption" that the majority had relied upon in *Wyeth*. The *Wyeth* dissent harshly criticized that reliance, explaining that a court should merely ask "whether there is an 'actual conflict' between state and federal law" "without ... invoking [any] 'presumption.'" In this respect, *Merck* essentially vindicates the *Wyeth* dissent: preemption is not a disfavored doctrine, and courts should not put a thumb on the scales when evaluating it.

In these respects, *Merck* should help rein in the deep-seated anti-preemption views of some lower courts. Unfortunately, however, beyond these unanimous core holdings, *Merck* creates some potential for confusion. The lead opinion—written by Justice Breyer, and joined by the other three "liberal" Justices, as well as Justices Thomas and Gorsuch—recognized that the only "determinative question before [the Court]" was *who decides* the preemption issue. However, that lead opinion included a section that went beyond this "determinative question" and attempted to "elaborate *Wyeth's* requirements" for preemption. (Although the prologue of the Court's opinion described this section as "hold[ing]," because it was not necessary to the actual judgment, it is technically *dicta*.) Specifically, the Court stated that, under *Wyeth*, what is necessary to establish preemption "is evidence ... [(1)] that the drug manufacturer fully informed the FDA of the justifications for the warning [allegedly] required by state law, and [(2)] 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." Both clauses of this sentence raise significant questions.

Start with the first. Read literally, this clause suggests that preemption can occur only where "*the drug manufacturer*"—as opposed to someone else—brought the "justifications for the warning" to the agency's attention. But there is no basis in preemption doctrine for such a requirement. In the Court's own words, the "underlying question for this type of impossibility pre-emption defense is whether ... FDA actions ... prohibited the drug manufacturer from adding [the] warnings ... that would satisfy state law." As a doctrinal matter, if the FDA was informed of the relevant science but forbade the warning, it should make no difference *how* the science happened to come to the agency's attention—*e.g.*, via a submission from the manufacturer, a submission from a competitor, a public citizen petition, or an internal literature review. Under any of these scenarios, it is equally impossible for the manufacturer to add the warning. *See, e.g., Cerveney v. Aventis, Inc.*, 855 F.3d 1091, 1095 (10th Cir. 2017) (finding preemption under *Wyeth* where a third-party citizen petition asking FDA to alter the drug's label had "presented arguments [that were] virtually identical to [plaintiffs' arguments]," and the FDA rejected those arguments).

Given how sharp and unjustified a departure from the Court's preemption principles a literal reading of this passage would require, it is best understood as mere loose language—attributable to the fact that *Merck* itself was a case where the *manufacturer*, and not a third party, had provided relevant information to the FDA. That's how Justice Thomas, who joined the majority opinion, reads it: "As I understand the Court's opinion," he explained in a separate concurrence, "if proper agency actions ... 'prohibited the drug manufacturer from ... satisfy[ing] state law,' state law would be pre-empted ... regardless of whether the manufacturer 'show[ed] that *it* ... informed the FDA of the justifications for the warning'" (emphasis added). Justice Alito's concurrence in the judgment, joined by Chief Justice Roberts and Justice Kavanaugh, agrees: the preemption analysis "does not

depend on whether the relevant drug manufacturer, as opposed to some other entity or individual, brought the new information to the FDA’s attention.” Hopefully, lower courts will take these comments to heart.

The second clause of the majority’s standard is also perplexing. It appears to require, for a finding of preemption, “that the FDA ... *informed* the drug manufacturer that [it] would not approve [the relevant] change to the drug’s label” (emphasis added). The majority goes on to suggest that the manner in which the FDA decision was “communicate[d]” must be one recognized by statute or duly enacted regulation, such as a notice-and-comment rulemaking or a “complete response letter” from the agency. But it’s not clear why an affirmative communication to the manufacturer should be necessary at all. As Justice Alito points out, a statute post-dating *Wyeth*, 21 U.S.C. § 355(o)(4)(A), *affirmatively requires* the FDA “to initiate a label change ‘[i]f [it] becomes aware of new information ... that [it] determines should be included in the labeling of the drug.’” Thus, whenever the FDA receives new information but doesn’t commence a label change, “the logical conclusion is that the FDA determined”—pursuant to this statutory command—“that a label change was unjustified.” To establish preemption, therefore, it should be enough that the FDA knew about the relevant science but took no action.

Notably, this was the position taken by the FDA itself, through the pen of the Solicitor General. So why does the majority disagree? It doesn’t say. Indeed, it’s not even clear that the majority *does* disagree: at the end of its list of FDA “actions” capable of effecting preemption, the majority includes a catchall reference to “other agency action carrying the force of law.” Those words are followed by this citation: “cf., *e.g.*, 21 U.S.C. § 355(o)(4)(A).” That is the same statutory provision that Justice Alito cites in support of his point that FDA inaction is itself preemptive. With its Delphic “cf., *e.g.*” citation to that statutory provision, is the *Merck* majority insinuating that it agrees with Justice Alito and the FDA on the significance of FDA inaction? Suffice it to say—as Justice Alito observed—that lower courts will now need to sort out “the effect of § 355(o)(4)(A) on the preemption issue,” since the majority did not clearly do so.

Given the likely debate over the meaning of *Merck’s* dicta, it is important to emphasize that the *Wyeth* “clear evidence” analysis (as “elaborated” by *Merck*) is just one of multiple ways preemption can be shown in a pharmaceutical failure-to-warn case. Most obviously, if the case involves a generic drug—as opposed to a name-brand drug, as was true in *Merck* and *Wyeth*—failure-to-warn claims are preempted almost as a rule. That is because FDA regulations prohibit generic manufacturers from using the unilateral label-change process (known as “Changes Being Effected” or “CBE”) that the Court analyzed in *Merck* and *Wyeth*. Without access to the CBE process, it is inherently impossible for a generic manufacturer to bring its label into compliance with what state law purportedly requires, without either violating federal law or obtaining the FDA’s advance permission. That results in preemption. See *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011).

Even in a name-brand-drug case, preemption exists outside the *Wyeth-Merck* framework. The reasoning in those two cases turns on the fact that name-brand manufacturers—unlike generic manufacturers—may sometimes use the CBE process to make unilateral label changes, pending the FDA’s decision to approve or disapprove those changes. However, as the Seventh Circuit recently noted, name-brand manufacturers may invoke the CBE process only in “narrow circumstances.” *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 806 (7th Cir. 2018), *cert. denied*, No. 18-803 (May 28, 2019). If the regulatory prerequisites for invoking that process aren’t satisfied, a name-brand manufacturer is in the exact same position as a generic manufacturer: it can’t make a unilateral change to its label, so a failure-to-warn claim is automatically preempted—*whether or not* the FDA considered and rejected the relevant warning and/or communicated that to the manufacturer.

Most importantly, the CBE process is available only where the proposed label change “reflect[s] *newly acquired information*.” 21 CFR 314.70(c)(6)(iii) (emphasis added); see *Dolin*, 901 F.3d at 806; *In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d 34, 41-42 (1st Cir. 2015). “Newly acquired information” is a term of art, defined as “data, analyses, or other information” (1) that were “not previously submitted to the [FDA]” and (2) that “reveal risks of a different type or greater severity or frequency than previously included in submissions to

[the] FDA.” *Id.* at 42 (quoting 21 C.F.R. § 314.3(b)). Each of the three opinions in *Merck* recognizes that access to the CBE process—and thus, the applicability of *Merck*’s preemption analysis—depends on the existence of such “newly acquired information.”

Thus, if a potential label change is supported only by data already known to the FDA, there is no “newly acquired information,” and a failure-to-warn claim is preempted for that reason alone. *See Celexa*, 779 F.3d at 43. Likewise, if a potential label change is supported by “nominally ‘new’ information” that is not specifically known to the FDA, but that information “concern[s] risks of a materially similar type, severity, and frequency as those revealed in information previously evaluated by FDA.” Brief of the United States as Amicus Curiae, *Merck v. Albrecht*, No. 17-290, at 28 n.11; *see Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 665 (S.D.N.Y. 2017). In these situations, because the CBE process is categorically unavailable, a failure-to-warn claim is preempted at the threshold, independent of the *Wyeth-Merck* analysis. (*Merck*, however, does teach that the judge, and not the jury, must make any factual determinations needed to assess whether “newly acquired information” exists.)

But that’s just one scenario where a name-brand manufacturer can invoke preemption outside the *Wyeth-Merck* framework. Another involves so-called “black box” warnings: those highlighted in a black rectangle, meant to signal the most serious risks. FDA regulations don’t allow manufacturers to unilaterally add or change “black box” warnings; they “are permitted ... only when specifically required by the FDA.” 44 Fed. Reg. 37434, 37448 (Jun. 26, 1979); *see also* 21 C.F.R. § 201.57(e). Thus, a state-law claim asserting that a “black box” warning should have been added or modified is automatically preempted, *whether or not* the manufacturer has “newly acquired information” and *whether or not* the FDA considered and rejected the relevant label change. *See In re Depakote*, 87 F. Supp. 3d 916, 923-24 (S.D. Ill. 2015); *Dopson-Troutt v. Novartis Pharms Corp.*, 975 F. Supp. 2d 1209, 1218-19 (M.D. Fla. 2013). For analogous reasons, the same should be true of a state-law claim asserting that a manufacturer should have warned about the risks associated with an “off label” (FDA-unapproved) use of a drug. *See Byrd v. Janssen Pharms., Inc.*, 333 F. Supp. 3d 111, 117-18, 120 (N.D.N.Y. 2018) (citing 21 C.F.R. § 201.57(e)).

Because *Merck* mentioned the key “newly acquired information” prerequisite only in passing, and did not deal with the other scenarios discussed above, a casual reader could come away thinking that, if the test described by the majority is not satisfied, then *ipso facto*, a failure-to-warn claim is not preempted. As just explained, that is decidedly not the case. The *Wyeth-Merck* “clear evidence” analysis is just one piece in a much broader preemption puzzle, and nothing in the Court’s opinion says otherwise.

In sum, although *Merck* could have done more to clarify this vital corner of the law, its central lesson is unambiguous. Preemption is not a disfavored defense that courts should apply grudgingly; nor is it a factual question that courts may punt to juries. Rather, judges should objectively “evaluate the nature and scope of [the FDA’s] determination[s]” and regulations—just as they would objectively construe any other “written instruments”—and then unhesitatingly find preemption, as a matter of law, if there is any “actual conflict” with what state tort law supposedly requires. This should come as no surprise: as the Supreme Court once noted, the very “heart of” the federal Food, Drug, and Cosmetic Act is Congress’s “grant of primary jurisdiction to [the] FDA, the expert agency it created.” *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 627 (1973). Respect for the FDA’s primacy, and Congress’s intent, requires nothing less.