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Pre-approval Design Defect Claims Against Pharmaceutical Companies

By Christopher McKeon

This article delves into this emerging trend of pre-approval design defect claims in pharmaceutical litigation and examines their implications for defense counsel and their clients.

A Divided Legal Landscape

Litigants nationwide are increasingly filing lawsuits against pharmaceutical companies, focusing on—not the design of an FDA-approved drug but rather—the safe design of drugs prior to submission of new drug applications to the FDA. These claims have seen limited success.

This article delves into this emerging trend of pre-approval design defect claims in pharmaceutical litigation and examines their implications for defense counsel and their clients. By understanding the nuances of these claims and the judicial responses to them, defense attorneys can better strategize their defenses and anticipate potential legal hurdles. The discussion includes an analysis of key cases, such as *Yates v. Ortho-McNeil-Janssen Pharmaceuticals* and *Holley v. Gilead Sciences*, and offers insights into how courts are construing preemption arguments. This information is crucial for pharmaceutical companies and their legal teams to navigate the evolving landscape of product liability litigation effectively.

Typically, a design defect claim for an FDA-approved drug requires allegations that the drug's design was defective thereby posing an unacceptable risk of injury, that the plaintiff suffered that injury due to the drug's faulty design, and that the plaintiff would not have been injured if they had consumed a properly designed version of the same drug. These claims generally require a change in design—namely, a change to the chemical composition of the drug—that would require FDA approval prior to being brought to market. Some plaintiffs have split up their allegations into post-approval and pre-approval claims. A subset of courts has bought into this approach. The post-approval claims are routinely dismissed as preempted because they require a major change necessitating prior FDA approval. The so-called pre-approval claims have however, in some instances, been a successful side-step to preemption. *See, e.g., Holley v. Gilead Sciences*, 379 F. Supp. 3d 809 (N.D. Cal. 2019).

Cases Finding Pre-approval Claims Are Preempted

A majority of courts, including the only federal court of appeals to rule on the issue, have found pre-approval claims, like post-approval ones, are preempted. In *Yates v. Ortho-McNeil-Janssen Pharmaceuticals*, the Sixth Circuit Court of Appeals held that a pre-approval design defect claim was preempted. 808 F.3d 281, 299-300 (2015). Plaintiff Yates brought a product liability action after suffering a stroke while utilizing a birth-control patch designed by defendant Ortho. The plaintiff contended that the defendants had a duty under state law to design their product "safely in the first instance, before submitting its new drug application to the FDA." Id. at 293. This contention was squarely rejected by the court. Id.

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The court in *Yates* began by applying the federal impossibility preemption analysis set out in *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 480, (2013), the court first noted that the applicable state law followed a "risk-utility" approach, which imposed liability if "the risk of injury might have been reduced or avoided if the manufacturer had used a feasible alternative design." *Yates*, 808 F.3d at 297. This rendered compliance with federal law impossible because, under

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FDA regulations, once a drug is approved, the manufacturer is prohibited from making any major changes to the "qualitative or quantitative formulation of the drug product or in the specifications provided in the approved application." Id. at 298 (cleaned up). The plaintiff's claim that the defendants should have altered the formulation of their product *after* the FDA had approved it was thus "clearly preempted." Id.

The plaintiff, however, additionally argued that "no federal law prohibited defendants from adopting a safer design" when the defendants first devised their product. Id. at 299. The court found this claim also preempted because the plaintiff's pre-approval duty argument was "too attenuated." Id. The court would have had to speculate not only that the FDA would have approved the alternate design, but that plaintiff would have utilized this different product, and not been similarly harmed. Id. This was, according to the court "several steps too far," and impossibility preemption under *Mensing* persisted, because the "ultimate availability" of the product to plaintiff remained predicated on the FDA's approval. Id. at 299-300.

Furthermore, the court reasoned that if, as claimed, the pre-approval duty would have resulted in a different product, then the plaintiff was functionally alleging that the FDA-approved formulation should have never been sold. However, in *Bartlett*, the Supreme Court disavowed a "stop-selling" rationale as "incompatible with preemp-

tion jurisprudence," which "presume[s] that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability." 1333 S.Ct at 2477. A "never-start-selling" rationale, the Sixth Circuit ruled, had to be rejected for the same reasons.

Utts v. Bristol-Myers Squibb Co., applying California law, deemed a negligent design defect claim based on a pre-approval duty preempted for the same reasons as in *Yates*. 226 F. Supp. 3d 166, 186 (S.D.N.Y. 2016). Plaintiff Utts alleged he suffered severe internal bleeding caused by taking Eliquis, a prescription drug manufactured, marketed, and distributed by the defendants. Also applying *Bartlett* and *Mensing*, the court reasoned that to find a pre-approval duty, it would have had to "speculate" that, had the defendants' product been designed differently: the FDA would have approved the alternate design, the plaintiff would have been prescribed the alternate Eliquis, and the alternate design would not have caused the plaintiff's injuries. Id. at 185-86. Therefore, to assert preemption, defendants would have had to "continually [] prove the counterfactual conduct of the FDA and brand-name manufacturer," as explicitly disavowed in *Mensing*. Id. The court also found that, insofar as the design defect claim suggested that the defendants should never have sold the FDA-approved formulation of Eliquis, this was incompatible with *Bartlett*.

In *Gustavsen v. Alcon Lab'ys, Inc.*, the District Court of Massachusetts followed *Yates* in barring the plaintiffs' claim that the defendant manufacturer should have initially submitted a differently designed product for FDA approval. 272 F.Supp.3d 241, 255 (D. Mass. 2017). The court emphasized that the principal question in impossibility preemption analysis is "whether the private party could independently do under federal law what state law requires of it." Id. (quoting *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 618 (2011)). As in *Bartlett* "defendants here could not have marketed droppers that complied with state… laws in the manner plaintiffs advocate without the FDA's prior approval. It is irrelevant that the defendants could have designed an entirely different product before they sought approval, which may never have been granted." Id. (citing *Yates*, 808 F.3d at 299). In the court's view, this holding did not create a "safe-harbor" shielding FDA-approved drugs from state law liability (as many of the "no preemption" decisions state), because state claims are still available to challenge brand-name manufacturers' failures to warn adequately of a drug's risks, as well as to challenge failures to make "moderate" or "minor" changes to a product's design. Id. at 255.

In *Bossetti v. Allergan Sales LLC*, the plaintiffs brought a defective design claim against defendant Allergan alleging that using Lexapro while pregnant resulted in their children being born with autism spectrum disorder. 2023 WL 4030681 (S.D. Ohio June 15, 2023). Extensively citing *Yates*, the court ruled plaintiff's pre-approval design defect theories were preempted. Id. at *5. Plaintiffs sought to avoid the *Yates* outcome by distinguishing their procedural posture, claiming that discovery was necessary before the court could rule on the defendant's preemption defense. Id. They argued that, unlike the plaintiffs in *Yates*, they had "not fully benefited from discovery" nor had an opportunity to "precisely explain" the duty they alleged Allergan violated. Id. However, the court reasoned that any pre-approval duty conceived of by plaintiffs would have led to an equivalent of the "stop selling" rationale disavowed in *Yates* and *Bartlett*, and therefore had to be dismissed. Id.

In sum, the courts finding pre-approval claims preempted primarily focus on the claims' attenuated and speculative nature, which is problematic alone, but the pharmaceutical drug context compounds the issue. These courts are seemingly driven by a concern that such claims are an unlawful end-run around preemption. Additionally, the successful assertion of a pre-approval duty "functionally" requires that the FDA-approved formulation of the drug should have never been sold and the claims, therefore, run afoul of the "stop-selling" rational specifically prohibited in *Bartlett*. *See also, Fleming v. Janssen Pharms., Inc.*, 186 F.Supp.3d 826, 833 (W.D. Tenn. 2016) (following *Yates* to find pre-approval claim too attenuated, and rejecting the plaintiff's argument that that *Bartlett* applied only to generic, as opposed to branded drugs); *Fortner v. Bristol-Myers Squibb Co.*, 2017 WL 3193928, at *3 (S.D.N.Y. July 26, 2017) (pre-approval claim preempted, following *Utts* and *Yates*); *Evans v. Gilead Scis., Inc.*, 2020 WL 5189995, at *9 (D. Haw. Aug. 31, 2020) (impossible for defendant to independently (without FDA approval) comply with plaintiff's theory and it was therefore preempted); *Brashear v. Pacira Pharmaceuticals, Inc.*, 2023 WL 3075403 at *3 (S.D. Ohio 2023) (pre-approval claim preempted since the alternative drug would have required FDA approval and the plaintiff failed to "specifically alleged facts that support the hypothetical scenario in which the FDA would have approved a differently formulated [drug].").

Cases Finding Pre-approval Claims Are Not Preempted

In the other camp, there are decisions where courts did not find pre-approval claims preempted. *Guidry v. Janssen Pharmaceuticals, Inc.* featured a set of claims similar to those in *Fleming*, which found they were preempted. 206 F.Supp.3d 1187 (E.D. La 2016). After a brief discussion of *Levine* and the relevant Louisiana state law, the court agreed with the *Yates* court "that, to the extent the plaintiff contends that the defendants should have adopted a new design for Invokana after it was approved by the FDA, her defective design claim is preempted." Id. at 1206. However, the District Court of Louisiana found that plaintiff's pre-approval defective design claims under Louisiana law were not preempted by federal law. Id. at 1209. In addressing the pre-approval claim, the court prefaced its discussion by stating that if it were to find the claim preempted "the result is that a Louisiana plaintiff can never bring a defective design claim against a drug manufacturer." Id. It then cited the Supreme Court's *Levine* decision, finding that a drug label may be inadequate under state tort law, even if it has been approved by the FDA, as evidence that "the FDA is not the be-all-end-all in drug regulations." Id. at 1207.

The court noted the defendant's reference to the Supreme Court's statement in *Mensing* that "the question for 'impossibility' is whether the private party could independently do under federal law what state law requires of it," and conceded that "the defendants cannot independently sell pharmaceutical drugs without FDA

approval." Id. at 1208; *Mensing*, 564 U.S. at 620, 131 S.Ct. 2567. Nevertheless, the court asserted that "the dispositive question presented" in this case was whether a drug manufacturer could independently design a safe drug in compliance with its state law duties before seeking FDA approval. *Guidry*, F.Supp.3d at 1208. The District Court was "unpersuaded" by the *Yates* reasoning. Id. First, regarding "attenuation" of the pre-approval duty, it reasoned that "*all* defective design claims" under the Louisiana Products Liability Act require assumptions, and the only *additional* assumption "is that the FDA would have approved the safer, hypothetical drug." Id. Second, it did not "share the Sixth Circuit's reservations" about the "never-start selling argument," because, in its view, the whole point of products liability litigation is to "penalize manufacturers who design unreasonably dangerous products *in hopes that they never start selling them*." Id.

In *Holley v. Gilead Sciences*, the District Court for the Northern District of California declined to follow Yates and found "persuasive the weight of authority against a finding of preemption" of pre-approval design defect claims. 379 F. Supp. 3d 809, 824 (N.D. Cal. 2019). In the underlying lawsuit, as in *Evans* (which found the pre-approval claims preempted), plaintiffs alleged that they suffered kidney and bone damage when taking Gilead's drugs containing TDF. The court's analysis followed *Guidry*, framing the question as "not whether a drug manufacturer can 'independently sell pharmaceutical drugs without FDA approval," but whether "a drug manufacturer [can] independently design a reasonably safe drug in compliance with its state-law duties before seeking FDA approval." Id. (citing *Guidry*, 206 F.Supp.3d at 1208). It emphasized the absence of a federal law "that restricts a brand-name drug manufacturer from designing a reasonably safe product prior to FDA approval," as well as the lack of a federal law that would prevent Gilead from developing and submitting for approval drugs that contained TAF rather than TDF, or a lower dosage of TDF. *Holley*, 379 F. Supp. 3d at 824. Because the defendant had not presented "clear evidence that the FDA would not have approved" the alternative product, the court concluded plaintiff's claims were not preempted. Id.

In rejecting the *Yates* approach, the Court in *Holley* largely cited the reasoning in *Guidry*. First, *Holley* agreed that "it is not too attenuated to assume that the FDA would approve a safer, alternative design of a drug that it has already approved." Id. at 824. Without addressing the other steps in the chain of causality laid out by the Court in *Yates*, it found this inference "especially" credible because the three allegedly safer drugs at issue in the litigation were actually approved by the FDA years later. Id. at 825. Additionally, the court agreed with the holding in *Young*, another case finding no preemption, that "[t]he preapproval theory does not argue that a manufacturer should have stopped acting, just that it should have acted differently." *Young v. Bristol-Myers Squibb Co.*, 2017 WL 706320 (N.D. Miss. Feb. 22, 2017), at *8. Under this view, a pre-approval duty is compatible with *Barlett's* rejection of the "stop-selling" rationale because if Gilead had initially offered for FDA approval the alternative TAF-containing drug, it would have complied with both state and federal law. *Holley*, 379 F. Supp. 3d at 825.

In *In re Xarelto (Rivaroxaban) Products Liability Litigation*, the bellwether plaintiff alleged to have suffered severe bleeding and other injuries due to Xarelto's allegedly defective design. 2017 WL 3188456 (E.D. La 2017). The District Court for the Eastern District of Louisiana, finding *Guidry* "directly on point", deemed plaintiff's Mississippi state law claims for design defect pre-approval not barred. Id. at *6. The court refused to engage in, what in its view was, an expansion of the preemption doctrine because doing so, according to the court, "would free pharmaceutical companies from state common-law liability—and limit states' constitutional right to protect its residents' welfare," thereby jeopardizing the interests the Supreme Court sought to protect in *Levine*. Id. at 4, 6. The court sought to distinguish *Bartlett* and *Mensing* because they applied to generic drug manufacturers, and neither Congress nor the Supreme Court had, in the court's view, directly spoken on the issue of preemption of claims against brand-name drug manufacturers. Id. (citation omitted).

In *Gaetano v. Gilead Sciences, Inc.*, the plaintiff brought similar claims regarding the same drug as were at issue in *Holley*, alleging Gilead should have brought TAF to market instead of TDF. The District Court for the District of New Jersey held plaintiff's New Jersey design defect state law claims not preempted. 529 F.Supp.3d 333, 341 (D.N.J. 2021). The court agreed with *Holley* on the relevant question: "whether a drug manufacturer can independently design a reasonably safe drug in compliance with its state-law duties before seeking FDA approval." Although it conceded that *Gilead* could not sell a drug without FDA approval, the court stated that this did not bring the case within the holding of *Mensing* because the mere "possibility of rejection" is not sufficient to require preemption. *Id.* at 342. Second, echoing *Guidry*, the court stated that "sheer scope of Gilead's argument imperils both preemption doctrine and state police powers" since it "carries the implication that a plaintiff could never bring a design defect claim involving any drug that required FDA approval." Id. The court found that the claim was not "too attenuated" because an alternative, TAF-based drug was later approved by the FDA. Id. at 343.

In short, these courts largely find pre-approval claims are not "too attenuated" and that it's not an unreasonable assumption that the FDA would have approved the alternatively formulated drug. The courts appear driven by a concern that preemption of these claims would strip litigants of a remedy and prop up an unwarranted shield around pharmaceutical makers. They also reject the *Yates* never-start selling analysis in favor of the conclusion that the claims only require defendants to act differently and not cease acting all together. *See also, Estate of Cassel v. Alza Corp.*, 2014 WL 856023 (W.D. Wis. 2014) (claims not preempted, citing concern that doing so would foreclose "all design-defect claims"); *Trahan v. Sandoz, Inc.*, 2015 WL 2365502 (M.D. Fla. 2015) (rejecting preemption assertion reasoning it would "shield" drugmakers who have obtained FDA approval "from any future liability"); and *Young*, 2017 WL 706320 at *8 (agreeing with *Guidry* and adding there can be no preemption issue if no state law duty conflicting with a federal duty is identified).

Which is Correct?

To begin, the analysis largely depends on the specific state law duty that's being imposed. Implied preemption occurs when "state and federal law conflict" such that it is "impossible for a private party to comply with both state and federal requirements." *Mensing*, 564 U.S. at 618 (quotations omitted). In the pharmaceutical context, implied "conflict" preemption bars state law claims "when a party cannot satisfy its state duties without the federal government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency." Id. at 623–24. The alleged duty likely shapes the court's approach in determining whether such claims are too attenuated. However, consistent across all claims, regardless of the alleged duty, is that they require the assumption the FDA would have approved the alternatively formulated drug.

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This assumption alone is one too far and an unreasonable one. If there is a design defect claim asserted in the case, then necessarily the plaintiff is alleging the drug's design is faulty in some way or to some degree. In turn, it cannot reasonably or safely be assumed that an alternative formulation of a *faulty* drug would receive FDA approval, that belies logic. This assumption contains or implicates several sub-assumptions as well: that the alternative design would remedy the alleged defect, that plaintiff would have purchased and consumed the alternative drug despite its difference in design, and the alternative design would not have some other undetected defect that could harm the plaintiff. Forcing defendants to continually prove the counterfactual conduct of the FDA "is precisely the type of 'Mouse Trap' game the Supreme Court has disavowed." *Utts* 226 F. Supp. 3d at 186 (citation omitted).

The assumption turned out to be a fact in *Holley*, where the alternatively designed drugs were actually later approved by the FDA. The exceptional facts of *Holley* cannot be understated though. And in most cases, FDA approval cannot be assumed and there is only a mere possibility that the defendant could have developed and submitted approval for an alternatively designed drug. "*Mensing*, however, rejected a similar rationale." *Evans*, 2020 WL 5189995, at *9 (another court construing TAF / TDF claims and rejecting a pre-approval theory). "Merely requesting FDA assistance or asking the FDA for help in complying with state law would have satisfied Gilead's federal duty, but it would not have satisfied Gilead's state tort-law duty to provide an allegedly safer drug composition." Id. (cleaned up) "The only action Gilead could independently take—asking for the FDA's help by submitting a TAF-containing drug application—is not a matter of state-law concern." Id. (cleaned up).

Additionally, the *Yates* framing on the "stop-selling" rationale is far more consistent with Bartlett than *Holley*'s. The pre-approval claim necessarily requires that the defendant manufacturer should have never sold the FDA-approved formulation of its drug in the first place. The precedent is clear that a defendant manufacturer cannot be required to pull its approved drug from the market in order to comply with both state and federal law, the contention by the court in *Holley* that said rationale does not apply to initially bringing the drug to market is a non sequitur. *Bartlett*, 570 U.S. at 475. *Holley* and similar decisions found that pre-approval claims merely require the defendant to have "acted differently" but the different course of action necessarily requires the defendant "never start selling … [which] collides with the FDCA as a matter of law." *Bossetti v. Allergan Sales, LLC*, 2023 WL 4030681, at *5 (S.D. Ohio June 15, 2023).

Last, preemption of pre-approval claims does not create a "safe-harbor" forever shielding FDA-approved drugs from state law scrutiny. For starters, other non-design defect claims remain viable. This includes general negligence, failure to warn, manufacturing defect claims, and a litany of consumer protection laws. It is also not the case that a litigant could never bring a defective design claim. Design defect claims alleging alternative designs that were already FDA-approved persist. Similarly, design defect claims grounded in allegations that the defendant should have made "moderate" or "minor" changes to a product's design, which don't require FDA prior approval, can also still go forward. States are not without remedies and may still protect their interests through other, non-preempted claims.

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Conclusion

A majority of courts, including the Sixth Circuit Court of Appeals, have found pre-approval claims preempted. The consensus among these courts is that such claims are too speculative and attenuated. These courts have also found that such claims effectively suggest the FDA-approved formulation should never have been sold, conflicting with the Supreme Court's rejection of the "stop-selling" rationale in *Bartlett*. A small number of courts have come out the other way, driven by extraordinary facts and a concern of unjustly protecting faulty drugs from state law liability.