UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ANTHONY GAETANO, **Plaintiff,** **v.** **GILEAD SCIENCES, INC.,** **Defendant.**	Civ. No. 21-01418 (KM) (JBC) **OPINION**

KEVIN MCNULTY, U.S.D.J.:

Gilead Sciences, Inc., makes Truvada, the leading drug for prevention and treatment of HIV. Anthony Gaetano took Truvada until experiencing chronic pain. He sues Gilead, alleging New Jersey products liability claims that Gilead should have used a safer ingredient and that Gilead failed to warn about Truvada's risks. Gilead moves to dismiss, arguing that all of Gaetano's claims are preempted and that his failure-to-warn claim is precluded by New Jersey law. (DE 4.)[1] For the following reasons, the motion is **DENIED**.

I. BACKGROUND

The federal Food, Drug, and Cosmetic Act, ("FDCA"), 21 U.S.C. § 301 *et seq.*, regulates how drugs gain approval to enter the market and what labeling they must contain. *See In re Suboxone (Buprenorphine Hydrochlorine & Naloxone) Antitrust Litig.*, 967 F.3d 264, 267 (3d Cir. 2020); *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668, 1672–73 (2019). The Food and Drug

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[1] Certain citations to the record are abbreviated as follows:
DE = docket entry
Compl. = Complaint (DE 1-1)
Mot. = Gilead's Brief in Support of its Motion to Dismiss (DE 4-3)
Opp. = Gaetano's Opposition to Gilead's Motion to Dismiss (DE 4-4)
Reply = Gilead's Reply Brief (DE 4-5)

Administration ("FDA") administers the FDCA and approves drugs and labels. *See id.*

In 2004, the FDA approved Truvada for the treatment of HIV. (Compl. ¶ 31.) Truvada uses the active ingredient tenofovir disoproxil fumarate ("TDF"). (*Id.* ¶ 27.) Gilead had developed and sold other TDF-based drugs in the years before marketing Truvada. (*Id.* ¶¶ 29–30, 32.) Gilead's research showed that TDF caused bone and kidney problems. (*Id.* ¶¶ 33–36.) Nonetheless, Gilead's labeling failed to warn doctors that all patients taking Truvada should be monitored for adverse kidney or bone effects. (*Id.* ¶¶ 40–41.) The labeling also failed to warn doctors as to what ongoing testing was needed. (*Id.* ¶¶ 46–49.) All the while, Gilead was "provid[ing] stronger monitoring recommendations and warnings to physicians and patients in the European Union." (*Id.* ¶ 50.)

Before TDF medications were introduced, Gilead discovered a similar active ingredient, tenofovir alafenamide fumarate ("TAF") that did not pose the same risks as TDF. (*Id.* ¶¶ 58–60.) Yet Gilead discontinued its development of a TAF medication in 2004, opting instead to focus on gaining FDA approval for the TDF-based medication. (*Id.* ¶¶ 61–63.) Gilead intended to maintain TDF drugs' market dominance for as long as possible, even if that meant downplaying risks, and only thereafter introduce TAF medications, which would then enjoy their own period of dominance and exclusivity. (*See id.* ¶¶ 65–71.) *See generally Suboxone*, 967 F.3d at 267–68 (brand-name drugs enjoy a period of exclusivity and market domination until generics are introduced).

Gilead ultimately developed a TAF medication that was approved in 2015, although it allegedly could have been approved years earlier if Gilead had not forgone it in favor TDF drugs. (Compl. ¶¶ 70–71.) A generic version of TDF-based Truvada was introduced five years later in 2020. (Id. ¶ 71.)

Gaetano began taking Truvada daily in 2005. (*Id.* ¶ 8.) Around the same time, he was diagnosed with kidney diseases. (*Id.* ¶¶ 15–16.) About a year after starting Truvada, he began experiencing pain in his hands, elbow, and left shoulder. (*Id.* ¶ 19.) Almost a decade later, Gaetano's doctor switched him from

Truvada to a different prescription but did not tell him why. (*Id.* ¶ 18.) Gaetano continued to experience pain in his right shoulder and hand, and in 2018, he was diagnosed with chronic pain related to musculoskeletal disorders. (*Id.* ¶¶ 10–11.) He later learned that Truvada was associated with bone and kidney problems. (*Id.* ¶ 12.)

Gaetano sued Gilead in New Jersey Superior Court, asserting claims under the New Jersey Product Liability Act ("NJPLA"), N.J. Stat. Ann. § 2A:58C-2. He alleges two theories: (1) Truvada was defective because it caused kidney and bone damage, while a safer alternative (TAF) was available; and (2) Truvada's label failed to warn of risks. (*Id.* ¶¶ 72–80.) Gilead removed the case to this Court, invoking diversity jurisdiction under 28 U.S.C. § 1332(a), and moved to dismiss. (DE 1, 4.)[2]

II. STANDARD OF REVIEW

Federal Rule of Civil Procedure 8(a) does not require that a pleading contain detailed factual allegations but "more than labels and conclusions." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555 (2007). The allegations must raise a claimant's right to relief above a speculative level, so that a claim is "plausible on its face." *Id.* at 570. That standard is met when "factual content [] allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009). Rule 12(b)(6) provides for the dismissal of a complaint if it fails to state a claim. The defendant bears the burden to show that no claim has been stated. *Davis v. Wells Fargo*, 824 F.3d 333, 349 (3d Cir. 2016). I accept facts in the complaint

[2] Originally, Gaetano also sued the doctor and healthcare provider who prescribed him Truvada. (Compl. ¶¶ 4–5.) In New Jersey Superior Court, Gilead moved to dismiss, and its motion was fully briefed. (*See* DE 1-1.) Then the doctor and healthcare provider stipulated to a dismissal. (DE 1 ¶ 6.) That dismissal entailed that the only remaining parties, Gilead and Gaetano, were of diverse state citizenship, enabling Gilead to remove the case to this Court. (*Id.* ¶ 10.) Gilead then, with the Court's permission, lodged the already-briefed motion to dismiss with this Court, so it is ripe for decision.

as true and draw reasonable inferences in the plaintiff's favor. *Morrow v. Balaski*, 719 F.3d 160, 165 (3d Cir. 2013) (en banc).

III. DISCUSSION

Gilead moves to dismiss both the design-defect claim and the failure-to-warn claim, arguing that they are preempted. Alternatively, Gilead moves to dismiss the failure-to-warn claim based on the "presumption of adequacy" that attaches to FDA-approved labels under the NJPLA. I take up those arguments in turn.

A. Preemption

"The doctrine of preemption has constitutional roots in the Supremacy Clause," which provides that federal law is "supreme." *Sikkelee v. Precision Airmotive Corp.*, 907 F.3d 701, 709 (3d Cir. 2018) (second quotation quoting U.S. Const. art. VI, cl. 2). "Congress thus has the power to preempt state law." *Id.* The preemption doctrine most pertinent here applies "when it is impossible for a private party to comply with both state and federal requirements." *Merck Sharp*, 139 S. Ct. at 1672 (quotation marks and citation omitted).

"Impossibility" preemption issues arise with some regularity in litigation asserting state-law tort claims against prescription-drug manufacturers. In such cases, plaintiffs assert that manufacturers violated state-law duties by the manner in which they designed their products or wrote their labels; the FDA, however, sets its own standards as to what drug compositions can be marketed and what their labels must say. *Id.* Those two sets of duties may conflict, and in a proper case, the state law may have to yield to the federal. In a series of cases, the Supreme Court has explained when the FDCA/FDA scheme preempts state-law claims. *Sikkelee*, 907 F.3d at 713 (surveying cases).

Because Gilead relies on that line of cases, I begin by describing their holdings. (Section III.A.1, *infra*.) I then apply that case law to Gaetano's design-defect claim (Section III.A.2, *infra*) and failure-to-warn claim (Section III.A.3, *infra*).

1. Preemption and Prescription Drugs at the Supreme Court

As to the issue of preemption now before the Court, there are three essential Supreme Court cases.

First, in *Wyeth v. Levine*, the Court held that a state-law failure-to-warn claim against a brand-name drug manufacturer was not preempted because FDA regulations allow those manufacturers to change labels without immediate agency approval. 555 U.S. 555, 568 (2009). Because the manufacturer could change the label to comply with state law, it was not impossible to comply with both state and federal labeling requirements. *Id. Wyeth* recognized an exception, however: If a manufacturer can provide "clear evidence" that the FDA would have rejected the label, then the manufacturer can show that it would have been impossible to amend the label in compliance with state law while simultaneously complying with federal law. *Id.* at 571.

Wyeth, which involved a branded drug, left unaddressed the case of a generic drug, which is subject to a different regulatory regime. "Under federal law, a generic drug manufacturer may produce a drug that is identical to one made by a brand-name manufacturer, but when it receives permission to do so, it must use the same FDA-approved design and warning labels as the brand-name manufacturer." *Sikkelee*, 907 F.3d at 712. Unlike brand-name manufacturers, then, a generic manufacturer cannot unilaterally change its label consistent with federal law. *Id.*

Accordingly, in a second case, *PLIVA, Inc. v. Mensing*, the Court distinguished *Wyeth* and held that a state-law failure-to-warn claim was preempted as to a generic drug. 564 U.S. 604, 617–18 (2011). *Mensing* reasoned that, if the generic manufacturer changed its label to comply with state law, then the label would not match the brand-name label, and thus would violate federal law. *Id.* The Court also rejected the argument that complying with both state and federal law was not impossible because the manufacturer could ask the FDA to update the brand-name label. *Id.* at 620–21. The Court explained that "[t]he question for 'impossibility' is whether the

private party could *independently* do under federal law what state law requires of it." *Id.* at 620 (emphasis added). "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, . . . that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623–24.

While *Mensing* involved a failure-to-warn claim, the Court applied the same logic to a design-defect claim in a third case, *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013). That state design-defect claim, if sustained, would have required the generic manufacturer to alter the drug's composition to reduce the risk of an adverse reaction. *Id.* at 483. The Court held that such a claim was preempted because a generic drug's composition (like its label) cannot differ from that of the brand-name drug. It was therefore impossible for the manufacturer to redesign the drug in accordance with state law, while simultaneously complying with the federal prohibition against redesigning the drug. *Id.* at 483–84.

The upshot of this trio of cases is that a court should first identify what changes to the drug or label the state-law claim would require, and then determine whether, under federal law, a manufacturer could unilaterally implement that change. If the manufacturer could do so, then federal law does not make it impossible to comply with a state-law duty, and preemption does not apply.

2. Design-Defect Claim

Gaetano's first claim is that the design of Truvada is defective because the drug causes kidney and bone damage. (Compl. ¶ 73.) Under New Jersey law, a design-defect plaintiff may succeed by proving that "the product could have been designed in an alternative manner so as to minimize or eliminate the risk of harm." *Lewis v. Am. Cyanamid Co.*, 715 A.2d 967, 980 (N.J. 1998). Gaetano alleges that Gilead had such a safer alternative, namely, a TAF-based medication. Thus, he asserts, Gilead should have swapped in TAF as the active

ingredient and sought FDA approval for that TAF-based medication, instead of the less safe TDF-based medication. (*See* Compl. ¶ 73; Opp. at 5, 7, 11.)[3]

Neither the Supreme Court nor the Third Circuit has addressed preemption in relation to the specific claim that a brand-name manufacturer should have developed and sought FDA approval for a different, safer drug. The closest precedent is *Bartlett*, which addressed a claim that a generic manufacturer should have *re*designed the drug's composition *after* FDA approval. 570 U.S. at 484–85. *Bartlett* held that such a claim is preempted, but *Bartlett* is distinguishable because it involved (1) a generic manufacturer, and (2) a claim that the drug composition should be changed post-approval. Post-approval, as noted above, a generic manufacturer is not permitted to make such changes; even if state law imposes a duty to alter the drug's composition,

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[3] Gilead argues that the Complaint does not allege a pre-approval theory, but only a post-approval theory that, *after* Truvada was approved and on the market, Gilead should have replaced Truvada with a TAF-based formula. (Mot. at 15; Reply at 3.) I disagree. The Complaint alleges that "a practical and feasible, safer, alternative design existed that would have reduced or prevented the harm caused to the Plaintiff." (Compl. ¶ 73.) This is a broad allegation that is clear enough to encompass a pre-approval theory.

Gilead latches onto the allegation that a TAF medication "could have been conceivably approved in 2009 had Gilead not purposefully paused their research and development of TAF in 2004." (*Id.* ¶ 70.) Since TDF-containing Truvada was approved in 2004, Gilead reasons that the Complaint only alleges that Gilead should have replaced Truvada with a TAF medication once such a medication was ready for approval five years after Truvada's approval. (Reply at 3.) But I read the allegation in paragraph 73 as broad enough to allege that Gilead should have continued with the development of a TAF medication *instead* of seeking approval for TDF-based Truvada. *See Smith v. Pro Custom Solar LLC*, Civ. No. 19-20673, 2021 WL 141336, at *4 (D.N.J. Jan. 15, 2021) (explaining that courts do not finely parse a pleading's allegations and home in on "infelicities in phrasing").

Gaetano also confirms in his brief that he is asserting a pre-approval theory. (Opp. at 5, 7, 11.) Moreover, Gaetano does not seem to dispute that a post-approval theory would likely be preempted because a brand-name manufacturer cannot unilaterally change a drug's composition following approval. *See* Opp. at 10, 11; 21 U.S.C. § 355(a) (requiring approval of a new drug application to market a drug); 21 C.F.R. § 314.70(b)(2)(i) (defining "changes in the . . . formulation of the drug" as "major changes" that "requir[e] supplement submission and approval").

the generic manufacturer cannot do so and still maintain FDA approval. *Id.* A brand-name manufacturer, particularly during the pre-approval process of designing the drug, does not labor under the same federal-law constraints.

Indeed, the distinctions between this case and *Bartlett* strongly suggest that Gaetano's design-defect claim is not preempted. Gaetano's claim is that Gilead should have designed Truvada differently (*i.e.*, with TAF instead of TDF) from the get-go. Federal law does not dictate the manner in which a manufacturer must design a drug in the first place. *E.g.*, *Sullivan v. Aventis, Inc.*, No. 14-CV-2939-NSR, 2015 WL 4879112, at *6 (S.D.N.Y. Aug. 13, 2015). Moreover, there are no federal requirements dictating which compositions among available alternatives a manufacturer must submit for approval. *Id.* Here, Gaetano effectively claims that, under state law, a manufacturer has a duty to pursue a safe alternative if available. Pursuant to that state-law duty, Gilead could have submitted an alternative design to the FDA without creating any conflict with its federal duties. *See Kaiser v. Johnson & Johnson*, 947 F.3d 996, 1009–10 (7th Cir. 2020) (federal law did not stop medical device from satisfying state-law duties relating to medical device design before seeking FDA clearance).

This case is thus closer to *Wyeth* than to *Bartlett* or *Mensing*. In the latter two cases, "the defendant generic manufacturers were obligated to use the design and labeling of their brand-name counterparts," but Gilead "is not in that position." *Sikkelee*, 907 F.3d at 713. Gilead's position is analogous to that of the brand-name manufacturer in *Wyeth,* which could make changes consistent with its federal-law duties. Given the lack of specific duties imposed by federal law at the design stage, before FDA approval is sought, *Bartlett* and *Mensing* are inapplicable. *See Gremo v. Bayer Corp.*, 469 F. Supp. 3d 240, 257 (D.N.J. 2020) (*Bartlett* does not require preemption of all claims that a drug could have been designed differently); *Crockett v. Luitpold Pharms., Inc.*, Civ. No. 19-276, 2020 WL 433367, at *8 (E.D. Pa. Jan. 28, 2020) (same).

In response, Gilead argues that (1) it could not have independently marketed a TAF-based version of Truvada without FDA approval, and (2) the only Court of Appeals to address pre-approval design-defect claims has rejected them. (Mot. at 11–13; Reply at 5.) Neither argument is persuasive.

a. The Independence Requirement

Gilead argues that it could not have independently and unilaterally marketed an alternative, TAF-based formulation of Truvada without FDA approval. (Reply at 5.) Of course, that is true, as it is of any drug. The argument thus threatens to prove far too much.

This is not the first products-liability suit against Gilead for its TDF drugs, and this is not the first time Gilead has raised this preemption argument. The cases are split.

Some courts have credited Gilead's argument, relying on *Mensing*'s language that a party cannot act "independently" if the action in question would require FDA approval. *Evans v. Gilead Scis., Inc.*, for example, is closely parallel to this case, except that the state claims arose under Hawaii law. No. 20-cv-123, 2020 WL 5189995, at *9 (D. Haw. Aug. 31, 2020) Citing *Mensing, Evans* held that the design-defect claims were preempted because Gilead could not market an alternative formula of Truvada (containing TAF) without FDA approval. *Id.* at *9–10.[4] *See also Epstein v. Gilead Scis., Inc.*, Civ. No. 19-81474, 2020 WL 4333011, at *2 (S.D. Fla. July 27, 2020).

Other courts disagree, however. In *Holley v. Gilead Sciences, Inc.*, plaintiffs sued Gilead, alleging California-law products liability claims after taking TDF-based medications (including Truvada) and experiencing bone and kidney damage. 379 F. Supp. 3d 809, 814 (N.D. Cal. 2019). Those plaintiffs raised the California-law equivalent of Gaetano's claims here, and Gilead raised the same preemption defenses. *Id.* at 815, 818-19. *Holley* rejected Gilead's

[4] *Evans* held, however, that the failure-to-warn claims were not preempted. *See infra.*

preemption defenses, on grounds discussed more fully below. *Id.* at 821–30.[5] *See also Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1208 (E.D. La. 2016) (similar preemption defense rejected in case involving Invokana, a diabetes drug).

I find the preemption reasoning of *Holley* more persuasive, for two specific reasons.

First, Gilead mischaracterizes the claim here. Gaetano's claim is that, instead of going ahead and obtaining FDA approval for the TDF-based Truvada drug, Gilead should have designed and sought FDA clearance for a safer, TAF-based drug. Thus, "[t]he question is not whether a drug manufacturer can independently *sell* pharmaceutical drugs without FDA approval; it is whether a drug manufacturer can independently *design* a reasonably safe drug in compliance with its state-law duties *before* seeking FDA approval." *Holley*, 379 F. Supp. 3d at 825 (cleaned up; emphases added). Gaetano's claim goes to Gilead's pre-approval design choices, which were actions independent of the FDA. *See id.*

That Gilead needs FDA approval to sell a drug does not bring this case within the holding of *Mensing*. In *Mensing*, the change to the label required FDA permission before it could occur. Here, Gilead can design or redesign a drug to comply with state law in advance of any FDA approval process. To be sure, once the alternative drug is submitted for approval, the FDA might reject it. But the same was true in *Wyeth;* where a brand-name manufacturer unilaterally changes a drug's label, the FDA may later review and reject that change. 555 U.S. at 571. That possibility of rejection is not sufficient to require preemption. *Holley* harmonized the Supreme Court's *Mensing* and *Wyeth* holdings in terms with which I agree: "An action is independent . . . if the manufacturer can take such action without prior FDA approval, even if the

[5] With one exception: *Holley* held that a claim that Gilead should have improved its labels post-approval was preempted. *Id.* at 821–30. I discuss that claim and distinguish that holding *infra*.

FDA may subsequently reject approval of the action post hoc." *Holley*, 379 F. Supp. 3d at 821. This case thus resembles *Wyeth,* because a manufacturer can unilaterally make design choices, even if they lead to a drug for which FDA approval may or may not be forthcoming.

Second, the sheer scope of Gilead's argument imperils both preemption doctrine and state police powers. Gilead's argument carries the implication that a plaintiff could never bring a design-defect claim involving any drug that required FDA approval. *Guidry*, 206 F. Supp. 3d at 1206; *Estate of Cassel v. Aka Corp.*, No. 12-CV-771, 2014 WL 856023, at *5 (W.D. Wis. Mar. 5, 2014). That result cannot be squared with two fundamental principles. First, the Supreme Court stressed that impossibility is not to be found easily, *Merck*, 139 S. Ct. at 1679, implying that it is the exception, not the rule. Gilead's approach, however, would require preemption of a wide swath of design-defect claims. Second, "Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." *Id.* Likewise, "federal law establishes no safe-harbor for drug companies." *Bartlett*, 570 U.S. at 490. State law, too, has an important role to fill here, a role that would be severely impaired if Gilead's argument were accepted.

Gilead's argument turns FDA approval into a kind of talisman to ward off state-law claims. I think it stretches impossibility preemption farther than the Supreme Court intended. Gilead does not furnish a valid basis to extend the impossibility-preemption doctrine to pre-approval design-defect claims.

b. The Sixth Circuit's View

As noted, Gilead's second response is based on Court of Appeals case law. Gilead relies most heavily on *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*, 808 F.3d 281 (6th Cir. 2015), the only Court of Appeals case to address pre-approval claims. *Yates* rejected a pre-approval design defect claim for two reasons. Most respectfully, I find those reasons off-point and unpersuasive.

First, the Sixth Circuit reasoned that the claim there was "too attenuated," because it required the court to speculate that if a manufacturer had designed the drug differently, the FDA would have approved the alternative formulation; that the plaintiff would have taken this alternative drug; and the alternative drug would not have caused plaintiff harm. *Id.* at 299. These, of course, are weighty concerns, but they go primarily to causation; the specific connection to preemption is less clear. As one court sees it, "the Sixth Circuit merely outlines the requisite assumptions for *all* defective design claims." *Guidry*, 206 F. Supp. 3d at 1208. Here, as it happens, an alternative, TAF-based drug *was* approved by the FDA, although not until 2015. "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.* "This is especially true where, as here, [Gaetano] allege[s] that . . . the allegedly safer drugs were actually approved by the FDA years later." *Holley*, 379 F. Supp. 3d at 824.

Of course, a defendant manufacturer may attempt to prove that the alternative drug is not safer, or that it was not or would not have been approved. The issue here, however, is whether a plaintiff's claim is preempted at this, the motion-to-dismiss stage. Where a plaintiff plausibly alleges that the manufacturer could have changed the formulation, consistent with federal law, the allegation may be worthy of further exploration in discovery.

Second, *Yates* relied on *Bartlett*'s rejection of a rationale that a manufacturer can comply with both federal and state law by pulling an approved drug from the market and seeking approval of a different one. *Yates* reasoned that the plaintiff was "essentially argu[ing] that defendants should never have sold the FDA-approved formulation . . . in the first place." 808 F.3d at 300. That "never-start selling rationale," in the Sixth Circuit's view, was too close to the "stop-selling rationale" rejected in *Bartlett*. *Id.*

I am convinced, however, that the "stop selling" rationale is misapplied in this different context. *See Young v. Bristol-Myers Squibb Co.*, No. 16-CV-108, 2017 WL 706320, at *8 (N.D. Miss. Feb. 22, 2017) ("*Yates* misstates the 'stop

selling' rationale."). *Bartlett* held 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." 570 U.S. at 488. In short, this is another argument that proves too much, at too high a cost. Of course, any actor can avoid regulation by simply ceasing the regulated activity altogether. The pre-approval theory, however, is different. It does not require a manufacturer to abandon its investment and marketing efforts with respect to an efficacious drug that the FDA has approved. "The preapproval theory does not argue that a manufacturer should have stopped acting, just that it should have acted differently." *Young*, 2017 WL 706320, at *8; *see also, e.g.*, *Holley*, 379 F. Supp. 3d at 825; *Guidry*, 206 F. Supp. 3d at 1208. That state-law directive to act "differently" applies pre-approval, at the development stage, when the manufacturer is choosing among alternatives and its choice is not dictated by federal law.

For those reasons, I decline to follow *Yates*. In that, I am not alone: "Of those courts that are not bound by . . . *Yates*, a majority has found no preemption under these circumstances." *Holley*, 379 F. Supp. 3d at 823 (collecting cases).

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In sum, I hold that Gaetano's claim that Gilead should have developed a drug using TAF instead of TDF is not preempted. I will therefore deny Gilead's motion to the extent it seeks dismissal of that design-defect claim.

3. Failure-to-Warn Claim

Gaetano alleges that Truvada's label inadequately warned of all the risks associated with Truvada, or of the need to monitor patients' bone and kidney health while taking Truvada. (Compl. ¶¶ 40–49, 77–78.) A failure-to-warn claim requires that a defendant knew or should have known about a risk (the duty) but failed to warn about that risk (the breach). *See Whelan v. Armstrong Int'l Inc.*, 231 A.3d 640, 652–53 (N.J. 2020). So the state-law duty Gaetano seeks to impose here is one to warn of the full extent of Truvada's risks and how to

monitor patients. The breach is that its label failed to do so, or did so inadequately.

Gilead argues that this claim is preempted for two reasons. First, to the extent the claim is premised on a theory that Gilead failed to propose an adequate label to the FDA when seeking approval of the drug, courts have rejected such pre-approval theories. (Reply at 8–9.) Second, to the extent the claim is premised on a theory that Gilead should have amended the label post-approval, Gaetano has not identified any "newly acquired information" that would have allowed Gilead to unilaterally change the label consistent with federal law. (*Id.* at 10–12.) I discuss each contention in turn.

a. Pre-Approval Theory

Gilead argues that a pre-approval failure-to-warn claim is preempted because it "second-guesses" the FDA's judgment that the label was adequate. (Mot. 18; Reply at 9.) Neither the Supreme Court nor the Third Circuit has addressed whether a pre-approval failure-to-warn claim is preempted in this way. *Wyeth*, *Mensing*, and *Bartlett* all dealt with whether a manufacturer could change a label post-approval. Nonetheless, based on the principles of those cases, I conclude that Gaetano's pre-approval failure-to-warn claim is not preempted.[6]

I start with the "central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times." *Merck*, 139 S. Ct. at 1677 (citation omitted). More specifically, when applying for FDA approval for a drug, manufacturers propose labeling. 21 U.S.C. § 355(b)(1)(A)(vi); 21 C.F.R. § 314.50(c)(2)(i). The FDA's approval of the drug

[6] I do not interpret the Complaint to be alleging a fraud-on-the-FDA claim, and Gaetano's brief disavows any such claim. (Opp. at 13 n.5.) Claims that a manufacturer made fraudulent representations to the FDA during the approval process are preempted because they "conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001). The claim here, however, is the distinct one that the proposed warnings could have been stronger, and a stronger warning would have prevented Gaetano's injuries. *Holley*, 379 F. Supp. 3d at 825.

includes the approval of the proposed label. *See* 21 C.F.R. § 314.105(b). Thus, "[a] drug manufacturer is charged . . . with crafting an adequate label." *Merck*, 139 S. Ct. at 1677 (quotation marks and citation omitted).

As a result, "[j]ust as Gilead has pointed to no federal law that would have prevented it from submitting TAF drugs rather than TDF drugs for approval in the first instance, it has also cited no federal law that would prevent a drug manufacturer from submitting a different warning label to the FDA prior to initial approval of a drug." *Holley*, 379 F. Supp. 3d at 826. That is, Gilead "possessed the ability to implement stronger warning language into labeling" it proposed to the FDA, so state law could have imposed a duty to make a stronger label without running afoul of federal law. *In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 12-CV-64, 2014 WL 60298, at *7 (W.D. La. Jan. 7, 2014). There was no federal duty constraining what label Gilead could propose, so state law could fill that gap. *See Wyeth*, 555 U.S. at 578 (failure-to-warn claims "offer[] an additional, and important, layer of consumer protection that complements FDA regulation").

Gilead falls back on the idea that *after* the FDA approved Truvada's label, Gilead could not "use state law to 'second guess . . . an FDA judgment.'" (Mot. at 18 (quoting *In re Celexa & Lexapro Mktg. & Sales Pracs. Litig.*, 779 F.3d 34, 41 (1st Cir. 2015))). But *Wyeth* rejected the very similar argument that, "[o]nce the FDA has approved a drug's label, a state-law verdict may not deem the label inadequate." 555 U.S. at 573–74. Rather, the FDCA and FDA regulations preempt state-law based changes only when the manufacturer is constrained from making changes under federal law. *See Mensing*, 564 U.S. at 618; *Bartlett*, 570 U.S. at 484–85. There are no such constraints upon a manufacturer when it is choosing what labeling to propose to the FDA; only after a label is approved is the manufacturer's discretion constrained by federal law.

The cases cited by Gilead do not persuade me otherwise. I focus here on two.

The first is the opinion of the United States Court of Appeals for the First Circuit in *Celexa*. There, plaintiffs claimed that California law required an FDA-approved drug label to include different information about a drug's efficacy. 779 F.3d at 38. The Court of Appeals held that claims based on information available at the time of the approval process are preempted because "the FDA [is] the exclusive judge of safety and efficacy based on information available at the commencement of marketing." *Id.*; *see also Maze v. Bayer Healthcare Pharm. Inc.*, No. 18-CV-21, 2019 WL 1062387, at *3 (E.D. Tenn. Mar. 6, 2019) (adopting *Celexa*'s position).

That view, however, contradicts the Supreme Court's holdings that the "FDA's power to approve or to disapprove labeling changes" does not "by itself, pre-empt[] state law" and that "FDA oversight" is not "the exclusive means of ensuring drug safety and effectiveness." *Merck*, 139 S. Ct. at 1677 (citing *Wyeth*, 555 U.S. at 574). The First Circuit purported to draw its rule from *Wyeth* and *Mensing*, 779 F.3d at 41, but those cases considered only a manufacturer's duties post-approval, an important distinction. What is more, the First Circuit cited *Wyeth* and *Mensing* for a general rule that state-law requirements cannot "second guess" the FDA's judgment. 779 F.3d at 41. That is too broad a statement. The Supreme Court in *Wyeth* and *Mensing* considered only preemption based on the impossibility of compliance with both federal and state law. The First Circuit's more general "obstacle preemption" or "second guessing" principle cannot be found there. *See Mensing*, 564 U.S. at 618 n.4 ("We do not address whether state and federal law directly conflict in circumstances beyond impossibility." (quotation marks and citation omitted)).[7]

[7] To explain a little further, the manufacturer in *Wyeth* argued that state-law claims were preempted under two lines of preemption cases: (1) a line that holds that state requirements are preempted if it is impossible to comply with state and federal requirements, and (2) a line that holds that that state law is preempted when it stands as an obstacle to federal law, such as by second-guessing a federal agency's judgment. 555 U.S. at 564 (citations omitted). The Court held that there could be preemption in the prescription drug context under the first line of cases, known as impossibility preemption. *Id.* at 568–73. But the Court rejected the argument that preemption could

On just those grounds, at least one court has declined to follow *Celexa*, and I agree. *See Holley*, 379 F. Supp. 3d at 826.

Next, Gilead relies on *Utts v. Bristol-Myers Squibb Co.*, 226 F. Supp. 3d 166 (S.D.N.Y. 2016). That court held that pre-approval failure-to-warn claims are preempted because FDA-approved labeling reflects "the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." *Id.* at 184. For that proposition, it cited a regulatory preamble, "Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products," 71 Fed. Reg. 3,922, 3,934 (Jan. 24, 2006)). The court thus reasoned, like *Celexa*, that pre-approval claims impermissibly second-guess the FDA's judgment.

Not only has the Supreme Court generally disapproved that argument (as explained above); the Court in *Wyeth* expressly rejected reliance on the regulatory preamble cited by *Utts*. In *Wyeth*, the manufacturer relied on that preamble to argue that the FDA "leaves no room for different state-law judgments." 555 U.S. at 575. The Court held that the preamble did not have anything like that effect. To find that the preamble requires preemption of failure-to-warn claims, says *Wyeth*, would undermine (a) a federal legislative scheme that allowed for state tort liability (the FDCA has no express preemption provision); and (b) the FDA's longstanding position that "federal labeling standards [are] a floor upon which States could build." *Id.* at 577–78.

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be found based on obstacle preemption or the idea that state law cannot second-guess the FDA. *Id.* at 573–81. The Court has maintained the distinction that impossibility preemption is recognized in the prescription drug context, but obstacle preemption is not. *See Mensing*, 564 U.S. at 618 n.4. Thus, the First Circuit in *Celexa* adopted an obstacle preemption rule which the Supreme Court has rejected in one context and expressed skepticism about in another. *See Wyeth*, 555 U.S. at 573–81 (rejecting obstacle preemption argument); *Mensing*, 564 U.S. at 618 n.4 (declining to address obstacle preemption argument).

Accordingly, I am unwilling to adopt the holding of *Utts,* which is in considerable tension with Supreme Court authority.[8]

* * *

In sum, I conclude that Gaetano's claim under New Jersey law that Gilead should have proposed a stronger label to the FDA is not preempted.

b. Post-Approval Theory

Gaetano alleges that Gilead should have amended the label post-approval to reflect its evolving understanding of Truvada's risks. (*E.g.*, Compl. ¶¶ 40–49.) *Wyeth* held that a failure-to-warn claim is not preempted if the manufacturer could change the label without FDA approval. Specifically, the FDA's "changes being effected" ("CBE") regulation allows a brand-name manufacturer to change a label without first obtaining FDA approval (subject, of course, to FDA review thereafter). 555 U.S. at 568–69.[9] The CBE regulation provides, however, that the labeling change must be based on "newly acquired information." *Id.* at 568.[10] Accordingly, courts hold that a failure-to-warn claim

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[8] The Second Circuit affirmed *Utts* in *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019). But in affirming, the court focused on "the requirements to properly plead and then prove a state law failure-to-warn claim based on *post-drug-release information*." *Id.* at 708. The court did not discuss *Utts*'s reasoning regarding pre-approval failure-to-warn claims.

[9] Based on the FDA's ability to later reject the label, *Wyeth* created a fairly narrow exception to its holding. If a manufacturer can provide "clear evidence" that the FDA *would* reject the label, *Wyeth* allows that a manufacturer could demonstrate that it would be impossible to amend the label and remain compliant with federal law. *Wyeth*, 555 U.S. at 571. Gilead does not argue that Gaetano's stronger proposed warnings would have been rejected, so I do not consider the issue.

[10] There is a wrinkle. The "newly acquired information" requirement was added to the CBE regulation in 2008. *Wyeth*, 555 U.S. at 568. So Gaetano argues that Gilead is liable for failing to add additional warnings prior to 2008 regardless of whether Gilead had newly acquired information then. (Opp. at 13.)

One court agrees with him, *see Holley*, 379 F. Supp. 3d at 828, but I do not. Although the newly acquired information requirement was not codified until 2008, that requirement was previously "the agency's longstanding view." Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2,848, 2,849 (Jan. 16, 2008). Indeed, the FDA "proposed what is essentially the current CBE procedure in 1982," *id.*, and explained then that labeling

against a brand-name manufacturer is not preempted when the plaintiff's suggested label changes were supported by newly acquired information; in such a case, the manufacturer may invoke the CBE regulation to make such changes unilaterally. *Knight v. Boehringer Ingelheim Pharms., Inc.*, 984 F.3d 329, 337 (4th Cir. 2021); *Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699, 708 (2d Cir. 2019); *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 812 (7th Cir. 2018); *Celexa*, 779 F.3d at 41.

So unless the manufacturer possesses newly acquired information, it cannot unilaterally change the label. It follows, says Gilead, that Gaetano's Complaint cannot survive a motion to dismiss unless it alleges that Gilead possessed newly acquired information, as defined by FDA regulations. (Mot. at 16–18.) Newly acquired information is defined as that which "reveal[s] risks of a different type or greater severity or frequency than previously included in submissions to [the] FDA." 21 C.F.R. § 314.3(b). "[N]ewly acquired information is not limited to new data, but also encompasses new analyses of previously submitted data." *Wyeth*, 555 U.S. at 569. The risks Gaetano complains of, Gilead argues, were all risks Gilead knew about when Truvada was approved, so they do not constitute newly acquired information.

But the question of whether a plaintiff must *plead* that the manufacturer possessed newly acquired information presents a different, procedural issue. This is so because "[p]reemption is an affirmative defense." *Lupian v. Joseph Cory Holdings Co.*, 905 F.3d 127, 130 (3d Cir. 2018). As a result, "dismissal is appropriate under Rule 12(b)(6) only when preemption is manifest in the

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changes should be made "to correct concerns about newly discovered risks," New Drug & Antibiotic Regulations, 47 Fed. Reg. 46,622, 46,623 (Oct. 19, 1982). Further, the FDA had consistently interpreted the CBE mechanism as applicable when a manufacturer has newly discovered information. Brief for the United States as Amicus Curiae, *Wyeth v. Levine*, No. 06-1249, 2008 WL 2308908, at *4 (June 2, 2008). Thus, the FDA effectively had the newly acquired information requirement in place prior to 2008, even if it was not codified in the regulation. *See Ramsay v. Nat'l Bd. of Med. Exam'rs*, 968 F.3d 251, 258 n.8 (3d Cir. 2020) ("[T]he preamble to a regulation may be used as an aid in determining the meaning of a regulation." (citation omitted)).

complaint itself." *Id.* at 130–31 (quotation marks and citation omitted). Affirmative defenses generally depend on extrinsic facts, and the Third Circuit therefore requires that a court tread warily, dismissing under Rule 12(b)(6) only when the plaintiff has effectively pled itself out of court.[11]

Dismissal is thus appropriate only if it is manifest from the face of the Complaint that the risks Gilead allegedly failed to warn about did *not* meet the definition of newly acquired information. *See id.*; *In re Asbestos Prods. Liab. Litig. (No. VI)*, 822 F.3d 125, 133 & n.6 (3d Cir. 2016) (a complaint's omission of facts relevant to a preemption inquiry will preclude dismissal based on a preemption defense).[12] This Gilead cannot show, because some of Gaetano's allegations, interpreted in the light most favorable to him, do seem to concern newly acquired information. Gaetano alleges that "[f]rom October 2001 through May 20, 2007, Defendant's labelling . . . failed to warn doctors that all patients should be monitored for adverse kidney effects, . . . although Defendant knew through its studies that otherwise healthy individuals were experiencing adverse kidney events." (Compl. ¶ 40.) It cannot be gleaned from the face of the

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[11] *Cf. Fried v. JP Morgan Chase & Co.*, 850 F.3d 590, 604 (3d Cir. 2017) (statute of limitations, an affirmative defense, must generally be pled in an answer and cannot be the basis of a Rule 12(b)(6) dismissal unless its application is apparent on the face of the complaint); *Rycoline Prods., Inc. v. C & W Unlimited*, 109 F.3d 883, 886 (3d Cir. 1997) (similar holding as to res judicata defense).

[12] Most courts to address how the newly acquired information requirement fits into the preemption inquiry have done so outside the context of a motion to dismiss. *Wyeth*, 555 U.S. at 562–63 (appeal of denial of post-judgment motions); *Knight*, 984 F.3d at 337 (same); *Dolin*, 901 F.3d at 812 (same). The First and Second Circuits, however, have held that, to survive a motion to dismiss, a plaintiff must plausibly allege newly acquired information. *Gibbons*, 919 F.3d at 708; *Celexa*, 779 F.3d at 41–43; *accord Holley*, 379 F. Supp. 3d at 828 (adopting standard from *Gibbons* and *Celexa*). Neither court acknowledged that preemption is an affirmative defense, and that impossibility preemption in the prescription-drug context is especially "demanding." *Wyeth*, 555 U.S. at 573. I find that these courts' pleading requirement is incompatible with the Third Circuit's approach to evaluating preemption on a motion to dismiss. *See Lupian*, 905 F.3d at 130–31; *Asbestos Prods.*, 822 F.3d at 133 & n.6; *see also Evans*, 2020 WL 5189995, at *10 (rejecting requirement to plead newly acquired information based on similar case law from the Ninth Circuit).

Complaint that the "studies" referred to all date from before Truvada's approval in 2004. That is a fact that must be developed in discovery. Further, throughout the late 2000's, Gilead provided stronger monitoring recommendations and warnings to physicians and patients in the EU. (*Id.* ¶ 50.) And through at least 2018, Gilead strengthened its US label multiple times. (*Id.* ¶¶ 41–47.) From those allegations, I can infer that Gilead, in the post-approval period, came into possession of new information that warranted stronger warnings.[13] Thus, I cannot say that it is "manifest" on the face of the Complaint that Gilead lacked newly acquired information in the post-approval period. Accordingly, any finding of preemption would be premature in the context of this Rule 12(b)(6) motion.

* * *

To sum up, none of the possible theories Gaetano may pursue for his product liability claims is preempted. Gilead's motion to dismiss, to the extent it is based on preemption, is therefore denied.

B. Presumption of Adequacy

Apart from preemption, Gilead argues that Gaetano's failure-to-warn claim fails as a matter of New Jersey law, based on the "presumption of adequacy" of FDA-approved warnings. (Mot. at 19–21.) The NJPLA provides that "the manufacturer . . . shall not be liable for harm caused by a failure to warn if the product contains an adequate warning." N.J. Stat. Ann. § 2A:58C-4. An "adequate product warning" is defined as "one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product." *Id.* The NJPLA further provides that if a warning

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[13] That Gilead strengthened its warnings does not preclude Gaetano's failure-to-warn claim for two reasons. First, he alleges that the warnings, even as strengthened, were still inadequate. (Compl. ¶ 46, 48–49.) Second, he may press a theory that Gilead should have made the revisions earlier, *i.e.*, that Gilead knew about the risks but unreasonably delayed in amending the label. *See In re Accutane Litig.*, 194 A.3d 503, 530 (N.J. 2018).

was approved by the FDA, then "a rebuttable presumption shall arise that the warning . . . is adequate." *Id.*

The New Jersey Supreme Court treats this presumption of adequacy not as an affirmative defense, but as a carve-out from substantive liability. I reach this conclusion based on the context, as well as the court's requirement that the plaintiff plead around the presumption in the complaint. *See Cornett v. Johnson & Johnson*, 48 A.3d 1041, 1056 (N.J. 2012) ("To overcome this presumption, a plaintiff asserting a failure to warn claim based on an inadequate label or instructions has stricter pleading requirements."), *abrogated on other grounds by McCarrell v. Hoffmann-La Roche, Inc.*, 153 A.3d 207 (N.J. 2017). In federal-procedure terms, that equates to a requirement that a plaintiff plausibly allege that the presumption can be overcome.[14] *See Lara v. Cool Clouds Distrib., Inc.*, Civ. No. 20-8030, 2021 WL 613842, at *13 (D.N.J. Feb. 26, 2021); *Greisberg v. Bos. Sci. Corp.*, Civ. No. 19-12646, 2020 WL 4435409, at *4 (D.N.J. Aug. 3, 2020); *Fellner v. Tri-Union Seafoods, L.L.C.*, Civ. No. 06-0688, 2010 WL 1490927, at *6 (D.N.J. Apr. 13, 2010). The complaint need not establish unequivocally that a plaintiff "will ultimately overcome the presumption," but it must plausibly allege that plaintiff will do so with the aid of discovery. *Fellner*, 2010 WL 1490927 at *6.

The presumption can be overcome in three ways: (1) "a plaintiff can establish deliberate concealment or nondisclosure of after-acquired knowledge of harmful effects"; (2) "a plaintiff can demonstrate economically-driven manipulation of the post-market regulatory process"; and (3) "a plaintiff can prove by clear and convincing evidence that a manufacturer knew or should have known in the postmarketing phase that the drug warnings were inadequate based on the label warning updating requirements in [the CBE

[14] I do not suggest, of course, that state pleading standards govern a motion to dismiss in federal court; obviously, the Federal Rules of Civil Procedure control here. But the state court's definition of the elements of substantive liability do provide the rule of decision in this diversity case. I believe that principle accounts for the approach of the District of New Jersey cases cited in this paragraph.

regulation]." *In re Accutane Litig.*, 194 A.3d 503, 531 (N.J. 2018) (quotation marks and citations omitted).

Gaetano pleads facts that fall into all three of these categories. First, his allegation about stronger warnings in the EU gives rise to an inference that Gilead knew of harmful effects but did not disclose them to the US market. Second, he alleges that Gilead took on a business strategy of downplaying risks and published studies understating the seriousness of kidney problems associated with TDF drugs—all while the FDA issued warnings to stop. (Compl. ¶¶ 37–38, 55–57.) What is more, this was allegedly done to maintain demand for TDF-based drugs. (*See id.* ¶ 70.) Such conduct is similar to a manufacturer's financially motivated downplaying of risks, misrepresentation of studies, and resistance to proposals by the FDA for a stronger warning label that represented "economically-driven manipulation" in *McDarby v. Merck & Co., Inc.*, 949 A.2d 223, 259–60 (N.J. Super. Ct. App. Div. 2008). *See also Accutane*, 194 A.3d at 533 (adopting *McDarby*). Third, for the reasons explained in Section III.A.3.b, *supra*, Gilead allegedly possessed "newly acquired information" that should have prompted label changes via the CBE regulation, or at least prompted them earlier. Thus, it is plausibly alleged that these facts, if proven and developed, could overcome section 2A:58C-4's presumption of adequacy. *See Lara*, 2021 WL 613842, at *13; *Fellner*, 2010 WL 1490927, at *6.

To the extent Gilead moves to dismiss the failure-to-warn claim based on the presumption of adequacy, its motion is denied.

IV. CONCLUSION

For the reasons set forth above, the motion to dismiss is denied.

A separate order will issue.

Dated: March 26, 2021

/s/ Kevin McNulty

Hon. Kevin McNulty
United States District Judge