UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

ADRIAN HOLLEY, et al.,

Plaintiffs,

v.

GILEAD SCIENCES, INC.,

Defendant.

Case No. 18-cv-06972-JST

ORDER GRANTING IN PART AND DENYING IN PART DEFENDANT'S MOTION FOR SUMMARY JUDGMENT ON COMMON ISSUES

Re: ECF No. 1126

Before the Court is Defendant Gilead Sciences, Inc.'s motion for summary judgment on common issues. ECF No. 1126. The Court will grant the motion in part and deny it in part.

I. BACKGROUND

Plaintiffs in these cases have taken one of more of Gilead's drugs containing tenofovir disoproxil fumarate ("TDF"): Viread, Truvada, Atripla, Complera, and Stribild. The Court has consolidated approximately 75 cases for pretrial purposes only, with over 3,000 remaining plaintiffs from the District of Columbia and every state except for California and Delaware.[1]

Plaintiffs contend that they have suffered unnecessary kidney and bone damage caused by Gilead's failure to provide adequate warnings and its profit-driven decision to develop drugs containing TDF rather than the allegedly safer tenofovir alafenamide fumarate ("TAF"). Under their respective states' laws, Plaintiffs assert claims based on design defect, failure to warn, negligence, fraud, breach of the implied warranty of merchantability, and violation of consumer protection laws.

The Food and Drug Administration ("FDA") first approved Viread in 2001, with approvals

[1] These cases do not include plaintiffs from California or Delaware because their inclusion would deprive the Court of diversity jurisdiction. ECF No. 123 at 8, 12; ECF No. 138 at 4–5, 10.

for Truvada, Atripla, Complera, and Stribild coming in 2004, 2006, 2011, and 2012, respectively. Gilead has also received FDA approval for three TAF drugs: Genvoya in 2015 and Odefsey and Descovy in 2016. All of these drugs are used to treat and, in some cases, prevent HIV/AIDS.

Prior to the approval of Viread, Gilead had already started developing TAF. It completed its first clinical trial of TAF, GS-120-1101 or Study 1101, in 2003, and it stopped development of TAF in 2004. Gilead contends that it did so because there did not appear to be significant differences between TDF and TAF, and a toxicology study in dogs showed potentially new side effects for TAF as compared to TDF. Plaintiffs argue that Gilead knew that TAF was a safer alternative to TDF, but that it was driven by profits and believed that developing TAF drugs would harm sales of TDF drugs already in development or on the market. With FDA approval, Gilead re-started TAF development in 2010. It argues that it did so at that time because the HIV patient population was evolving, and Gilead viewed TAF as a potential lower-dose alternative for an aging population that had higher risks of renal and bone-density issues.

The Court has resolved two rounds of motions to dismiss. When ruling on the first motion, the Court dismissed with leave to amend "Plaintiffs' failure-to-warn claims based on post-approval, post-2008 labeling changes, and . . . Plaintiffs' fraud and consumer protection claims to the extent those claims are based on misrepresentations and not omissions." ECF No. 75 at 30. The Court subsequently dismissed without leave to amend "Plaintiffs' fraud and consumer protection claims to the extent they rely on allegations of affirmative misrepresentations rather than omissions, as well as Plaintiffs' post-approval, post-July 2012 failure-to-warn claims." ECF No. 123 at 12. Of relevance to Gilead's motion for summary judgment, the Court concluded that Plaintiffs' design-defect claims, pre-approval failure-to-warn claims, and post-approval, pre-July 2012 failure-to-warn claims were not preempted. *Id.* at 12–24; ECF No. 123 at 8–11.

Now before the Court is Gilead's motion for summary judgment on common issues, in which it seeks summary judgment on all of Plaintiffs' claims. ECF No. 1126.

II. JURISDICTION

The Court has jurisdiction under 28 U.S.C. § 1332(a).

III. LEGAL STANDARD

Summary judgment is proper when a "movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). A dispute is genuine only if there is sufficient evidence "such that a reasonable jury could return a verdict for the nonmoving party," and a fact is material only if it might affect the outcome of the case. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). When deciding a motion for summary judgment, the court must draw "all justifiable inferences" in the nonmoving party's favor and may not weigh evidence or make credibility determinations. *Id.* at 255.

Where the party moving for summary judgment would bear the burden of proof at trial, that party "has the initial burden of establishing the absence of a genuine issue of fact on each issue material to its case." *C.A.R. Transp. Brokerage Co. v. Darden Rests., Inc.*, 213 F.3d 474, 480 (9th Cir. 2000). Where the party moving for summary judgment would not bear the burden of proof at trial, that party "must either produce evidence negating an essential element of the nonmoving party's claim or defense or show that the nonmoving party does not have enough evidence of an essential element to carry its ultimate burden of persuasion at trial." *Nissan Fire & Marine Ins. Co. v. Fritz Cos.*, 210 F.3d 1099, 1102 (9th Cir. 2000). If the moving party satisfies its initial burden of production, the nonmoving party must produce admissible evidence to show that a genuine issue of material fact exists. *Id.* at 1102–03. It is not the court's duty "to scour the record in search of a genuine issue of triable fact"; instead, the nonmoving party must "identify with reasonable particularity the evidence that precludes summary judgment." *Keenan v. Allan*, 91 F.3d 1275, 1279 (9th Cir. 1996) (quoting *Richards v. Combined Ins. Co.*, 55 F.3d 247, 251 (7th Cir. 1995)) . If the nonmoving party fails to make the required showing, the moving party is entitled to summary judgment. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322–23 (1986).

IV. DISCUSSION

A. Design Defect

1. Preemption

This Court has previously explained the analytical framework for the "demanding" defense of impossibility preemption, *Wyeth v. Levine*, 555 U.S. 555, 573 (2009), in the drug-

manufacturing context:

> First, courts must determine whether a drug manufacturer may independently take action that complies with both state and federal law. An action is independent under this analysis if the manufacturer can take such action without prior FDA approval, even if the FDA may subsequently reject approval of the action post hoc. If independent action is not possible, then the state-law claims are preempted. If independent action is possible, then the claims are preempted only if there is clear evidence that the FDA would not grant approval.

ECF No. 75 at 11–12. The preemption analysis begins with considering a manufacturer's duties under both state and federal law. *Id.* at 12 (citing *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472, 480 (2013); *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 611 (2011)). In their briefs on the motion to dismiss, the parties did not "attempt[] to describe Gilead's duties under any particular state law," and "the Court assume[d] without deciding that the state laws invoked by Plaintiffs required Gilead to use TAF rather than TDF, and to use a lower dose of TDF before submitting Stribild to the FDA for approval." *Id.* at 12–13.

Gilead now argues that the laws of the relevant states require a manufacturer "to market and distribute a reasonably safe product."[2] ECF No. 1126 at 24–25. It further argues that a manufacturer therefore has no duty "to design a safer product *in the abstract* that may or may never become available to consumers." *Id.* at 24 (emphasis added). However, the allegations in this case do not occur in the abstract. Plaintiffs do not argue that Gilead is liable because it had an independent duty to design drugs containing TAF in a vacuum. Instead, they allege that the TDF drugs they consumed were defective because Gilead failed to consider TAF as a safer alternative and that, instead of seeking approval for the TDF drugs, Gilead should have offered a different formulation for FDA approval. There is no dispute that Gilead distributed TDF drugs that were consumed by Plaintiffs, and it is to those drugs that the relevant duty applies. Even if, as Gilead argues, no duty arises from a drug manufacturer to a consumer until a transaction occurs, the transactions occurred in this case when Plaintiffs purchased Gilead's TDF drugs.

The Court discusses two states as illustrative. First, under Illinois law, "[t]he doctrine of

[2] For purposes of this motion "Gilead accepts . . . Plaintiffs' contention that the laws of their resident states govern their claims." ECF No. 1126 at 17.

strict liability was not intended to encompass injuries resulting from a 'product' which is in an unmarketable state and which had not yet been released into the stream of commerce by sale or display to the consumer." *Genaust v. Ill. Power Co.*, 343 N.E.2d 465, 470 (Ill. 1976). Gilead attempts to characterize TAF drugs as the product "in an unmarketable state" for which strict liability would not apply. Plaintiffs, however, do not claim injury from the "unmarketable" TAF drugs. Instead, their alleged injuries are from the TDF drugs, which Gilead indisputably "released into the stream of commerce." *Id.* Similarly, Gilead argues that preemption is supported by Arizona law, under which "[t]he essence of a negligence action based on defective design is that defendant distributed a product when it was reasonably foreseeable that its design presented an unreasonable risk of harm." *Jones v. Pak-Mor Mfg. Co.*, 700 P.2d 819, 823 (Ariz. 1985). Gilead contends that Plaintiffs' design-defect claims are preempted because Gilead requires FDA approval before distributing a drug. Plaintiffs' claims, however, are based on the distribution of TDF drugs, not TAF drugs, and the inability of Gilead to distribute TAF drugs without FDA approval is not relevant to the preemption analysis.

Plaintiffs' design-defect claims are not preempted.

2. Merits

a. Strict Liability in Certain States

The parties agree that five states—Massachusetts, North Carolina, Pennsylvania, Virginia, and Utah—do not recognize design-defect claims for prescription drugs based on strict liability. Summary judgment is therefore granted to Gilead as to those claims.

b. Alabama

The parties dispute whether Alabama law allows design-defect claims based on strict liability and negligence. In *Stone v. Smith, Kline & French Laboratories*, the Alabama Supreme Court opined that Alabama's adoption of comment k to Section 402A of the Restatement (Second) of Torts "provides for drugs and vaccines an exception to the strict liability defined in Section 402A." 447 So. 2d 1301, 1303 (Ala. 1984). It concluded "that in the case of an 'unavoidably unsafe' yet properly prepared prescription drug, the adequacy of the accompanying warning determines whether the drug, as marketed, is defective or unreasonably dangerous." *Id.* at 1304

(footnote omitted).

Relying on *Stone*, courts have held that, "no . . . design defect claim for prescription drugs exists [under Alabama law] apart from a challenge to the adequacy of the warning," and that this includes claims under both strict liability and negligence theories because "[t]he Alabama Supreme Court has found the safety element common to both strict liability and negligence claims." *Barcal v. EMD Serono, Inc.*, No. 5:14-cv-01709-MHH, 2016 WL 1086028, at *3 (N.D. Ala. Mar. 21, 2016) (citing *McMahon v. Yamaha Motor Corp.*, 95 So. 3d 769, 772 (Ala. 2012)); *see also McDaniel v. Mylan, Inc.*, No. 7:19-cv-00209-LSC, 2019 WL 11638407, at *5 (N.D. Ala. Dec. 16, 2019) (following *Barcal*); *Tatum v. Schering Corp.*, 795 F.2d 925, 926 (11th Cir. 1986) ("Because ethical drugs are considered unavoidably unsafe products, they are defective only when not accompanied by an adequate warning."); *Cooper v. Bristol-Myers Squibb Co.*, Civ. Action No. 07-885 (FLW), 2013 WL 85291, at *10 (D.N.J. Jan. 7, 2013) ("[U]nder Alabama law, only those drugs that are 'not accompanied by ethical warnings' may form the basis of a defective design claim." (quoting *Stone*, 447 So. 2d at 1304)); *Moss v. Wyeth, Inc.*, 872 F. Supp. 2d 162, 167-68 (D. Conn. 2012) (listing Alabama as a state that "provide[s] all prescription drugs categorical immunity from strict liability for design defects"); *In Re Yasmin & Yaz (Drospirenone) Mktg., Sales Pracs. & Prods. Liab. Litig.*, 870 F. Supp. 2d 587, 595 (S.D. Ill. 2012) ("[U]nder *Stone*, with a properly prepared product, the element of 'defect' in a drug case under [Alabama law] turns on the adequacy of the warning that accompanied the product.").

Plaintiffs have cited no case interpreting *Stone* to permit strict liability or negligence claims for prescription drugs based on design defect. Although they cite three cases where "courts have permitted design defect claims involving drugs or devices to proceed under Alabama law," ECF No. 1156 at 31, none of those cases engaged with the question of whether Alabama law categorically bars liability for prescription drugs or devices, and it appears that the parties in those cases did not raise that question. *See Houston v. Bayer Healthcare Pharms., Inc.*, 16 F. Supp. 3d 1341, 1348–49 (N.D. Ala. 2014); *Woodcock v. Mylan, Inc.*, 661 F. Supp. 2d 602, 611–12 (S.D.W. Va. 2009); *In re Tylenol (Acetaminophen) Mktg., Sales Pracs. & Prods. Liab. Litig.*, MDL No. 2436, 2015 WL 7075949, at *14–20 (E.D. Pa. Nov. 13, 2015).

The Court follows the authority of every court to have decided the question and grants summary judgment to Gilead on Plaintiffs' design-defect claims under Alabama law, under both strict liability and negligence theories.

c. Remaining States

The parties agree that in the remaining jurisdictions, with two exceptions,[3] the risk-utility analysis applies.[4] The parties also do not dispute that expert testimony is required to assist the finder of fact with the risk-utility analysis, but Gilead argues that Plaintiffs have not presented expert testimony on necessary issues.

Plaintiffs present testimony regarding the risks of TDF and the relative safety of TAF as to kidney and bone toxicities—for example: that "TDF is clearly associated with kidney injury and disease," ECF No. 1157-26 ¶ 6; "Gilead did not adequately investigate the kidney toxicities or TDF in its early clinical trials," *id.* ¶ 10 (emphasis omitted); "TAF is much safer for the kidneys than is TDF and is capable of preventing or reducing kidney injury compared to TDF," *id.* ¶ 18; and studies "demonstrate[d] that TAF was safer than TDF while still being at least as effective for HIV control," *id.* at 75. They also present testimony that "scientific evidence from multiple sources that accumulated from the launch of TDF in 2001 through October of 2004 clearly established a reasonable probability that TDF had serious adverse effects on kidneys and bones,"

[3] The parties debate whether Nebraska and Nevada have rejected the risk-utility test in favor of a consumer-expectations test, but they discuss that issue only in footnotes. ECF No. 1126 at 18 n.2; ECF No. 1156 at 26 n.8; ECF No. 1189 at 12 n.1. The Court has previously explained that raising arguments only in footnotes is improper. ECF No. 75 at 30 (citing *Estate of Saunders v. Comm'r*, 745 F.3d 953, 962 n.8 (9th Cir. 2014), and *Sanders v. Sodexo, Inc.*, No. 2:15-cv-00371-JAD-GWF, 2015 WL 4477697, at *5 (D. Nev. July 20, 2015)). Accordingly, the Court does not reach the parties' arguments about Nebraska and Nevada. Gilead may renew its arguments, if appropriate, if individual Plaintiffs' claims from those states come before the Court.

[4] Gilead's motion cites Section 6(c) of the Restatement (Third) of Torts: Product Liability, which states: "A prescription drug or medical device is not reasonably safe due to defective design if the foreseeable risks of harm posed by the drug or medical device are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers, knowing of such foreseeable risks and therapeutic benefits, would not prescribe the drug or medical device for any class of patients." ECF No. 1126 at 18. But Gilead has cited no authority that any jurisdiction has adopted this stringent test. Section 6(c) "is a conscious rejection of the risk-utility test, which would ask whether the manufacturer could have reasonably produced a drug just as beneficial without the risks," and "thus far courts have rejected it." Dan B. Dobbs, Paul T. Hayden and Ellen M. Bublick, *The Law of Torts* § 461 (2d ed.).

ECF No. 1157-2 ¶ 8(a); "preclinical studies with TAF confirmed it had a significant safety margin over TDF," ECF No. 1157-17 ¶ 49; and evidence before October 2004 suggested "a high likelihood of TAF being a safer prodrug than TDF, primarily due to its lower systemic exposure to tenofovir," *id.* ¶ 56.

Gilead argues that testimony about the risks of TDF, without weighing those risks against TDF's undisputed benefits in treating and preventing HIV, is insufficient. The Court disagrees. First, the cases relied on by Gilead for the proposition that expert testimony is required to prove a design defect do not establish that experts must specifically weigh risks and benefits. *See* ECF No. 1126-1 at 2–4. For example, Gilead relies on a Georgia case where the court stated that, at summary judgment, plaintiffs "must produce evidence from an expert who is qualified to conduct the risk-utility analysis and to opine that the risks inherent in [the challenged product's] design outweigh the utility or benefit derived from the product." *In re Mentor Corp. ObTape Transobturator Sling Prods. Liab. Litig.*, 711 F. Supp. 2d 1348, 1365 (M.D. Ga. 2010). However, for that proposition, the court relied on *Dean v. Toyota Industrial Equipment Manufacturing, Inc.*, 540 S.E.2d 233 (Ga. Ct. App. 2000), which did not impose such a stringent requirement. To the contrary, *Dean* stated that "the weighing of the risk-utility factors is to be done *by the trier of fact*," and that "a product's risks and benefits will rarely be determined as a matter of law when any of the *Banks* factors is disputed." *Id.* at 237 (emphasis in original). The *Banks* factors include "the state of the art at the time the product is manufactured" and "the manufacturer's ability to eliminate the danger without impairing the product's usefulness or making it too expensive"—issues on which Plaintiffs here have presented expert testimony. *Id.* (citing *Banks v. ICI Americas*, 450 S.E.2d 671, 675 & n.6 (Ga. 1994)). The *Dean* court explained that, "by adopting the risk-utility analysis, Georgia has actually increased the burden of a defendant, in seeking a judgment as a matter of law, to show plainly and indisputably an absence of *any* evidence that a product as designed is defective." *Id.* (emphasis in original). Thus, although "[t]here was also evidence supporting [the defendant's] position that the risks of the [product] as manufactured did not outweigh the benefits," entering summary judgment for the defendant was improper because "it was not for the trial court to resolve the facts or reconcile the issues." *Id.* This Court does not

read *Dean* as requiring the specific type of expert testimony that Gilead contends Plaintiffs must present; instead, under *Dean*, the evidence presented by Plaintiffs is sufficient to withstand summary judgment because it raises disputes as to some of the relevant factors under *Banks*. Similarly, that some courts have *allowed* expert testimony that a product's risks outweigh its benefits does not mean that such testimony is *required* to prove a design defect. *See, e.g.*, *Dalbotten v. C.R. Bard, Inc.*, No. 1:20-cv-00034-SPW, 2023 WL 1068771, at *2 (D. Mont. Jan. 27, 2023) ("Whether a product is ultimately defective under Montana law is a question solely for the jury, but an expert is permitted to testify that the filter suffered from several flaws and that, in his opinion, the risks outweighed the benefits without that testimony constituting a legal opinion.").

Second, the Court is not persuaded by Gilead's argument that presenting evidence that a reasonable alternative design existed is insufficient to create a disputed fact over whether a design was defective. Gilead has cited no authority, and the Court has located none, for the proposition that a plaintiff cannot withstand summary judgment on a design-defect claim by presenting evidence of a reasonable alternative design. To the contrary, courts have denied summary judgment when plaintiffs have introduced such evidence. *E.g., In re Xarelto (Rivaroxaban) Prods. Liab. Litig.*, No. MDL 2592, 2017 WL 3140422, at *5–6 (E.D. La. July 21, 2017); *In re Tylenol (Acetaminophen) Mktg.*, 2015 WL 7075949, at *14–19; *Hunt v. McNeil Consumer Healthcare*, 297 F.R.D. 268, 273–74 (E.D. La. 2014).[5] Similarly, the Georgia Supreme Court has described "the reasonableness of choosing from among various alternative product designs and adopting the safest one if it is feasible" as "the 'heart' of design defect cases," and explained that a manufacturer cannot avoid liability if the plaintiff "adduce[s] evidence that a feasible alternative design, which could have prevented or minimized the plaintiff's injury, was available at the time

[5] The *Tylenol* court concluded: "Viewing all the facts in the light most favorable to the plaintiff, a reasonable jury could find that a feasible design existed at the time of [the decedent's] death and the defendants breached their duty to market a safe product." 2015 WL 7075949, at *19. Gilead argues that this means "that plaintiffs still must prove that a defendant 'breached their duty to market a safe product'" in addition to proving the existence of a reasonable alternative design. ECF No. 1189 at 12. However, this Court reads *Tylenol* as stating that a jury could conclude that the defendants breached their duty to market a safe product *because* they could conclude that a feasible design existed. The two inquiries are not separate questions.

the manufacturer made its design, manufacturing, and marketing decisions." *Banks*, 450 S.E.2d at 674 (quoting 78 A.L.R.4th 154); *id.* at 675. And, in Mississippi, "a plaintiff establishes a design defect by proving a product could have been made safer by the adoption of a reasonable alternative design," and, "once sufficient evidence has been presented to the judge so the judge can determine that reasonable people could conclude a reasonable alternative design could have been practically adopted, the issue can be entrusted to a trier of fact." *Williams v. Bennett*, 921 So. 2d 1269, 1275 (Miss. 2006) (citing Restatement (Third) of Torts: Prod. Liab. § 2 (1998)). While Plaintiffs' evidence of a reasonable alternative design may not ultimately convince a jury that Gilead's TDF drugs were defectively designed, Gilead has not persuaded the Court that no reasonable juror could find such evidence dispositive. Accordingly, summary judgment on Gilead's remaining design-defect claims is denied.

B. Negligence

To the extent Plaintiffs' negligence claims are based on the presence of a design defect, summary judgment is denied for the reasons discussed above. Gilead also seeks summary judgment on the question of whether Plaintiffs can prevail on a negligence claim if they fail to "prove that the product was unreasonably dangerous." ECF No. 1126 at 27.

The Court rejects Gilead's argument to the extent it asserts it cannot be held liable for negligence if it is not liable under a strict-liability theory. *E.g., Toner v. Lederle Lab'ys*, 828 F.2d 510, 513 (9th Cir. 1987) (explaining that negligence and strict liability law "require[] the jury to examine the case from two different points of view," such that "it is reasonable" to read jury verdicts finding negligence but not strict liability "as saying that" the defendant's failure to develop an allegedly safer product "was unreasonable conduct, although the danger posed by the product itself was not greater than an ordinary consumer would reasonably expect"). In addition, as stated in cases relied on by Gilead, "a manufacturer may act negligently without its product being unreasonably dangerous." *Slisze v. Stanley-Bostitch*, 979 P.2d 317, 320 (Utah 1999); *see also Morden v. Continental AG*, 611 N.W.2d 659, 673 (Wis. 2000) (negligence theory requires "an underlying product defect," but the plaintiff in a negligence action need not "show that the condition of the product reached the level of unreasonable dangerousness").

However, this does not mean that *all* negligence claims can be successful in the absence of an unreasonably dangerous product. In *Slisze*, for example, the Utah Supreme Court concluded that a manufacturer cannot be "negligent in simply marketing a product that is less safe than another," and noted that it had "never, nor has any other jurisdiction, recognized a duty on the part of a manufacturer to refrain from marketing a non-defective product when a safer model is available, or a duty to inform the consumer of the availability of the safer model." 979 P.2d at 320. Thus, Gilead is entitled to summary judgment on negligence claims based on these asserted duties under Utah law.

The *Slisze* court cited no authority for its conclusion that no other jurisdiction has recognized these duties, and this Court does not find the opinion persuasive on that question. *Prentis v. Yale Manufacturing Co.*, in which the court stated that "the plaintiff must, *in every case, in every jurisdiction*, show that the product was defective," is similarly not persuasive because it cites no out-of-state authority. 365 N.W.2d 176, 181–82 (Mich. 1984) (emphasis in original).

In the absence of briefing from the parties regarding specific duties Plaintiffs assert under each jurisdiction's negligence laws, the Court declines to rule at this time which particular claims are supported by each jurisdiction's laws—aside from the Utah claims discussed above. If appropriate, Gilead may renew its arguments in case-specific summary judgment motions. In preparing for each early trial case, the parties shall meet and confer so that it is clear what duties, if any, Plaintiffs contend Gilead breached.

C. Failure to Warn

Gilead argues that both Plaintiffs' pre-approval and post-approval failure-to-warn claims are preempted.

1. Pre-approval

Gilead concedes that state laws require it to "provide adequate warnings and instructions to consumers" but argues that Plaintiffs' pre-approval failure-to-warn claims are preempted because it "cannot do so without FDA's approval of the proposed initial label." ECF No. 1126 at 31 (emphasis omitted). However, Gilead again "has 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." ECF No. 75 at 18 (order denying motion to dismiss pre-approval failure-to-warn claims as preempted). Nor has Gilead cited any authority for the proposition that FDA approval is dispositive of a pre-approval failure-to-warn claim—i.e., that FDA approval establishes that a drug manufacturer has complied with its duty to provide adequate warnings. To the contrary, the Supreme Court has characterized as a "fundamental misunderstanding" the position "that the FDA, rather than the manufacturer, bears primary responsibility for drug labeling," and explained that the manufacturer "is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market." *Levine*, 555 U.S. at 570–71. Although "the labeling language must not deviate from that which was approved by the FDA, [a manufacturer] still possesse[s] the ability to implement stronger warning language into labeling, by submitting stronger warning language for FDA approval"; thus, "the mere fact that the FDA approved, at various times, labeling language proposed by [the manufacturer] . . . do[es] not offer conclusive proof of preemption." *In re Actos (Pioglitazone) Prods. Liab. Litig.*, No. 12-cv-00064, 2014 WL 60298, at *7 (W.D. La. Jan. 7, 2014). Plaintiffs' pre-approval failure-to-warn claims are not preempted.

2. Post-approval

Plaintiffs argue that "[p]ost-approval failure to warn claims against brand manufacturers are not preempted where the manufacturer can take independent action to strengthen its warnings via the 'changes being effected" (CBE) regulation." ECF No. 1156 at 36. The Supreme Court has explained the FDA drug labeling requirements as follows:

> The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label. See 21 U.S.C. § 355; 21 CFR § 314.105(b) (2008). Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. There is, however, an FDA regulation that permits a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this "changes being effected" (CBE) regulation provides that if a manufacturer is changing a label to "add or strengthen a contraindication, warning, precaution, or adverse reaction" or to "add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product," it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval. §§ 314.70(c)(6)(iii)(A), (C).

Levine, 555 U.S. at 568. As this Court has explained, post-approval failure-to-warn claims against brand-name manufacturers like Gilead "are not preempted if the manufacturer could independently alter the drug label under the CBE regulation and there is not 'clear evidence that the FDA would not have approved a change to [the drug's] label.'"[6] ECF No. 75 at 19–20 (citing *Levine*, 555 U.S. at 568–72) (alteration in original).

Changes under the CBE regulation require that there be "newly acquired information," 21 C.F.R. § 314.70(c)(6)(iii), which is defined as "data, analyses, or other information not previously submitted to the Agency," 21 C.F.R. § 314.3(b). Such information "may include (but is not limited to) data derived from new clinical studies, reports of adverse events, or new analyses of previously submitted data (e.g., meta-analyses) if the studies, events, or analyses reveal risks of a different type or greater severity or frequency than previously included in submissions to FDA." *Id.* The Supreme Court explained that:

> [This definition] accounts for the fact that risk information accumulates over time and that the same data may take on a different meaning in light of subsequent developments: "[I]f the sponsor submits adverse event information to FDA, and then later conducts a new analysis of data showing risks of a different type or of greater severity or frequency than did reports previously submitted to FDA, the sponsor meets the requirement for 'newly acquired information.'"

Levine, 555 U.S. at 569 (quoting 73 Fed. Reg. at 49607).

A defendant manufacturer is entitled to summary judgment on preemption grounds if "there is no newly acquired information that would justify invoking the CBE procedure." *In re Zofran (Ondansetron) Prods. Liab. Litig.*, 57 F.4th 327, 341 (1st Cir. 2023); *see also id.* at n.10 (noting that a manufacturer "is entitled to a finding of preemption due to the lack of newly acquired information"). The parties presume that determining whether "newly acquired information" exists is a legal question, and the Court "follow[s] the parties' lead." *Id.* at 337 (citing *Knight v. Boehringer Ingelheim Pharms., Inc.*, 984 F.3d 329, 337–38 (4th Cir. 2021)); *cf.*

[6] The Court drew a distinction between pre-2008 and post-2008 claims based on the date of an amendment to the CBE regulation. ECF No. 75 at 21–22. Gilead now argues, and Plaintiffs do not dispute, that "newly acquired evidence" is also required for pre-2008 claims. The Court's analysis below therefore applies to all of Plaintiffs' post-approval failure-to-warn claims.

id. at n.7 (noting that, in *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019), the Supreme Court decided that whether "clear evidence" of FDA disapproval exists is a question of law, but the Court "seemingly left open the question whether what constitutes 'newly acquired information' is a question or law or a question of fact"). In resolving that question, "courts may have to resolve subsidiary factual disputes," *Albrecht*, 139 S. Ct. at 1680 (quoting *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 327 (2015)), which do not "warrant submission alone or together with the larger pre-emption question to a jury," *id.*

Gilead argues, and Plaintiffs do not dispute, that Plaintiffs bear the burden of demonstrating that "newly acquired information" exists. This is in accord with the Court's prior ruling that, to survive a motion to dismiss, Plaintiffs must plead a labeling deficiency that Gilead could have corrected using the CBE regulation, which includes pleading the existence of "newly acquired information." ECF No. 75 at 20–24. Additionally, although preemption is an affirmative defense for which Gilead bears the ultimate burden, one court has held that the plaintiff "bears the burden of coming forward with evidence sufficient to conclude that the defendant could and should have availed itself of the applicable federal regulations and given a different warning(s) advocated by the plaintiff," and then the burden shifts to the defendant to present "'clear evidence' that the FDA—even if presented with such 'new' evidence—nonetheless would have rejected the warning(s) advocated by the plaintiff." *Ridings v. Maurice*, 444 F. Supp. 3d 973, 980 (W.D. Mo. 2020). Another court is in accord: "[I]f the plaintiff can point to the existence of 'newly acquired information' to support a labeling change under the CBE regulation, the burden then shifts to the manufacturer to show by 'clear evidence' that the FDA would not have approved the labeling change made on the basis of this newly acquired information." *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 661 (S.D.N.Y. 2017), *aff'd sub nom. Gibbons v. Bristol-Myers Squibb Co.*, 919 F.3d 699 (2d Cir. 2019). As is the Seventh Circuit, which has concluded that preemption bars claims where, at trial, the plaintiff "failed to offer evidence that [the defendant manufacturer] acquired new information." *Dolin v. GlaxoSmithKline LLC*, 901 F.3d 803, 815 (7th Cir. 2018). In the absence of any contrary authority, the Court places the burden on Plaintiffs to establish the existence of "newly acquired information."

Plaintiffs cite a variety of information that they contend was "newly acquired" under the regulation. First, they argue that Gilead's 2010 internal analysis of study 907, a pre-approval clinical study, showed significant differences in urine phosphorus excretion that were not reported to the FDA. However, Plaintiffs do not argue that Gilead should have modified its labeling to require that type of monitoring. To the contrary, Plaintiffs' expert, Dr. Derek Fine, agreed at his deposition that he was not suggesting that the labels should have recommended monitoring urine phosphate excretion; instead, he said "that it should have been further studied. It may have resulted in it being on the label. . . . I haven't said that . . . these things should have been on the label. I think that . . . we should have had more knowledge about them and . . . how to use them. . . ." ECF No. 1189-3 at 5 (emphasis added). Another of Plaintiffs' experts, Dr. Michael Shlipak, similarly explained that after the 902 and 907 studies, "Gilead stopped studying and reporting findings of urine phosphorus wasting in randomized comparisons of TDF with alternative treatments" and opined that Gilead should have "measured urine levels of phosphorus in all participants of their TDF trials and presented these findings to the clinical community." ECF No. 1157-26 ¶¶ 12–13. But asserting that a manufacturer could or should have done more studies—i.e., "that a manufacturer should have created the 'newly acquired information'"—is insufficient to avoid preemption under the CBE regulation. *Gayle v. Pfizer Inc.*, 452 F. Supp. 3d 78, 88 (S.D.N.Y. 2020), *aff'd*, 847 F. App'x 79 (2d Cir. 2021).

Second, Plaintiffs argue that various case reports, physician statements, medical literature, and research studies recommended monitoring beyond that which Gilead included in its labeling. They also assert that Gilead's 2005 analysis of its safety data in response to a request of European regulators would have supported a label change. However, as Gilead correctly observes, Plaintiffs have not explained how this information differed from the information that had already been presented to the FDA. "[T]he question of whether there is 'newly acquired information' to support a CBE submission" must be considered "against the backdrop of the FDA's years-long attention to, and evaluation of, the . . . safety of [TDF] drugs." *In re Incretin-Based Therapies Prods. Liab. Litig.*, 524 F. Supp. 3d 1007, 1018–19 (S.D. Cal. 2021), *aff'd on other grounds*, No. 21-55342, 2022 WL 898595 (9th Cir. Mar. 28, 2022). For example, information is not "newly

acquired information" where an article has been made available to the FDA or the plaintiffs do not dispute that the manufacturer "submitted all clinical trial data to the FDA." *Id.* at 1024–25.

In this case, as Gilead's expert states, and as Plaintiffs do not dispute, the FDA history involves 40 periodic post-marketing safety reports ("PSURs") on Gilead's TDF medications, and 35 FDA-approved updates "to TDF-based medications' labeling." ECF No. 1126-2 at 2–4. These reports, each of which "consisted of hundreds or thousands of pages," "contain[ed] post-approval safety data, such as spontaneous adverse event reports, as well as information regarding international regulatory compliance, ongoing clinical trials, estimated patient exposure, medical literature references, and recommend labeling changes." *Id.* at 2–3. In "almost every PSUR starting in 2003, Gilead submitted to FDA cumulative reviews of data on kidney or bone adverse effects," including "reviews in response to requests by FDA or its international regulatory counterparts." *Id.* at 4–5. Plaintiffs' experts testified at their depositions that they have no reason to believe, or were offering no opinion, that Gilead withheld any adverse event reports or other information from the FDA and, in fact, relied on the information given by Gilead to the FDA to form their opinions.[7] ECF No. 1126-5 at 37–38, 44–45, 94–95, 102–04, 112–13, 123, 126. Nor have Plaintiffs introduced any evidence explaining how the information they contend is "new" differs from what was presented to the FDA. That makes this case unlike those relied on by Plaintiffs, where there was evidence of analyses or other evidence that the manufacturer did not share with the FDA. *E.g.*, *In re Taxotere (Docetaxel) Prods. Liab. Litig.*, 508 F. Supp. 3d 71, 84–85 (E.D. La. 2020) (2006 presentation at breast cancer conference was not presented to the FDA); *Duncan v. Allergan, Inc.*, No. CV 18-8047 FMO (Ex), 2020 WL 6204563, at *6 (C.D. Cal. Sept. 4, 2020) ("According to defendant's lead safety officer for [the drug in question], defendant

[7] This includes testimony by one expert, Dr. Akhilesh Nagaich, that he was not "opining that Gilead failed to satisfy any requirements relating to the reporting of adverse events" or "withheld data from FDA relating to adverse events." ECF No. 1126-5 at 123, 126. Thus, the Court does not find Nagaich's conclusory statements in his report—that unidentified "post-approval data demonstrating TDF patients were experiencing kidney and bone adverse effects" or "new research reflecting the need for better monitoring of renal function in all TDF users broad categories" "*could* have satisfied [the] 'newly acquired information' requirement," ECF No. 1126-5 at 245 (emphasis added)—to be sufficient to satisfy Plaintiffs' burden of identifying "newly acquired information."

could have shared the relevant internal analyses with the FDA, but simply chose not to do so.").[8] The evidence Plaintiffs cite goes to the merits of whether Gilead's labeling was sufficient, but Plaintiffs have not demonstrated that this evidence is "newly acquired information" that would have allowed Gilead to unilaterally implement labeling changes.

Similarly, that the FDA asked Gilead to make labeling changes in 2008 is evidence that the agency would not have rejected a request from Gilead to make those changes. But Plaintiffs do not explain how any of the information relied on by the FDA was not previously submitted to the agency. Whether the underlying information constitutes "newly acquired information" under the CBE regulation is a separate inquiry—and independent basis for finding preemption—from the question of whether the FDA would have accepted or rejected a proposed labeling change. *See In re Zofran*, 57 F.4th at 341.

Plaintiffs have not met their burden of demonstrating the existence of "newly acquired information" such that Gilead could have made a labeling change without FDA approval under the CBE regulation. This is the sole basis on which Plaintiffs argue their post-approval failure-to-warn claims are not preempted, and the Court therefore grants summary judgment to Gilead on these claims.

D. Fraud

The Court granted—without opposition from Plaintiffs—Gilead's motion to dismiss fraud and consumer protection claims based on misrepresentations, so only fraud claims based on omissions remain in this case. ECF No. 123 at 7–8. Consequently, Plaintiffs' argument that their fraud claims are not preempted because "Gilead told doctors not to monitor serum phosphorus, even though it was in the label" is not persuasive, as this is a misrepresentation rather than an omission claim. ECF No. 1156 at 39 (emphasis omitted). Similarly, claims regarding other

[8] In a third case relied on by Plaintiffs, an unpublished opinion from the Eleventh Circuit, the court noted that medical literature and reports of renal impairment would have been sufficient to support a stronger monitoring instruction, but the court did not address whether the identified information had previously been presented to the FDA. *Blackburn v. Shire U.S., Inc.*, No. 20-12258, 2022 WL 16729466, at *2 (11th Cir. Nov. 7, 2022). It did, however, conclude that the identified sources were included in the definition of "newly acquired information" under 21 C.F.R. § 314.3(b), which defines such information as "data, analyses, or other information not previously submitted to the [FDA]." *Id.*

alleged misrepresentations, such as "marketing TDF as 'extremely safe' with 'no toxicities,'" "dismissing TDF-associated kidney and bone toxicity as merely a competitive issue, not a 'real' one," and "publicly announc[ing] that TAF was not sufficiently differentiated from TDF," are not part of this lawsuit. *Id.* at 40.

To the extent Plaintiffs' fraud claims are based on inadequate labeling, they are preempted for the reasons discussed above.

Plaintiffs also assert fraud claims based on promotional and marketing materials. They affirmatively "do not claim that Gilead should have provided additional or stronger warnings in those materials that were not FDA-approved," but they do "claim that Gilead downplayed and undercut the FDA-approved warnings that appeared in its label, including by concealing important safety information and omitting the true risks of TDF and the importance of patient monitoring in its promotional and other communications with physicians." ECF No. 1156 at 39. Claims based on alleged omissions in promotional and marketing materials of information contained in FDA-approved labels are not preempted. Although "advertising and promotional materials are considered labeling" and so "must be consistent with the drug's approved labeling," *Strayhorn v. Wyeth Pharms., Inc.*, 737 F.3d 378, 394 (6th Cir. 2013), that principle does not bar claims based on representations or omissions that do not conflict with the approved labeling. *City and County of San Francisco v. Purdue Pharma L.P.*, 491 F. Supp. 3d 610, 665–68 (N.D. Cal. 2020).

Plaintiffs' fraud claims also rest in part on their contentions that "Gilead decided to keep secret the positive results of TAF clinical study 1101, which showed that a much lower dose of TAF was just as, if not more effective, than TDF," and that Gilead failed to disclose the reasons it delayed TAF development. ECF No. 1156 at 40. Plaintiffs do not dispute that Gilead could not have promoted TAF as "safe or effective" until after it had been approved by the FDA. 21 C.F.R. § 312.7(a). Nor do they dispute that Gilead could not advertise that TAF was safer than TDF unless TAF was "demonstrated to be safer or more effective . . . by substantial evidence or substantial clinical experience," 21 C.F.R. § 202.1(e)(6)(ii), a showing that Plaintiffs do not contend was made during the relevant time period. However, Gilead has cited no authority that it could not have disclosed the results of Study 1101, or that—if a jury were to believe Plaintiffs'

theory—it stopped TAF development to avoid harming TDF sales. These claims are therefore not preempted.

The Court nonetheless grants summary judgment to Gilead on these claims because, even if Gilead owed a duty to disclose such information, Plaintiffs have presented no evidence of materiality, which Plaintiffs do not contest is an element of their claims.[9] *See, e.g.*, Restatement (Second) of Torts § 538 (defining "material" information as information as to which a reasonable person "would attach importance to its existence or nonexistence in determining [their] choice of action" or "the maker of the representation knows or has reason to know that its recipient regards or is likely to regard the matter as important in determining [their] choice of action, although a reasonable [person] would not so regard it"). Study 1101 concluded that TAF "show[ed] greater potency than [TDF] in reducing plasma levels of HIV-1 RNA" and "showed a safety profile similar to" TDF, not that TAF was safer than TDF. ECF No. 1126-3 at 23. Plaintiffs have presented no evidence that this information, about a drug that had not yet been approved by the FDA and was not available on the market, would have caused physicians to have acted differently, either by prescribing a different medication that was available on the market or by changing how they monitored patients on Gilead's TDF drugs. Nor have Plaintiffs introduced any evidence concerning the materiality of information that Gilead may have stopped TAF development for financial reasons. Gilead is therefore entitled to summary judgment on these claims.

E. Implied Warranty and Consumer Protection

Gilead argues that it is entitled to summary judgment on Plaintiffs' implied-warranty and consumer-protection claims because Plaintiffs' other claims fail. To the extent that Plaintiffs' design-defect, negligence, and fraud claims survive for the reasons discussed above, their implied-warranty and consumer-protection claims also survive. Summary judgment is granted to Gilead on Plaintiffs' implied-warranty and consumer-protection claims to the extent these claims rest on Plaintiffs' failure-to-warn claims, which are preempted for the reasons discussed above.

Gilead also argues that Plaintiffs cannot prevail on their implied-warranty claims because

[9] Gilead does not argue that any omissions about TDF were not material, or that it owed no duties to disclose information regarding TDF.

"the TDF medications were highly effective in treating HIV, and Plaintiffs do not contend that there was anything amiss with the FDA approval process." ECF No. 1126 at 42. One court has held that "FDA's approval of [a defendant's medical] device through the PMA [Premarket Approval] process belies . . . a claim [for breach of implied warranty] and preempts any claim that [the plaintiff's] device was unfit for its intended purpose." *Bishoff v. Medtronic Inc.*, No. 1:09CV171, 2010 WL 4852650, at *3 (N.D.W. Va. Nov. 22, 2010). However, as Gilead concedes, FDA approval is not dispositive of design-defect claims except in Michigan, where Plaintiffs do not assert design-defect claims. *See* ECF No. 1126 at 19 ("The fact of FDA's initial approval alone . . . creates a 'rebuttable presumption' in some states, and serves as significant evidence in other states, that the medications are not defective."); ECF No. 1189 at 17 n.3 ("Plaintiffs do not assert a design claim in Michigan, where FDA approval is a complete defense. *See* Mich. Comp. Laws § 600.2946(5)."). And it is hornbook law that "courts find goods to be unfit for their ordinary purposes when they can identify one of three general types of defects," including "design defects." 1 Matt Crockett, *The Law of Prod. Warranties* § 5.5; *see also Ducat v. Ethicon, Inc.*, 534 F. Supp. 3d 152, 160 (D. Mass. 2021) ("Warranty liability may be based on . . . a design defect.").

Finally, citing *AIDS Healthcare Foundation, Inc. v. Gilead Sciences Inc.*, No. C 16-00443 WHA, 2016 WL 3648623, at *9 (N.D. Cal. July 6, 2016), *aff'd*, 890 F.3d 986 (Fed. Cir. 2018), Gilead argues that Plaintiffs cannot prevail on consumer-protection claims by "invoking antitrust-type principles to argue that Gilead acted unfairly or unconscionably." ECF No. 1126 at 43. This Court has already held that *AIDS Healthcare Foundation* is not dispositive and concluded that it "does not warrant dismissal of any of Plaintiffs' claims," in part because "[c]oncluding that Gilead owed no duty to its competitors says nothing about any duties Gilead might owe to consumers under state tort law." ECF No. 75 at 6–8.

CONCLUSION

For the reasons discussed above, Gilead's motion for summary judgment on common issues is granted in part and denied in part. Summary judgment is granted to Gilead on the following claims: (1) Plaintiffs' strict-liability design-defect claims in Massachusetts, North

Carolina, Pennsylvania, Virginia, and Utah; (2) Plaintiffs' strict-liability and negligence design-defect claims in Alabama; (3) Plaintiffs' negligence claim, if no design defect is found, based on an alleged duty "to refrain from marketing a non-defective product when a safer model is available, or a duty to inform the consumer of the availability of the safer model," in Utah, *Slisze*, 979 P.2d at 317; (4) Plaintiffs' post-approval failure-to-warn claims; (5) Plaintiffs' fraud claims based on allegedly inadequate labeling, omissions regarding TAF clinical study 1101, and omissions regarding Gilead's alleged reasons for delaying TAF development; and (6) Plaintiffs' implied-warranty and consumer-protection claims to the extent they rest on any of the above claims. Summary judgment is denied as to Plaintiffs' remaining claims.

The Court does not rule on Gilead's evidentiary objections, ECF No. 1189 at 10, because it did not rely on any of the disputed evidence in ruling on Gilead's motion.

IT IS SO ORDERED.

Dated: September 28, 2023

JON S. TIGAR
United States District Judge

United States District Court
Northern District of California