SUPERIOR COURT OF CALIFORNIA

COUNTY OF SAN FRANCISCO

DEPARTMENT 613

COORDINATION PROCEEDING SPECIAL TITLE [RULE 3.550(c)] **GILEAD TENOFOVIR CASES**	Case No. CJC-19-005043 JUDICIAL COUNCIL COORDINATION PROCEEDING NO. 5043 ORDER DENYING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT (COMMON ISSUES) (REDACTED)
This Order Relates to All Cases.	

INTRODUCTION

This matter came on regularly for hearing on May 20, 2022, in Department 613, the Honorable Andrew Y.S. Cheng, presiding. Andrew Silverman of Orrick Herrington & Sutcliffe LLP appeared for defendant Gilead Sciences, Inc. Elizabeth Graham of Grant & Eisenhofer P.A. appeared for Plaintiffs. All other appearances are noted in the Court's minutes.

Having reviewed and considered the pleadings, written submissions, and oral argument of all parties, and good cause appearing, the Court **DENIES** Gilead's motion for summary judgment (common issues).

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BACKGROUND

This action concerns Plaintiffs' alleged damages from ingesting Gilead's five tenofovir disoproxil fumarate ("TDF") medications—branded as Viread, Truvada, Atripla, Complera, and Stribild—for the prevention and treatment of infection with Human Immunodeficiency Virus-1 ("HIV" or "HIV-1") and resulting Acquired Immunodeficiency Syndrome ("AIDS"). (Master Complaint ("MC"), ¶¶ 10–12, 125.) After taking a TDF medication, Plaintiffs suffered kidney, tooth, and/or bone damage allegedly stemming from Gilead's failure to provide adequate warnings and its decision to design these drugs (and submit them for FDA approval) with TDF instead of the allegedly safer drug tenofovir alafenamide fumarate ("TAF"). (*Id.* ¶ 13.) In the long form master complaint, Plaintiffs assert claims for (1) negligence, (2) strict products liability, (3) breach of express warranty, (4) breach of implied warranty, and (5) fraud and concealment based on the following allegations.

I. Gilead Seeks FDA Approval of TDF-based Medications Over TAF-Based Medications.

TDF and TAF are two prodrug[1] versions of the same parent drug, tenofovir. (*Id.* ¶¶ 1, 42–43.) Gilead pioneered TAF before the FDA approved its first TDF-based drug. (*Id.* ¶ 1.) Long before Gilead submitted its TDF-based drugs for approval, Gilead knew that "because of the differences in bioavailability between TDF and TAF, *patients needed approximately 12 times more TDF (300 milligram dose) than TAF (25 milligram dose) in order to achieve the same therapeutic effect on viral replication.*" (*Id.* ¶ 50; see also *id.* ¶¶ 47, 49.) "Given the differences in effective dosage between TDF and TAF, Gilead [also] knew that TAF was associated with less toxicity and fewer side effects because the oral administration of TAF resulted in roughly 90% lower concentrations of active tenofovir in the kidneys, which in turn decreased the risk of renal injuries, as well as bone and tooth loss, when compared to TDF." (*Id.* ¶ 51; see also *id.* ¶¶ 15, 56 [Gilead's publications made clear that TAF had a "greater clinical efficacy"], 60.) From 1991 to 2012, "Gilead knew that tenofovir in the prodrug form of TDF was extremely toxic to patients' kidneys, bones and teeth" as compared to TAF. (*Id.* ¶ 14; see also *id.* ¶ 48.)

Despite knowing that "TAF was associated with less toxicity and fewer side effects because the oral administration of TAF resulted in roughly 90% lower concentrations of active tenofovir in the

[1] "A prodrug is a biologically inactive compound that, once metabolized by the body, converts into the pharmacologically active parent drug." (MC, ¶ 42.)

kidneys, which in turn decreased the risk of renal injuries, as well as bone and tooth loss, when compared to TDF," and that "TAF was a safer, more effective and overall better drug than TDF," Gilead designed and pursued FDA approval of the tenofovir drugs to contain TDF rather than the safer TAF. (*Id.* ¶¶ 51, 53, 61, 63, 66, 78 [Viread], 80 [Truvada], 113 [Viread], 122 [Genvoya], 123.)

From 2001 to 2015, Gilead received Food and Drug Administration ("FDA") approval for five TDF-based drugs for the treatment of HIV: Viread in 2001, Truvada in 2004, Atripla in 2006, Complera in 2011, and Stribild in 2012. (*Id.* ¶ 68; GSUMF[2], ¶¶ 2–6.)

Years later, Gilead began seeking FDA approval of its first TAF-based drug touted as "a 'better' option allowing for lower systemic tenofovir exposure, renal toxicity and bone effects without sacrificing efficacy when compared to TDF" based on "TAF data known to the company *as early as the mid-to-late 1990s* showing that: (1) TAF provided greater intracellular distribution of tenofovir while yielding lower plasma tenofovir levels than TDF; (2) TAF was less likely to accumulate in the renal proximal tubules, leading to an improved overall safety profile; and (3) TAF doses were far lower than necessary for equivalent TDF-based medications." (MC ¶¶ 119–120 [emphasis supplied].)

It was not until 2015 that Gilead received FDA approval for four drugs containing TAF that are counterparts to its previously approved TDF drugs: Genvoya in 2015, Odefsey and Descovy in 2016, and Biktarvy in 2018. (*Id.* ¶¶ 119–123; GSUMF, ¶ 25.) Gilead's decision to develop and submit TDF-based drugs for FDA approval before TAF-based drugs is at the heart of Plaintiffs' claims.

II. Gilead's Financial Motivation to Submit TDF Instead of TAF for FDA Approval.

Plaintiffs claim that Gilead's choice to first introduce TDF-based products over TAF-based products was financially motivated.

Plaintiffs allege that, in 2004, Gilead publicly stated it ceased developing TAF because TAF "did not have a 'profile that differentiate[d] it to an extent that support[ed] its continued development.'" (MC, ¶ 64; see also *id.* ¶¶ 79, 109.) According to Plaintiffs, Gilead's true motivator for stopping TAF development was "to unreasonably maximize its profits and maintain its stranglehold on tenofovir-based

[2] The Court uses GSS as shorthand for citation to facts in Gilead's separate statement that Plaintiffs confirm as undisputed; similarly, PSS is used as shorthand for facts in Plaintiffs' separate statement. To the extent Plaintiffs or Gilead identify facts as disputed in a responsive separate statement, the Court expressly notes such disagreement in relevant part throughout this order. The Court did not receive any responsive separate statement from Gilead.

antiretroviral medications . . . [by] devis[ing] a marketing scheme whereby it abandoned the immediate approval, manufacture and sale of TAF in favor of the less effective, less safe TDF." (*Id.* ¶ 61; see also *id.* ¶¶ 2, 4, 64, 79, 54–67.) By having two different periods of tenofovir drug exclusivity, one for TDF and one for TAF, Gilead also further maximized its profits. (*Id.* ¶¶ 34, 54–67, 78, 106–123.) Plaintiffs allege Gilead brokered numerous anticompetitive deals with other manufacturers to ensure it monopolized the tenofovir-based antiretroviral medication market. (*Id.* ¶¶ 62–63.) "It was only in response to market pressures—not concern for patient health and safety—that Gilead eventually applied for FDA approval of TAF for the first time in or about 2015, after maintaining an exclusive and extremely profitable monopoly on TDF for some 15 years." (*Id.* ¶ 2; see also *id.* ¶¶ 1, 23, 24–53, 54–67, 106–123 [describing the re-introduction of TAF into the market based on financial reasons].) Specifically, Gilead was only forced to re-introduce TAF because of its expiring exclusivity patent on TDF-based products. (*Id.* ¶ 107.) During the period when Gilead only marketed its five TDF-based products, Gilead profited at least $36 billion. (*Id.* ¶ 69; see also *id.* ¶¶70-105 [outlining specific profits associated with each of the five TDF-based drugs].)

III. Procedural History

On January 30, 2020, Plaintiffs filed a Master Complaint against Gilead alleging (1) negligence, (2) strict liability, (3) breach of express warranty, (4) breach of implied warranty, and (5) fraud and concealment. In the interim, Plaintiffs refined their theories of the case.

On March 15, 2022, Gilead filed three motions for summary judgment or summary adjudication of the remaining counts at issue in this action, namely negligence and fraud and concealment. Gilead's first motion, the subject of this order, addresses common issues with the complaint's first and fifth counts. Gilead's other two motions are directed to plaintiff Shelton Stile and plaintiff Craig DeMartino's claims, which are separately addressed in concurrently filed orders.

REQUESTS FOR JUDICIAL NOTICE

Pursuant to Evidence Code section 452, subdivision (c), the Court **GRANTS** Gilead's request for judicial notice and takes judicial notice of Exhibits A–L attached to Request for Judicial Notice in Support of Gilead Sciences, Inc.'s Motion for Summary Judgment or, in the Alternative, for Summary Adjudication (Common Issues).

EVIDENTIARY OBJECTIONS

Plaintiffs made eight evidentiary objections in connection with their response to Defendant's Separate Statement of Undisputed Material Facts Nos. 9, 17, 18, 23, 32, 33, 35, and 39. The objections are **OVERRULED** as to Nos. 9, 17, 18, 32, and 33 and **SUSTAINED** as to Nos. 23, 35, and 39.

LEGAL STANDARD

"A party may move for summary judgment in any action or proceeding if it is contended that the action has no merit or that there is no defense to the action or proceeding." (Code of Civ. Proc., § 437c, subd. (a)(1).) The moving party "bears an initial burden of production to make a prima facie showing of the nonexistence of any triable issue of material fact." (*Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 850.) That party also "bears the burden of persuasion that there is no triable issue of material fact and that he is entitled to a judgment as a matter of law." (*Ibid.*)

A defendant moving for summary judgment carries his burden of persuasion and/or production by "present[ing] evidence that would require such a trier of fact *not* to find any underlying material fact more likely than not. In the alternative, he may simply point out–he is not required to present evidence–that the plaintiff does not possess, and cannot reasonably obtain, evidence that would allow such a trier of fact to find any underlying material fact more likely than not." (*Id.* at p. 845.)

If the moving party carries his burden of production, "he causes a shift, and the opposing party is then subjected to a burden of production to make a prima facie showing of the existence of a triable issue of material fact." (*Id.* at p. 850.) But if the moving party fails to carry his initial burden, he would not be entitled to judgment as a matter of law and would have to present his evidence to a jury. (*Id.* at p. 851.)

DISCUSSION AND ANALYSIS

The Court first addresses Gilead's affirmative defense of preemption and then analyzes the negligence and fraud and concealment arguments.

I. Preemption

"Under the supremacy clause of the United States Constitution (art. VI, cl. 2). Congress has the power to preempt state law concerning matters that lie within the authority of Congress." (*Bronco Wine Co. v. Jolly* (2004) 33 Cal.4th 943, 955.) Under the Supremacy Clause, state laws that conflict with federal laws are without effect. (*Cipollone v. Liggett Grp.* (1992) 505 U.S. 504, 516.)

There is a presumption against federal preemption of state law; thus, to preempt state law, Congressional intent must be clear. (*Medtronic, Inc. v. Lohr* (1996) 518 U.S. 470, 485.) "In determining whether federal law preempts state law, a court's task is to discern congressional intent." (*Bronco Wine*, *supra*, 33 Cal.4th at p. 955.) "Congress's express intent in this regard will be found when Congress explicitly states that it is preempting state authority." (*Ibid.*) "Congress's implied intent to preempt is found (i) when it is clear that Congress intended, by comprehensive legislation to occupy the entire field of regulation, leaving no room for the states to supplement federal law; (ii) *when compliance with both federal and state regulations is an impossibility*; or (iii) when state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." (*Ibid.* [emphasis in original].)

The impossibility preemption at issue here is a demanding defense. (*Wyeth v. Levine* (2009) 555 U.S. 555, 573.) The "burden for demonstrating impossibility rests with the party asserting preemption." (*Holley v. Gilead Sciences, Inc.* (N.D. Cal. 2019) 379 F.Supp.3d 821, 819, citing *Wyeth, supra*, 555 U.S. at p. 573 [concluding that "Wyeth has failed to demonstrate that it was impossible for it to comply with both federal and state requirements"].) There is a two-step analysis for impossibility preemption in the drug manufacturing context: (1) "courts must determine whether a drug manufacturer may independently take action that complies with both state and federal law" and then if (2) "independent action is not possible, then the state-law claims are preempted." (*Holley, supra*, 379 F.Supp.3d at p. 821, citing *Wyeth, supra*, 555 U.S. at p. 571.)

The Court determines that Gilead does not carry its burden of establishing these elements with respect to Plaintiffs' theories below.

a. Count 1: Negligence

Plaintiffs claim that Gilead should have more quickly developed and obtained approval for TAF. Gilead contends that this claim is preempted because the availability of TAF is contingent upon FDA approval. Gilead maintains it was impossible for it to independently comply with any state-law duty because of the necessity of the FDA's intervention and assistance. Gilead paints with too broad of a brush in advancing this argument.

Gilead has not established that preemption should apply to it as a brand-name manufacturer with more control over the development process of the at issue drugs and outside of a labeling dispute context. (*See, e.g., T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, 158, distinguishing *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 625.) While Gilead relies almost exclusively on *PLIVA*, the Supreme Court and the California Supreme Court in *T.H. v. Novartis* explained that preemption may not apply equally to all manufacturers. (*Ibid.*) The Court notes this salient feature of preemption jurisprudence, not to raise a distinction between brand-name and generic manufacturers in a vacuum, but to illustrate the level of specific analysis undertaken for impossibility preemption. Courts have not broadly concluded that impossibility preemption applies in all cases, regardless of the case's unique circumstances, simply when there is some remote possibility that a federal agency and federal regulations may be implicated. Instead, the Supreme Court explained that there may be meaningful differences in how different types of manufacturers are regulated such that "different statutes and regulations may…lead to different pre-emption results." (*PLIVA, supra*, 564 U.S. at p. 626.) The Supreme Court has counseled that courts should not strain to "create similar pre-emption across a dissimilar statutory scheme." (*Ibid.*) Here, the Court finds Gilead's heavy reliance on *PLIVA* problematic as it involves distinct facts, distinct legal theories, and distinct FDA regulations. Given our unique facts here, Gilead has not established that *PLIVA's* holding should be expanded to these circumstances.

Contrary to Gilead's assertions, Gilead could have complied with both state and federal law. As with its demurrer, "Gilead 'has cited no federal law that restricts a brand-name drug manufacturer from designing a reasonably safe product *prior* to FDA approval' and, in particular, has identified no federal law that would have prevented it from developing and submitting for approval drugs that contained TAF rather than TDF…" (*Holley, supra*, 379 F.Supp.3d at p. 824.)

Gilead also argues that even if it had done everything that Plaintiffs say it should have done, the FDA would not have approved TAF before approval of three of the accused TDF medications. (MPA at p. 2.) The record before the Court does not establish this contention as a matter of undisputed fact. There is evidence in the record that Gilead took affirmative steps to delay the development and approval of TAF, which undercuts any theory that the FDA simply would not have approved TAF. (PSS, ¶¶ 47, 53, 64.) The fact that the FDA later approved the TAF drugs during the pre-approval period undercuts

Gilead's argument. (Egan Decl., ¶ 10 [In November 2015, the FDA approved the NDA for Gilead's first TAF-containing medication, Genvoya. Four additional TAF-containing medications were promptly approved in the following three years: Odefsey (2016), Descovy (2016), Vemlidy (2016), and Biktarvy (2018)].) The Court finds Gilead's evidence and analysis insufficient as there is not "clear evidence" that the FDA would not have approved TAF before three of the accused TDF medications. (*See Holley, supra*, 379 F.Supp.3d at p. 824.)

The Court also finds Gilead's arguments that the FDA could not have approved TAF in 2006 and, even if the FDA had approved TAF in 2006, it would have been after the TDF drugs' approvals, unpersuasive. When evaluating preemption, the inquiry is not when the FDA would have first approved TAF, but rather "whether 'a drug manufacturer can independently design a reasonably safe drug in compliance with its state-law duties before seeking FDA approval.' " (*Ibid.*) As stated above, Gilead does not establish that it could not have independently designed a reasonably safe drug in compliance with state law before later seeking FDA approval.

Furthermore, Gilead's TAF timeline is in dispute. (Silverman Decl., Ex. 9, at 15 [Stile interrogatory response that Gilead could have obtained FDA approval "as late as October 6, 2006"], Ex. 10, at 15 [DeMartino interrogatory response that Gilead could have obtained FDA approval "as late as October 6, 2006"]; Graham Decl., Ex. 56 [April 17, 2003 Development Committee Executive Report], Ex. 71 [Oct. 21, 2004 Gilead press release].)

Thus, preemption does not provide a basis for granting Gilead's motion.

b. Count 5: Fraud and Concealment

Gilead contends Plaintiffs' fraud and concealment claim is preempted because federal law prohibited Gilead from promoting, representing, or suggesting that unapproved TAF was safer than approved TDF. (MPA at pp. 19–21.) In support, Gilead cites 21 C.F.R. §§ 312.7(a), 202.1(e)(6)(ii), (iv). These regulations do not preempt Plaintiffs' claim.

Part 312.7(a) of Title 21 of the Code of Federal Regulations addresses promotion of an investigational new drug, stating:

> A sponsor or investigator, or any person acting on behalf of a sponsor or investigator, shall not represent in a promotional context that an investigational new drug is safe or effective for the purposes for which it is

> under investigation or otherwise promote the drug. This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media. Rather, its intent is to restrict promotional claims of safety or effectiveness of the drug for a use for which it is under investigation and to preclude commercialization of the drug before it is approved for commercial distribution.

Part 202.1(e)(6) prohibits drug advertisements that are false, lacking in fair balance or otherwise misleading. (21 C.F.R. § 202.1(e)(6).) Among other limitations, an advertisement cannot contain "a drug comparison that represents or suggests that a drug is safer or more effective than another drug in some particular when it has not been demonstrated to be safer or more effective in such particular by substantial evidence or substantial clinical experience" or "a representation or suggestion that a drug is safer than it has been demonstrated to be by substantial evidence or substantial clinical experience, by selective presentation of information from published articles or other references that report no side effects or minimal side effects with the drug or otherwise selects information from any source in a way that makes a drug appear to be safer than has been demonstrated." (21 C.F.R. § 202.1(e)(6)(ii), (iv).)

Plaintiffs are not taking issue with drug advertisements; thus, Part 202.1(e)(6) does not establish preemption. Additionally, Gilead's citation to Part 312.7(a) is unpersuasive because Gilead makes a strawman argument about preemption of a theory that is not Plaintiffs' actual theory of the case. Plaintiffs are not alleging that Gilead should have promoted TAF to patients or physicians while it was merely under investigation. Rather, Plaintiffs allege that Gilead wrongfully concealed the "full exchange of scientific information," which is not restricted under Code of Federal Regulations, title 21, part 312.7(a). (Graham Decl., Exs. 5, 21–24, 40–42, 57, 72–73, 86, 89–94; 21 C.F.R. § 312.7(a) ["This provision is not intended to restrict the full exchange of scientific information concerning the drug, including dissemination of scientific findings in scientific or lay media"].)

Gilead's preemption argument is undermined by the fact that, after restarting TAF development in 2010, Gilead was able to [redacted]. (Graham Decl., Ex. 114 [2011 CROI CCC Themes PowerPoint, at Slides 9 & 11].) Gilead published the study results in 2014, [redacted]

[redacted]. (*Id.*, Ex. 21, at 380:9–20 [Lee Dep. confirming article was published on Feb. 6, 2014], Ex. 95 [published study].)

The Court **DENIES** the motion on this ground.

II. Legal Propriety of Plaintiffs' Claims

Gilead also attacks the legal propriety of Plaintiffs' claims. The Court addresses each cause of action in turn.

a. Count 1: Negligence

Gilead argues that Plaintiffs' negligence claim fails as a matter of state law because "[s]tate law does not recognize a free-floating negligence claim for an injury caused by a product independent of a products-liability claim." (MPA at p. 12; Reply at pp. 5–8.) Gilead does not seek to disprove any essential elements of a negligence claim. Rather, Gilead argues that Plaintiffs' negligence claim is not legally cognizable as a general matter. Gilead repeatedly emphasizes that Plaintiffs have not cited any authority where a claim like theirs has proceeded. However, as the moving party, Gilead bears the initial burden of establishing that it is entitled to judgment as a matter of law. In actuality, Gilead's argument is contrary to California law: Plaintiffs may proceed on a theory of negligence and are not required to proceed on a product liability theory. (*Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89, 102 [distinguishing theories of liability, finding "no logical or legal inconsistency between allowing the suit for negligence and disallowing the suit for strict products liability"; *accord T.H., supra,* 4 Cal.5th at pp. 162, 175–80 [rejecting argument that liability should not exist based on out-of-state authority and practices in foreign jurisdictions]; *Milwaukee Elec. Tool Corp. v. Super. Ct.* (1993) 15 Cal.App.4th 547, 557; *Brown v. Super. Ct.* (1988) 44 Cal.3d 1049, 1061; *Scott v. C.R. Bard, Inc.* (2014) 231 Cal.App.4th 763, 774.) While it may be true that many plaintiffs proceed on a strict products liability theory—a theory offering plaintiffs a lesser burden of proof—it is simply not the case that a plaintiff *must* proceed on a products liability theory as negligence is available in California. (*Ibid.*) Consequently, the Court rejects Gilead's argument that a negligence claim is simply unavailable. Having established that there is no bright line categorical prohibition on asserting a negligence claim in this context, the Court observes that Gilead has not mounted any other challenge to Plaintiffs' ability to establish their ordinary negligence claim's essential elements.

A "plaintiff in any negligence suit must demonstrate a legal duty to use due care, a breach of such legal duty, and that breach is the proximate or legal cause of the resulting injury." (*Kesner v. Super. Ct.* (2016) 1 Cal.5th 1132, 1142.) "[E]ach person has a duty to use ordinary care and is 'liable for injuries causes by his failure to exercise reasonable care in the circumstances...'" (*Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456, 472.) Whether a party has a duty of care in a particular case is a question of law for the court. (*Kesner, supra*, 1 Cal.5th at p. 1142.) Gilead does not dispute the existence of its duty of care. (MPA at pp. 12–19; Reply at pp. 5–8.) To the extent Gilead believes that there is no cognizable negligence claim because it does not owe a legal duty or the duty as framed by Plaintiffs, Gilead does not brief such an argument as necessary to carry its initial burden. Gilead has not meaningfully grappled with the novel issues actually pled by Plaintiffs, distinguished California cases like *T.H. v. Novartis Pharmaceuticals Corp.*[3], or otherwise undertaken an analysis of the *Rowland* factors to establish that it did not owe the alleged duty of care under Civil Code section 1714.

Gilead's central argument regarding the general availability of negligence is contrary to California law.[4] Gilead does not otherwise contend that Plaintiffs cannot establish one or more elements of their negligence claim. Further, there are triable issues of material fact as to whether Gilead's conduct was negligent in light of its knowledge that TDF was toxic and that TAF did not carry the same risks as TDF. (Graham Decl., Exs. 1–5, 10–11, 17-24, 27–42, 49–50, 53–64, 66–73, 76–80, 85–86, 89–97, 105, 111–114, 116.) Thus, the Court cannot summarily adjudicate Plaintiffs' negligence claim.

The parties also dispute the viability of Plaintiffs' negligent design theory. Plaintiffs concede that they are not asserting that the TDF drugs are defective. (GSS, ¶ 15.) Gilead asserts that Plaintiffs' concession is fatal to their negligence claim. Although Plaintiffs' opposition does not directly address Gilead's point of law, they seem to maintain that they may proceed on a negligent design theory irrespective of their concession that: "Plaintiffs in this case do not allege that Gilead should have stopped selling TDF, do not allege that the risks of TDF outweigh its benefits, and do not allege that Gilead should have changed its formulation of TDF. ... Plaintiffs do not allege that *TDF* is defective..." (*Ibid.* [original

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[3] The Court also finds unpersuasive Gilead's parade of horribles (MPA at pp. 14:9–15:18) because the hypotheticals are rooted in a misconstruction of Plaintiffs' claim and the specific facts alleged and many of these policy arguments.

[4] Gilead does not present any choice-of-law analysis to support application of the law of another jurisdiction.

italics].) Ultimately, the parties' dispute appears to be, principally, a semantic one that may impact certain procedures and forms at trial, but is not currently outcome determinative.

First, based on the Court's prior analysis, the parties' arguments are not dispositive. A motion for summary judgment or summary adjudication must dispose of the entire action or cause of action, respectively.[5] (Code Civ. Proc., § 437c; *DeCastro West Chodorow v. Super. Ct.* (1996) 47 Cal.App.4th 410, 412.) Plaintiffs have one count for negligence. Because Gilead's argument focuses on a facet of that count, it does not justify granting its motion.

"One of the principal purposes behind the strict product liability doctrine is to relieve an injured plaintiff of many of the onerous evidentiary burdens inherent in a negligence cause of action." (*Barker v. Lull Eng'g Co.* (1978) 20 Cal.3d 413, 431.) "To recover damages, a plaintiff must show his or her injury was caused by a defect in the product." (*Milwaukee Electric, supra*, 15 Cal.App.4th at p. 556.) The plaintiff is relieved from proving that the manufacturer was negligent. (*Ibid.*) The analysis's focus is " 'not on the conduct of the manufacturer but on the product itself, and holds the manufacturer liable if the product was defective.' " (*Ibid.*, quoting *Brown, supra*, 44 Cal.3d at p. 1056.) The existence of a defect in the product is used as a proxy or shortcut for inferring a breach of the duty of care. (*Milwaukee Electric, supra*, 15 Cal.App.4th at p. 556.)

"A design defect exists when the product is built in accordance with its intended specifications, but the design itself is inherently defective. A product...is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor." (*Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110, 142 [citations and quotations omitted].) "[A] product may be found defective in design, so as to subject a manufacturer to strict liability for resulting injuries, under either of two alternative tests. First, a product may be found defective in design if the plaintiff establishes that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner. Second, a product may alternatively be found defective in design if the plaintiff demonstrates that the product's design proximately caused his injury and the defendant fails to establish, in light of the relevant

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[5] Gilead has not noticed a motion for summary adjudication of legal issues under Code of Civil Procedure section 437c, subdivision (t). Consequently, summary adjudication of individual legal issues that do not dispose of an entire cause of action is not proper.

factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design." (*Barker*, *supra*, 20 Cal.3d at p. 432; *accord Chavez v. Glock, Inc.* (2012) 207 Cal.App.4th 1283, 1303.)

The California Supreme Court has held that "a manufacturer of prescription drugs cannot be strictly liable for a design defect and that the appropriate test for determining a prescription drug manufacturer's liability for a design defect involves an application of the ordinary negligence standard." (*Garrett v. Howmedica Osteonics Corp.* (2013) 214 Cal.App.4th 173, 182, citing *Brown*, *supra*, 44 Cal.3d at p. 1049.) Under a negligence theory, a plaintiff must prove that a product defect caused injury and that the defect arose from negligence. (*Trejo*, *supra*, 13 Cal.App.5th at p. 110.) Thus, a plaintiff must establish all of ordinary negligence's elements: duty, breach, causation, and damages. (*See, e.g.*, *Tucker v. Wright Medical Technology, Inc.* (N.D. Cal. Mar. 19, 2013) 2013 WL 1149717, at *7, citing CACI No. 1220.) In the design context, evaluation of compliance with the standard of care " 'involves a balancing of the likelihood of harm to be expected from a machine with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm.' "[6] (*Chavez*, *supra*, 207 Cal.App.4th at p. 1303, quoting *Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 479–480; *see also* CACI No. 1221 [Negligence—Basic Standard of Care]; *see, e.g.*, *Tucker*, *supra*, 2013 WL 1149717, at *7.)

Thus, the first issue is whether a defect is necessary to a prima facie showing for a negligent design theory. It is true that the existence of a defective product is critical for a strict liability claim because it serves as a proxy for negligence. It is also true that a strict liability claim's focus, as compared to a negligence claim, is necessarily on the product's condition rather than the manufacturer's conduct because the defect makes up such a substantial part of the plaintiff's burden of proof. (*Barker*, *supra*, 20 Cal.3d at p. 434.) Plaintiffs' counterpoints fail. The fact that a negligence claim involves examining the reasonableness of the designing manufacturer's conduct does not mean that all of negligent design's elements can be established where it is conceded that the product is not defective. The California Supreme Court explains—and as evident from the function of the test for a design defect for a strict liability

[6] Notably, the facts and evidence that may be pertinent to evaluating negligent design overlap with what courts consider in applying the risk/benefit test for a strict liability claim.

claim—a negligent design theory raises whether there is a defect, regardless of how a plaintiff may have styled his or her claim. (*Merrill*, *supra*, 26 Cal.4th at p. 481.) Whether the word "defect" or "defective" appears verbatim as an essential element of a negligent design claim in CACI instructions or formulations of the essential elements recited by courts, a product defect seems to necessarily be part and parcel of a negligent design claim. The streamlined prima facie showing for strict liability is subsumed within a prima facie showing of negligence; thus, courts have frequently held that special verdicts are impermissibly inconsistent when there is a finding of negligence but not of strict liability. (*Trejo*, *supra*, 13 Cal.App.5th at p. 128 [compiling cases] & n. 14; *Lambert v. General Motors* (1998) 67 Cal.App.4th 1179, 1182–86 [special verdicts finding no defect in design but negligence in design was "fatally inconsistent" as required new trial].)

Gilead's core position is that Plaintiffs should be deemed to have irrevocably waived the negligent design component of their negligence claim. Plaintiffs respond that they are not asserting a product defect; however, they raise facts and theories, like negligent design, that courts (like the *Merrill* and *Lambert* courts) would construe as a product defect, even under a negligence theory. Nonetheless, the Court determines that the current record does not support granting Gilead's motion as to Plaintiffs' negligent design theory.

b. Count 5: Fraud and Concealment

"The elements of a cause of action for fraud based on concealment are: (1) the defendant must have concealed or suppressed a material fact, (2) the defendant must have been under a duty to disclose the fact to the plaintiff, (3) the defendant must have intentionally concealed or suppressed the fact with the intent to defraud the plaintiff, (4) the plaintiff must have been unaware of the fact and would not have acted as he did if he had known of the concealed or suppressed fact, and (5) as a result of the concealment or suppression of the fact, the plaintiff must have sustained damage." (*Kaldenbach v. Mutual of Omaha Life Ins. Co.* (2009) 178 Cal.App.4th 830, 850; see also *Boschma v. Home Loan Ctr. Inc.* (2011) 198 Cal.App.4th 230, 248.) In an action for fraud, "the fraudulent representation relied upon must be as to a material fact which is false and known to be false by the maker, or is recklessly made or made without reasonable grounds for believing its truth." (*Gonsalves v. Hodgson* (1951) 38 Cal.2d 91, 100.)

"A failure to disclose a fact can constitute actionable fraud or deceit in four circumstances: (1) when the defendant is the plaintiff's fiduciary; (2) when the defendant has exclusive knowledge of material facts not known or reasonably accessible to the plaintiff; (3) when the defendant actively conceals a material fact from the plaintiff; and (4) when the defendant makes partial representations that are misleading because some other material fact has not been disclosed." (*Collins v. eMachines, Inc.* (2011) 202 Cal.App.4th 249, 255; *Warner Constr. Corp. v. City of Los Angeles* (1970) 2 Cal.3d 285, 294; *Linear Tech. Corp. v. Applied Materials, Inc.* (2007) 152 Cal.App.4th 115.)

"[W]here material facts are known to one party and not to the other, failure to disclose them is not actionable fraud unless there is some relationship between the parties which gives rise to a duty to disclose such known facts." (*LiMandri v. Judkins* (1997) 52 Cal.App.4th 326, 337 [italics omitted].) The relationship "can only come into being as a result of some sort of transaction between the parties." (*Ibid.* [italics omitted].) "[A] duty to disclose may arise from the relationship between seller and buyer, employer and prospective employee, doctor and patient, or parties entering into any kind of contractual agreement. All of these relationships are created by transactions between parties from which a duty to disclose facts material to the transaction arises under certain circumstances." (*Ibid.* [citation omitted].)

Gilead concedes that a drug manufacturer ordinarily owes a duty to disclose to a prescribing physician. (MPA at p. 22; Reply at pp. 11–14; *T.H., supra,* 4 Cal.5th at p. 154 ["Under California law, a brand-name drug manufacturer has a duty to warn of known or reasonably knowable adverse effects arising from an individual's use of its drugs"]; Graham Decl., Ex. 103, at 2–3 [Regulatory Affairs Professional Society Code of Ethics addressing fundamental principles], Ex. 104, at 57:23-58:16 [Dep. of Erik Berglund, M.D., Ph.D. (Gilead VP of Global Regulatory Affairs)].) The First District Court of Appeal held that this duty additionally runs to patients. (*Conte, supra,* 168 Cal.App.4th at pp. 103–113.) Notwithstanding these principles, Gilead disputes whether there was a transaction giving rise to such a duty with respect to TAF as compared to TDF. Gilead also challenges the materiality of the representations raised by Plaintiffs. Ultimately, despite Gilead's framing, Gilead is not challenging the existence of a duty to disclose.[7] It solely and exclusively challenges whether information about TAF was

[7] The Court otherwise finds Gilead's granular view of what constitutes a transaction giving rise to a duty to disclose to be too granular and contrary to established law in this area.

material, including whether the disclosure of scientific information about safety would have led to doctors to avoid prescribing TDF. (MPA at pp. 22–23; Reply at pp. 11–14.) Here, the TAF medication information that Gilead did not share with prescribing physicians is material. (Graham Decl., Exs. 5, 18, 21–24, 40–42, 44, 57, 61-62, 71–73, 76, 80, 82, 86, 89–97, 100–103, 105–115.) Gilead's concealment of the material information is a triable issue of fact.

The Court **DENIES** the motion for summary adjudication.

CONCLUSION

The Court **DENIES** Gilead's motion for summary judgment.

IT IS SO ORDERED.

Dated: June 13, 2022

ANDREW Y.S. CHENG
Judge of the Superior Court

CERTIFICATE OF ELECTRONIC SERVICE
(CCP 1010.6(6) & CRC 2.251)

I, CLARK BANAYAD, a Deputy Clerk of the Superior Court of the County of San Francisco, certify that I am not a party to the within action.

On June 14, 2022, I electronically served the ATTACHED DOCUMENT(S) via File&ServeXpress on the recipients designated on the Transaction Receipt located on the File&ServeXpress website.

Dated: June 14, 2022

T. Michael Yuen, Clerk

By: _____
CLARK BANAYAD, Deputy Clerk