Case No. _____

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA FIRST APPELLATE DISTRICT

GILEAD SCIENCES, INC.,
Petitioner,

v.

SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF SAN FRANCISCO,
Respondent,

and

GILEAD TENOFOVIR CASES,
Real Parties in Interest.

Superior Court of California, San Francisco County
Case No. CJC-19-005043
Hon. Andrew Y.S. Cheng, (415) 551-3830

PETITION FOR WRIT OF MANDATE, PROHIBITION, OR OTHER APPROPRIATE RELIEF; MEMORANDUM OF POINTS AND AUTHORITIES IMMEDIATE RELIEF REQUESTED [Exhibits Filed Under Separate Cover]

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TO BE FILED IN THE COURT OF APPEAL **APP-008**

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Date: July 6, 2022

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INTRODUCTION

Never before has a court—in this State or anywhere else—held that a plaintiff can recover damages for injuries allegedly caused by a non-defective product. That is, until now.

This Petition arises from a Judicial Council Coordination Proceeding (JCCP) involving more than 24,000 plaintiffs who allege they were injured by taking HIV medications developed by Petitioner Gilead Sciences, Inc. (Gilead). Plaintiffs concede that the medications were effective and are *not* defective. Indeed, the medications were a giant leap forward in the fight against HIV/AIDS when launched in the early 2000s, saving countless lives including the lives of many Plaintiffs. And these medications remain approved by FDA, playing an important role treating HIV in patients around the world. According to Plaintiffs and the Superior Court, however, Gilead could be liable for purported injuries caused by these non-defective medications under the unprecedented theory that Gilead too slowly developed *different* medications, ones that Plaintiffs contend are marginally safer for some people.

The Superior Court's ruling threatens to radically transform mass tort litigation. The court's decision, allowing unprecedented "failure-to-innovate" claims to go to trial, is sure to have ripple effects far beyond the pharmaceutical industry. In permitting liability for failing to bring to market an allegedly marginally better product—even when the accused product is not defective—and requiring manufacturers to disclose information to physicians about products still in development, the ruling weaponizes

innovation itself. The result would be less product development, not more—and fewer safe and innovative products for consumers.

Furthermore, absent this Court's intervention, undue prejudice and harm will befall Gilead and this State's courts. Among other things, Gilead will be forced to undergo multiple trials and appeals as the first of over 24,000 trials in this JCCP is set to begin. Four bellwether cases have already been selected for trial, and at least those trials will occur before this Court has an opportunity to resolve any appeal following the first bellwether case. Moreover, California jurors will needlessly spend countless hours poring over the massive record and hearing dozens of lay and expert witnesses in lengthy six-plus week trials. Either Gilead or the bellwether plaintiffs (or both) will need to appeal endless legal and evidentiary issues, all of which could be unnecessary and irrelevant given that California law does not recognize Plaintiffs' novel claims.

The Superior Court's ruling warrants this Court's pretrial review for at least three reasons.

First, the court concluded that Gilead could be found liable for negligent design defect, even though Plaintiffs expressly concede that the medications that allegedly injured them are *not* defective. That was error because proof of a defect is an essential element of any *design-defect* claim.

Second, the court concluded that Gilead could be liable for alleged injuries caused by non-defective medications under a free-floating negligence theory, based on a purported failure to develop quickly enough *different* medications that Plaintiffs contend would

have avoided their injuries. That claim is unprecedented. It is contrary to the law in California—and in every other state. It also threatens to weaponize the uncertain and winding path of scientific inquiry, accusing scientists of wrongdoing for decisions made in real time based on 20/20 hindsight. And wrongdoing is not even a prerequisite: The accused product need not be unsafe, ineffective, or defective—rather, liability attaches for not developing a different, better product faster. If such claims are allowed and subsequent products can be used against manufacturers to create liability for their earlier non-defective products, it will undermine the incentive for manufacturers to innovate and to improve the safety and effectiveness of their products.

Third, the court held that Gilead had a duty to disclose to Plaintiffs and their doctors information about a different medication that Gilead was developing, that FDA had not yet approved, and that Plaintiffs' doctors therefore could not have prescribed. That claim too is unprecedented, since no manufacturer has ever been found to have a legal duty to disclose information to a consumer about a product that is not available to be used or purchased.

Although Plaintiffs will offer a fantastical and unsupported account of the facts of this case, this Petition assumes the truthfulness of that account and simply presents straightforward legal questions about the viability of Plaintiffs' claims under the law. This Court's guidance is needed to resolve these legal questions of widespread interest and great public importance—

questions whose impact will ripple far beyond this case and the pharmaceutical industry. What is more, early appellate resolution can prevent tens of thousands of unnecessary trials and the attendant waste of judicial resources and burden on the jurors of this State. The legal issues presented here will come to this Court one way or the other; the time to review them is now, before the parties and the courts expend any more resources in litigating theories that have no basis in law.

A writ should issue directing the Superior Court to enter judgment in Gilead's favor on Plaintiffs' claims.

PETITION

Gilead filed a common-issues motion for summary judgment or, alternatively, for summary adjudication (Motion), seeking dismissal of the claims brought by the more than 24,000 plaintiffs in the JCCP based on legal issues common to all Plaintiffs. Gilead petitions this Court for a writ of mandate, prohibition, or other appropriate relief, directing Respondent Superior Court of the State of California for the County of San Francisco to vacate its decision denying Gilead's Motion and to dismiss Plaintiffs' claims. To these ends, by this verified petition, Gilead alleges as follows.

THE PARTIES

Petitioner Gilead Sciences, Inc. is the defendant in the underlying litigation.

Respondent is the Superior Court of the State of California for the County of San Francisco, which denied Gilead's common-issues motion for summary judgment or, alternatively, summary adjudication.

Real Parties in Interest are approximately 24,000 plaintiffs who have sued Gilead in California in suits that have been coordinated for pretrial purposes in JCCP No. 5043. A list of those plaintiffs is appended to the end of this petition.

TIMELINESS OF PETITION

The Superior Court denied Gilead's common-issues motion for summary judgment or, alternatively, for summary adjudication, on June 14, 2022. (App. 3237-3253.) This petition is timely filed.

AUTHENTICITY OF EXHIBITS

App. 3158-3182 is a true and correct copy of the reporter's transcript of the May 20, 2022, hearing, and all other documents contained in the Appendix filed in support of this petition are true and correct copies of original documents submitted to or issued by the trial court.

STATEMENT OF JURISDICTION AND STANDING

This Court has jurisdiction under Code of Civil Procedure sections 1085 and 1103 to hear petitions for writs of mandate and prohibition that seek review of a trial court ruling. Petitioner Gilead is aggrieved and has standing because the trial court denied its common-issues motion for summary judgment or, alternatively, summary adjudication, allowing Plaintiffs' claims to proceed to trial.

RELEVANT FACTS AND PROCEDURAL HISTORY

A. Gilead develops lifesaving TDF medications to treat HIV.

1. Gilead Sciences, Inc. is a research-based biopharmaceutical company. Before Gilead began researching tenofovir disoproxil fumarate (TDF) in the early 1990s, HIV was a death sentence. (App. 221-222 [Campbell Dep. 27:23-28:5].) And not just a death sentence; people infected with HIV were all but guaranteed a fate of excruciating pain and physical, mental, psychological, and emotional suffering. (App. 228-231 [Kuritzkes Dep. 108:3-111:2]; App. 241-242 [Sagar Dep. 71:6-72:13].) What is more, many of the treatments at the time were not only ineffective, they were also complicated, costly, and toxic. (*See* App. 249-253 [Pitrak Dep. 185:16-186:9, 302:19-304:2]; App. 232-236 [Kuritzkes Dep. 150:7-152:9, 182:2-183:17].) Against this backdrop, Gilead licensed a portfolio of compounds in the early 1990s that it planned to research as possible treatments for HIV and other viruses. (App. 340-341 [Lee Dep. 14:6-18, 18:12-21].)

2. In March 1997, Gilead filed with FDA the investigational new drug application (IND) for TDF, seeking FDA approval to move from preclinical studies (testing on animals and in test tubes) to clinical trials (testing in human beings). (App. 146 [Gilead Stmt. of Undisputed Material Facts (SUMF) ¶ 1].)[1] Four years later, after clinical investigation and analysis, Gilead filed a

[1] All citations to Gilead's SUMF are to statements that Plaintiffs do not dispute (*see* App. 3095-3135 [Pls.' Resp. to Gilead SUMF]), and to evidence where objections, if any, were overruled (App. 3241 [Op. 5:1-4].)

new drug application (NDA) seeking permission to market and sell the first TDF medication, Viread®, which FDA approved in October 2001. (App. 146 [SUMF ¶ 2].) In subsequent years, Gilead requested and obtained FDA approval for four additional anti-HIV medications containing TDF, each combined with other antiretrovirals: Truvada®, Atripla®, Complera®, and Stribild®. (App. 147 [SUMF ¶¶ 3-6].)

3. As with any request for approval of a new drug, FDA reviewed the preclinical, clinical, manufacturing, and other information provided by Gilead about each proposed TDF-containing medication. (App. 201 [Egan Decl. ¶¶ 5, 7]; *see also* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50.) It is undisputed that Gilead provided FDA all the information necessary to determine whether to approve each TDF medication. (App. 3101 [Pls.' SUMF Resp. ¶ 11].)

4. In considering whether to approve each TDF medication, FDA was required to determine whether there was substantial evidence that the therapeutic benefits of each drug outweigh its risks of potential side effects. (App. 148 [SUMF ¶ 9]; *see* 21 U.S.C. § 355(d).) As to each of the five TDF medications, FDA found substantial evidence that the drug's benefits outweigh its risks for its intended use. (App. 146-148 [SUMF ¶¶ 2-6, 9].) Plaintiffs do not dispute that FDA's judgment was correct—that is, that FDA *correctly approved* each of the TDF medications. (App. 149 [SUMF ¶ 10].)

5. As additional protection required by law, each approved TDF medication includes a label containing (among

other things) safety information, warnings, and precautions. (App. 150 [SUMF ¶ 13].) From the day Viread® was approved in 2001, the label for each TDF medication has alerted patients and their doctors of possible kidney and bone side effects. (App. 151 [SUMF ¶ 14].)

6. In the 21 years since FDA approved Viread®, FDA has never once initiated proceedings to withdraw approval for any of the TDF medications. (App. 3103 [SUMF ¶ 15].) To the contrary, the medications have remained effective and safe for use. Indeed, TDF medications remain listed among the regimens for HIV antiretroviral therapy recommended by the U.S. Department of Health and Human Services, and the World Health Organization continues to refer to TDF as "essential" to HIV treatment. (App. 991-1061 [Gilead Request for Judicial Notice (Common Issues), Exs. K-L]; App. 3240 [Op. at 4:25-28] [granting Request for Judicial Notice].)

B. Plaintiffs file suit, and their theory morphs to focus on an entirely different class of Gilead medications—those containing TAF.

7. Plaintiffs—comprising more than 24,000 cases coordinated for pretrial purposes—all allege that they took one or more of the TDF medications. They do not allege that the medications failed to work as intended for HIV treatment—indeed, many of them are alive today because of TDF. Instead, they claim that the medications caused them kidney and/or bone injuries.

8. Originally, and as framed by the trial court, Plaintiffs asserted (among other things) a negligence (design-defect) claim focusing on TDF; a fraud-and-concealment claim; and strict-

liability, negligent failure-to-warn, and warranty claims centered around the TDF medication labels. (*See* App. 83, 85-86 [Demurrer Order].)

9. The trial court sustained in part and denied in part Gilead's demurrer and motion to strike. Following that decision, and as discovery progressed, Plaintiffs' theory of the case narrowed, as they agreed to dismiss several claims and limited others. Specifically, Plaintiffs stipulated to dismiss their failure-to-warn allegations, theories, and claims (as to all Counts); strict-liability claim (Count 2); and warranty claims (Counts 3 and 4). (App. 100 [Stip. & Order, ¶¶ 1-2 (Feb. 4, 2022)]; App. 107 (Stip. & Order, ¶¶ 1-2 (Feb. 23, 2022)].) Still pending are Plaintiffs' negligence claim (Count 1) and fraud-and-concealment claim (Count 5).

10. As for their negligence claim, Plaintiffs reformulated it to no longer focus on any problems with TDF. Most significantly, "Plaintiffs do not allege that *TDF* is defective." (App. 3103 [Pls.' SUMF Resp. ¶ 15].) Plaintiffs also no longer contend that FDA wrongly approved the TDF medications. (App. 3100 [Pls.' SUMF Resp. ¶ 10].) Nor do they contend that Gilead withheld any material information from FDA about the TDF medications. (App. 3101 [Pls.' SUMF Resp. ¶ 11].) And they do not contend that Gilead should stop selling, or was wrong in ever selling, the TDF medications. (*Id.* [Pls.' SUMF Resp. ¶ 12].)

11. Instead, Plaintiffs argue that in 2004, Gilead delayed the development of an entirely different compound (tenofovir alafenamide, or TAF) when it should have continued pursuing it.

(*See* App. 308-314 [Stile Interrogatory Resp. Nos. 203, 207, 211, 215, 219]; App. 330-331 [DeMartino Interrogatory Resp. Nos. 161, 162].)

12. It is undisputed, however, that as of that time, Gilead had not yet conducted any Phase III clinical trials of TAF, and the only clinical trial it had conducted was a 14-day, Phase I/II study (the 1101 Study) of 30 subjects, only 20 of whom received TAF. (App. 151 [SUMF ¶ 17].) (Plaintiffs' fraud-and-concealment claim is that Gilead should have disclosed earlier the results of that study.) It is further undisputed that FDA could not have approved any TAF-containing medication based on the data that was available in 2004. (App. 152 [SUMF ¶ 18] [citing, among other things, testimony from Plaintiffs' regulatory expert Dr. Pence].)

13. In actuality, it was not until years later that Gilead had the data it needed for FDA approval of a TAF-based medication. In or about 2010, Gilead elected to restart its investigation of TAF. (*Id.* [SUMF ¶ 21].) In 2011, Gilead filed an IND requesting permission to conduct clinical study of a TAF analogue to the TDF medication Stribild®. (App. 153 [SUMF ¶ 22].) Shortly after completing a Phase III study comparing the safety and efficacy of a TAF-containing regimen to a TDF-containing regimen, Gilead filed its first NDA seeking FDA approval for a TAF-containing medication to treat HIV. (*Id.* [SUMF ¶¶ 23-24].) FDA approved that medication (Genvoya®) in November 2015. (*Id.* [SUMF ¶ 25].)

14. In short, Plaintiffs have tailored their case to be about Gilead's development and disclosure of information regarding

TAF—and not about the TDF medications that supposedly injured them. They do not claim that the TDF medications were defective, but instead that Gilead should have more quickly developed—and disclosed information about—an entirely different set of medications (those containing TAF).

C. Even though Plaintiffs conceded away design defect and do not allege anything wrong with the TDF medications, the Superior Court allows Plaintiffs' claims to go to trial.

15. Gilead filed a motion for summary judgment and/or summary adjudication with respect to common issues across the 24,000 coordinated cases. (App. 109-114 [Gilead's Motion]; App. 115-144 [Op'g Br.]; App. 3136-3157 [Reply].) The Motion noted that Plaintiffs no longer had any viable negligent-design-defect claim, as they were no longer alleging that the TDF medications contained any defects.

16. Gilead also argued that Plaintiffs' "free-floating" negligence claim—one alleging no defect in the TDF medications that supposedly injured them, but instead claiming negligence for failing to more quickly develop a different medication—failed for similar reasons. As Gilead explained, neither California nor any other state recognizes a free-floating negligence claim for injury from a product, unmoored from a defect in the product. Instead, when someone is allegedly injured when using a product, they must demonstrate that the product is defective—in its design, manufacture, or warnings.

17. Gilead also explained that the defect standard exists for good reason: to protect consumers while avoiding unbounded

and standardless liability. Later motion practice in this very case, in fact, has revealed just how unworkable a free-floating negligence standard is: In tentatively excluding one of Plaintiffs' experts, the court explained that this is not a case of "professional negligence" or "malpractice"; the duty is not "compliance with standards for clinical trials, compliance with FDA regulations, or the safety of an assertedly defective product." (App. 3275 [*Sargon* Op. at 14:2-14].) Rather, the standard of care boils down to the jury's hindsight view of the reasonableness of "a business decision ... possibly informed by medical and financial concepts." (*Ibid.*)

18. Regarding Plaintiffs' fraud-and-concealment claim, as mentioned above, the claim is premised on Gilead not releasing earlier the results of that TAF Phase I/II study known as the 1101 Study. Although it is undisputed that Gilead did disclose the results years before any TAF medication was approved by FDA and available for prescription, Plaintiffs contend the results should have been released even earlier. Plaintiffs also contend that Gilead had a duty to release this information even though the study said nothing relevant about the safety of TDF; just that TAF had a safety profile "similar" to that of TDF. Gilead's Motion explained, among other things, that Gilead had no duty to disclose to Plaintiffs or their doctors information about a medication that Plaintiffs were not taking and would not be able to take for years because it had not even been submitted to FDA for approval, much less approved to be prescribed.

19. In response to Gilead's arguments on their negligent-design-defect claim, Plaintiffs again reiterated—both in their

opposition papers and at oral argument—that they "do not allege that TDF is defective." (App. 3103 [Pls.' SUMF Resp. ¶ 15] [italics omitted]; *accord* App. 3164 [MSJ Hr'g Tr. at 22:15-19].) They also conceded that they "do not allege that the risks of TDF outweigh[] its benefits"—as would be necessary to show a prescription drug is defective in design. (App. 3021 [Pls.' MSJ Opp'n at 12:8-10].) Yet they insisted that they still have a viable design-defect claim because they suffered an injury from TDF that they allege would have been avoided if Gilead developed earlier an entirely different medication (TAF). (App. 3011 [Pls.' MSJ Opp'n at 2:11-12].)

20. As for their free-floating negligence claim, Plaintiffs did not cite a single case that supports imposing liability on a defendant for injury caused by a non-defective product. (*See, e.g.*, App. 3165 [MSJ Hr'g Tr. at 27:22-24].) Instead, they cited only Civil Code Section 1714's general duty of "ordinary care," and erroneously asserted that Gilead was seeking an exception to that duty. (App. 3163 [MSJ Hr'g Tr. at 18:6-14].)

21. Gilead explained in reply that, to the contrary, this general duty is expressed in a more particular and specific form depending on the context. Where, as here, a plaintiff claims to have been injured by a product, the duty is to design and manufacture a reasonably safe product (one where the product's risks do not outweigh its benefits) and to warn of known or reasonably knowable risks—all duties that Plaintiffs concede that Gilead fulfilled.

22. On June 14, 2022, the Superior Court denied Gilead's Motion. The court acknowledged Plaintiffs' concessions that they

"do not allege that TDF is defective" nor do they contend that "the risks of TDF outweigh its benefits." (App. 3247 [Op. at 11:23-25].) The court recognized that, in doing so, Plaintiffs had conceded away a crucial element of a negligent-design-defect claim because, under such a claim, "a plaintiff must prove that a product defect caused injury and that the defect arose from negligence." (App. 3247-3250 [Op. 11:19-14:10] ["[A] product defect seems to necessarily be part and parcel of a negligent design claim."].) But after three pages of explaining why Plaintiffs' design-defect theory could not satisfy "all of negligent design's elements … where it is conceded that the product is not defective," (App. 3249 [Op. 13:23-25]), the court made an abrupt about-face, concluding: "Nonetheless, the Court determines that the current record does not support granting Gilead's motion as to Plaintiffs' negligent design theory," (App. 3250 [Op. 14:14-16].)

23. The court also denied Gilead's Motion with respect to Plaintiffs' free-floating negligence theory. Relying on inapposite cases never cited by Plaintiffs nor briefed by the parties, the court accepted Plaintiffs' claim even though Plaintiffs agreed that the product that allegedly injured them was not defective. The court did not address any of Gilead's caselaw. (App. 3246 [(Op. 10:8-28].)

24. As for Plaintiffs' fraud-and-concealment claim, the court denied Gilead's Motion. The court rejected Gilead's argument that it had no duty to disclose to Plaintiffs and their doctors information about a medication that was years from FDA approval, could not be prescribed by doctors, and was not being taken by Plaintiffs. Despite Gilead's argument, the court said that

"Gilead is not challenging the existence of a duty to disclose." (App. 3251 [Op. 15:24-25].) The court added in a footnote that Gilead's argument took too "granular [a] view of what constitutes a transaction giving rise to a duty to disclose" and was "contrary to [unspecified] established law." (App. 3251 [Op. at 15 fn.7].) The Court also rejected Gilead's separate materiality argument, reasoning that information about the safety of TAF from the 1101 Study would have been "material" to the doctors' decisions to prescribe TDF medications to Plaintiffs years before TAF medications had been approved.

25. As a result of the trial court's decision, Plaintiffs' claims are proceeding to trial in bellwether cases. The first bellwether trial is scheduled for October 3, 2022, with the second bellwether to be tried in early 2023, and the third and fourth bellwether trials to be tried thereafter (with Plaintiffs urging that the trials be set for 2023 as well).

26. Plaintiffs have made clear, through their submissions since the court's summary-judgment decision, that they intend to focus the duty and breach elements of negligence entirely on Gilead's development of TAF and not at all on whether the TDF medications that purportedly injured them are defective.

27. For example, Plaintiffs filed a motion *in limine* to preclude the jury from hearing evidence of FDA's approval of TDF and Gilead's compliance with FDA rules. The premise of Plaintiffs' motion is that Gilead's compliance with its duties to ensure the safety of the TDF medications that Plaintiffs took is irrelevant because Plaintiffs' "negligence cause of action was and remains

based on Gilead's conduct as to the delayed development of *TAF*, *not* TDF." (App. 3255 [Pls.' Reply in Support of Motion *In Limine* No. 1]; *accord* App. 3186 [Pls.' Motion *In Limine* No. 1] ["The jury will be asked to evaluate whether Gilead acted reasonably when it delayed the development and availability of TAF."].) As Plaintiffs see it, it is immaterial that TDF is not defective, that FDA correctly concluded that the benefits of TDF outweigh its risks, and that nothing has or should have caused FDA to reconsider that decision in over 20 years. That is because, even though Plaintiffs seek damages for injuries allegedly caused by taking TDF medications, Plaintiffs contend that "Gilead's conduct as it relates to *TAF* and Gilead's decision to delay *TAF* development are the issues central to Plaintiffs' negligence claims." (App. 3189 [Pls.' Motion *In Limine* No. 1].)

BASIS OF RELIEF AND INADEQUACY OF OTHER REMEDIES

28. It has long been settled that a plaintiff cannot bring a claim to recover damages for injury from a non-defective product. The Superior Court held otherwise, concluding that Plaintiffs can bring a negligence claim, and even a design-defect claim, without proving that the product that allegedly injured them is defective. The Superior Court also held that a manufacturer has a legal obligation to disclose information about a product in development that is years away from being on the market and available to consumers. The ruling recognizing these non-actionable claims is "of widespread interest," (*Omaha Indem. Co. v. Superior Ct.* (1989) 209 Cal.App.3d 1266, 1273), and "of great public importance,"

(*Henry M. Lee L. Corp. v. Superior Ct.* (2012) 204 Cal.App.4th 1375, 1383), warranting this Court's intervention. As described below, that ruling, if sustained, would transform mass tort litigation in California. The Superior Court's decision also governs these common issues across more than 24,000 coordinated TDF lawsuits pending in this State. (*See McGrath v. Superior Ct.* (Ct. App. 1995) 43 Cal.Rptr.2d 32, 34 [writ review warranted when lower court decision has "potential legal impact on numerous pending" cases], *opinion superseded on other grounds* (Cal. 1995) 904 P.2d 371.) The first bellwether trial is scheduled to start on October 3, 2022, with three subsequent bellwether trials to follow, almost certainly before this Court has an opportunity to decide a post-trial appeal from the first bellwether trial. As discussed below, that this Court's intervention now could prevent multiple unnecessary trials and appeals is reason enough to grant review. (*See County of Santa Clara v. Superior Ct.* (1992) 2 Cal.App.4th 1686, 1690-91 ["writ petition is appropriate to avoid a multiplicity of appeals raising the same issue"]; *People v. Superior Ct. (Caudle)* (1990) 221 Cal.App.3d 1190, 1193, fn. 2 ["interlocutory review is justified in the interest of avoiding multiple trials involving the same facts."].)

Basis of relief

29. Writ relief, while extraordinary, exists precisely for circumstances like this. The point of Gilead's Petition is that Plaintiffs have no actionable claims: The TDF medications that Plaintiffs took are concededly not defective, and thus Gilead had no legal obligation to develop some other medication or to publish

information about that other medication long before it was on the market. "'Where the trial court's denial of a motion for summary judgment will result in a trial on non-actionable claims, a writ of mandate *will* issue.'" (*Farmers Ins. Exch. v. Superior Court* (2013) 220 Cal.App.4th 1199, 1204 (as modified) [italics added]; *accord Diamond v. Superior Court* (2013) 217 Cal.App.4th 1172, 1182 (as modified) [same]; *City of San Diego v. Superior Ct.* (2006) 137 Cal.App.4th 21, 25 [same]; *Hill Bros. Chem. Co. v. Superior Ct.* (2004) 123 Cal.App.4th 1001, 1005 [same]; *Knowles v. Superior Ct.* (2004) 118 Cal.App.4th 1290, 1295 [same]; *Prudential Ins. Co. of America, Inc. v. Superior Ct.* (2002) 98 Cal.App.4th 585, 594 [same].)

30. As explained in the memorandum of points and authorities, none of the claims Plaintiffs have brought is actionable. Under the correct application of California law, the Superior Court should have granted Gilead's Motion and dismissed the thousands of pending coordinated cases.

31. **Negligent design defect and free-floating negligence**. It is undisputed that the TDF medications are not defective. Plaintiffs concede the point. That concession should have been fatal to their negligent-design-defect claim, which requires a plaintiff to "prove a defect caused injury" and "that the defect in the product was due to negligence of the defendant." (*Chavez v. Glock, Inc.* (2012) 207 Cal.App.4th 1283, 1304-05 [quotation marks omitted].) Although the Superior Court agreed that the absence of a defect in the TDF medications is fatal to any design-*defect* claim, it concluded nonetheless that the claim could proceed to trial. (App.

3247 [Op. 11:19-14:10].) In doing so, the court's ruling effectively eliminated the requirement to prove a design defect—in a design-defect claim, no less.

32. Notwithstanding the absence of any defect in the TDF medications, the Superior Court held that Gilead could be liable for not more quickly developing its TAF medications. In other words, the court held that a plaintiff has an actionable tort claim to redress injuries allegedly caused by a non-defective product—simply because a manufacturer did not sooner develop a different product that a plaintiff contends would have avoided the injuries. (App. 3246 [Op. 10:8-28].) That holding ignores that the manufacturer's duty is only "to produce defect-free products." (*Milwaukee Elec. Tool Corp. v. Superior Ct.* (1993) 15 Cal.App.4th 547, 551.) In holding that a manufacturer could be liable for not developing a different product more quickly—even if the accused product is not defective—the Superior Court created a negligence claim that no other court in this State, or anywhere else in the country, has ever recognized. (*Cf. Prentis v. Yale Mfg. Co.* (Mich. 1984) 365 N.W.2d 176, 181-82 ["Like the courts *in every other state*, whether a suit is based upon negligence or implied warranty, … the plaintiff must, *in every case*, *in every jurisdiction*, show that the product was defective."] [first italics added].) Moreover, because a negligent-design-defect claim requires proof of both a defective product and negligence (*Chavez*, *supra*, 207 Cal.App.4th at pp. 1304-05), the ruling below effectively writes such a claim out of existence—as a plaintiff would have no reason to pursue a cause

of action requiring proof of a defect *and* negligence if that plaintiff could obtain the same relief by proving only negligence.

33. By writing the defect requirement out of existence, the Superior Court's order effectively imposes an affirmative duty on manufacturers to bring to market any product that shows any glimmer of incremental benefit. In addition to being unprecedented, this purported duty is entirely unworkable. As the Superior Court made clear in its recent *Sargon* ruling, the question of liability comes down to the jury's view of the reasonableness of "a business decision ... possibly informed by medical and financial concepts." App. 3275 (*Sargon* Order at 14:9-11.) Unlike the question of a product's defectiveness—a well-defined standard that gives jurors ample guidance—the Superior Court's newly-minted duty provides no guidance on *how* the jury is to "possibly" consider a company's financial or profit motives (motives that every public company possesses). Does a company risk liability every time it considers a product's profitability in making development decisions? How does a jury evaluate the reasonableness of a company's decision to invest its finite resources elsewhere? The Superior Court's decision does not say.

34. **Fraudulent concealment**. The Superior Court also erroneously concluded that Plaintiffs could proceed to trial on their fraud-and-concealment claim, even though Plaintiffs concede that Gilead disclosed all relevant information about the TDF medications that allegedly injured them. Plaintiffs' claim is that, notwithstanding Gilead's disclosures about TDF, it should have disclosed sooner information about a different medication (TAF)

that Plaintiffs were *not* taking, was not FDA approved, was years from approval, and thus, by definition, could not be prescribed or used. (App. 3250-3252 [Op. 14-16].)

35. The question presented in this Petition is whether there is a duty to disclose such information, which is a "threshold question" of law. (*Bank of America Corp. v. Superior Ct.* (2011) 198 Cal.App.4th 862, 870-73.) Any duty to disclose here would be "created by transactions between [the] parties," with a "duty" to "disclose facts material to the transaction." (*LiMandri v. Judkins* (1997) 52 Cal.App.4th 326, 336-37.) The only transactions at issue here concern the prescription of Gilead's TDF medications to Plaintiffs. It would be unprecedented—and wrong—to hold that a plaintiff's use of one of the defendant's products required the defendant to disclose information about a different product that was not on the market and would not be for several years.

Absence of other adequate remedies

36. "The adequacy of an appellate remedy depends on the circumstances of the case." (*Fisherman's Wharf Bay Cruise Corp. v. Superior Ct.* (2003) 114 Cal.App.4th 309, 319.) As relevant here, Gilead has no "plain, speedy, and adequate remedy" at law, other than the relief sought in this Petition. (Code Civ. Proc. § 1086.)

37. "Where," as here, "there is no direct appeal from a trial court's adverse ruling, and the aggrieved party would be compelled to go through trial and appeal from a final judgment, a petition for writ of mandate is allowed." (*Fair Employment & Housing Com. v. Superior Ct.* (2004) 115 Cal.App.4th 629, 633; *see also Baeza v. Superior Ct.* (2011) 201 Cal.App.4th 1214, 1221

["'[T]he expense of proceeding with trial ... [is an appropriate] consider[ation] in evaluating the adequacy of the appellate remedy.'"]; *H.D. Arnaiz, Ltd. v. County of San Joaquin* (2002) 96 Cal.App.4th 1357, 1366-67 ["Avoiding an unnecessary trial … militate[s] towards writ review".].)

38. Critically, writ review is needed here to correct the trial court's mistaken recognition of non-cognizable claims. If these non-actionable claims are allowed to proceed, Gilead will be forced to undergo not just one but multiple unnecessary trials and appeals while facing potential liability across more than 24,000 cases. (*See, e.g.*, *Noe v. Superior Ct.* (2015) 237 Cal.App.4th 316, 324 ["writ review is appropriate to 'obviate a duplicative expenditure of resources for the courts and the parties'" that would result from having a "second trial" and thus permitting interlocutory review "to avoid the delay and expense of potentially unnecessary litigation and 'the attendant waste of judicial resources'"]; *McGrath*, *supra*, 43 Cal.Rptr.2d at 34 ["We conclude immediate writ review is warranted because the petition raises an issue with potential legal impact on numerous pending criminal prosecutions."]; *Caudle*, *supra*, 221 Cal.App.3d at p. 1193, fn. 2 ["interlocutory review is justified in the interest of avoiding multiple trials involving the same facts."]; *Anderson v. Superior Ct.* (1989) 213 Cal.App.3d 1321, 1328 [granting writ of mandate directing trial court to vacate "orders entered against the five petitioners" because the orders were "representative of orders the court has entered" in "hundreds" of cases]; *People v. Superior Ct. (Schomer)* (1970) 13 Cal.App.3d 672, 676 [concluding that "swift

relief through a single writ" was "appropriate to prevent a multiplicity of appeals raising an identical jurisdictional question" given the trial court's intention to "tak[e] similar action in 'several other cases now pending'"]; *see also California Highway Patrol v. Superior Ct.* (2006) 135 Cal.App.4th 488, 496 ["interlocutory writ review is appropriate because the petition raises an issue of first impression that is of widespread interest, as the multiplicity of similar lawsuits confirms"].) Writ review in Gilead's favor would avoid hundreds, if not thousands or tens of thousands, of unnecessary jury trials. And even a decision from this Court ultimately favoring Plaintiffs would resolve important legal questions about the viability, scope, and contours of their claims, avoiding unnecessary appeals on those questions.

39. An appeal of purely legal common issues presented in thousands of cases warrants this Court's immediate intervention, as the citations above to other multi-case litigations demonstrate. In *County of Santa Clara*, for example, the appellate court concluded that "direct appeal would not be an adequate alternative remedy" given that petitioner's case was "but one of at least 14 pending [similar] … matters" presenting the same legal issue. (*Supra*, 2 Cal.App.4th at pp. 1690-91.) Accordingly, the court stated, "[c]onsideration of the merits of the writ petition is appropriate to avoid a multiplicity of appeals raising the same issue." (*Ibid.* [collecting cases].) Where the material facts "are established without essential dispute," (*Hogya v. Superior Ct.* (1977) 75 Cal.App.3d 122, 131), and the question of law is one presented in various pending matters, "[j]udicial economy is

served by an early appellate resolution of the issue," (*California Highway Patrol*, *supra*, 135 Cal.App.4th at p. 496; *accord Fisherman*'s *Wharf*, *supra*, 114 Cal.App.4th at p. 319 ["[T]he issues presented are questions of law, making their immediate resolution on a petition for writ of mandate appropriate."].) There is no denying that the legal questions raised here about the viability of Plaintiffs' claims are presented across all the cases in this JCCP—that is why they were raised in a common-issues motion. There is also no denying that Gilead will face undue prejudice and harm if an erroneous ruling is allowed to stand: Gilead would be forced to undergo multiple trials before appellate review of a final judgment could hold that Plaintiffs' claims never should have gone to trial. Because multiple trials (and even appeals) could be obviated by early appellate resolution of the legal questions presented, writ review is especially warranted.

40. Moreover, an appeal after the first bellwether trial is wholly inadequate to protect Gilead's rights. While the legal questions could be raised in a post-trial appeal of the first bellwether trial, given the length of the trial, the size of the record, and the median time between filing a notice of appeal and appellate disposition, it is nearly certain that the next three bellwether trials will have already occurred before a decision could be reached in the first appeal. (*See* Judicial Council of Cal., 2021 Court Statistics Rep.: Statewide Caseload Trends (2021) p. 36 [median time between notice of appeal and final disposition in the First Appellate Division ranges from 489 to 626 days].) The real prospect of subjecting Gilead to multiple unnecessary trials and

appeals thus renders a post-trial appeal from the first bellwether trial completely inadequate. Furthermore, unlike any other appellate vehicle, writ review here provides a unique opportunity for this Court to review a ruling on the common issues across all the cases in this JCCP.

41. Finally, writ review is especially warranted here for three additional reasons:

First, as discussed above and established in the memorandum of points and authorities, the Superior Court's erroneous ruling breaks with established precedent, endorsing novel and unprecedented theories of liability. The "novel and important" nature of these invented and unsupported theories of liability weigh heavily in favor of writ review. (*JSM Tuscany, LLC v. Superior Ct.* (2011) 193 Cal.App.4th 1222, 1236.)

Second, as the Superior Court's opinion illustrates, the common-issues Motion presents an ideal vehicle for this Court to consider and resolve these dispositive legal questions about the viability of Plaintiffs' claims. Each legal question has been teed up, fully briefed, and addressed by the Superior Court in writing. And the common-issues, summary-judgment/adjudication posture avoids the unnecessary wrinkles and complications that will inevitably follow from a post-trial appeal of a single plaintiff's case.

Third, even if a direct appeal were an adequate remedy, a writ would still be warranted because "the issues presented are of great public importance and require prompt resolution." (*Henry M. Lee*, *supra*, 204 Cal.App.4th at p. 1383; *accord Powers v. City of Richmond* (1995) 10 Cal.4th 85, 113; *Anderson*, *supra*, 213

Cal.App.3d at p. 1328; *Silva v. Superior Ct.* (1993) 14 Cal.App.4th 562, 573.) That is so because the Superior Court's ruling threatens to upend mass tort litigation in California by creating liability for injuries from non-defective products and requiring disclosure of information about products still in development. The ruling also threatens to stifle medical innovation and research by holding that a drug manufacturer could be found liable for not developing quickly enough a medication that showed some promise in early studies. Many medications show initial promise but never make it to market. (App. 460-461 [Bischofberger Dep. 359:13-360:24].) If tort liability attaches anytime a drug company fails to fully investigate a medication that shows early promise, drug companies will intentionally limit the number of medications they investigate to avoid liability for failing to pursue that medication all the way through approval. The result will be less scientific inquiry, less innovation, and fewer lifesaving and pain-reducing medications—contrary to California public policy. (*See Brown v. Superior Ct.* (1988) 44 Cal.3d 1049, 1063.) The consequences of such a rule will also cascade beyond the pharmaceutical industry, affecting the willingness of all manufacturers to innovate, lest they face tort liability from developing new products or improving existing ones.

Ultimately, the pretrial resolution of the viability of Plaintiffs' claims is critical not only to Gilead and the thousands of plaintiffs in these cases, but also to the public, as it concerns the future of tort litigation and product development in this State.

NO STAY REQUESTED AT THIS TIME

The first bellwether trial is scheduled to start on October 3, 2022. With that trial still several months away, this Petition does not request a stay of the trial, but Gilead reserves the right to seek a stay from the Superior Court or this Court as that trial date approaches.

VERIFICATION IN SUPPORT OF PETITION

I, Andrew D. Silverman, declare as follows:

I am an attorney licensed to practice law in the State of California and am a partner in the law firm of Orrick, Herrington & Sutcliffe LLP, counsel of record for Petitioner in this action. I have read this Petition for Writ of Mandate, Prohibition, or Other Appropriate Relief and know its contents. The facts alleged in the petition are either true to my knowledge or, based on my review of the attached petition and supporting documents, I know the facts set forth to be true.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on July 6, 2022, in New York, NY.

/s/ Andrew D. Silverman
Andrew D. Silverman

MEMORANDUM OF POINTS AND AUTHORITIES

STANDARD OF REVIEW

"Since a motion for summary judgment or summary adjudication involves only questions of law, the standard of review is de novo." (*W. Shield Investigations & Sec. Consultants v. Superior Ct.* (2000) 82 Cal.App.4th 935, 946.) Such a motion "shall be granted" when the evidence—including documents, declarations, discovery responses, and depositions—establishes that a suit or a cause has "no merit." (Code Civ. Proc. § 437c(a)(1), (c), (o); *see id.* § 437c(b)(1).)

ARGUMENT

I. This Court's Immediate Intervention Is Necessary To Prevent Needless Trials, For Design Defect And Negligence, For A Product That Plaintiffs Concede Is Not Defective In Any Way.

A. There is no cognizable claim for free-floating negligence against a manufacturer for alleged injuries caused by a non-defective product.

It is undisputed that the TDF medications that allegedly injured Plaintiffs are not defective. Plaintiffs do not claim otherwise. On the contrary, knowing that the TDF medications have saved countless lives (including their own), "Plaintiffs concede that they are not asserting that the TDF drugs are defective[,] … do not allege that Gilead should have stopped selling TDF, [and] do not allege that the risks of TDF outweigh its benefits." (App. 3247 [Op. 11:19-25]; *accord* App. 3021 [MSJ Opp'n at 12:8-10]; App. 151 [Pls.' SUMF Resp. ¶ 15]; App. 3164 [MSJ Hr'g Tr. at 22:15-19].) To the Superior Court, however, none of that

matters. In its view, Plaintiffs can still impose liability on Gilead for its purported delay of an entirely *different* set of medications (containing TAF).

Plaintiffs' free-floating negligence theory—seeking to hold Gilead liable for not developing sooner a medication that was, in the words of one of Plaintiffs' experts, "slightly better," (App. 433 [Kesselheim Dep. 176:20-25])—has never been recognized by a California court. Indeed, courts in California and across the country unanimously reject any such theory and universally hold that a plaintiff who alleges injury from a product must show that something is *wrong* with the product—*i.e.*, that the product is defective. It is no wonder why courts are unanimous in that view: Plaintiffs' theory threatens to hold a manufacturer liable any time it declines to pursue a product that shows initial promise and any time the manufacturer makes improvements to a product that it could have conceivably made earlier. As recognized, this theory would weaponize scientific discovery, imposing hindsight liability on the difficult decisions drug companies make during the scientific discovery process that is drug development. It would also discourage innovation across all other industries, from carmakers to tech companies to medical device producers. In short, it would cause disastrous consequences not just for the more than 24,000 cases in this coordinated proceeding, but also for countless products-liability actions pending up and down the State.

1. In California, and in every other state, a manufacturer's duty is to produce a non-defective product.

California's general-duty statute is Civil Code Section 1714, which provides that "[e]veryone is responsible … for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person." California law makes clear that, "in the context" of a plaintiff's allegation of injury from a product, this general duty in Section 1714 takes on a specific form: the duty embodied by the products-liability caselaw. (*T.H. v. Novartis Pharms. Corp.* (2017) 4 Cal.5th 145, 163-64.) "Products liability," the California Supreme Court explains, "is the name currently given to the area of the law involving the liability of those who supply goods or products for the use of others … for losses of various kinds resulting from so-called defects in those products." (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 478 [quoting Prosser & Keeton, Torts (5th ed. 1984) § 95, p. 677].)

Products-liability law contains "three types of product defects" and specific articulations of the duties with respect to each category. (*Brown*, *supra*, 44 Cal.3d at p. 1057.) A plaintiff may allege a breach of the duty of care to warn of the product's known or knowable risks—a failure-to-warn claim. (*T.H.*, *supra*, 4 Cal.5th at p. 164 [explaining, after discussing Section 1714, that "[i]n the context of prescription drugs, a manufacturer's duty is to warn physicians about the risks known or reasonably known to the manufacturer"].) A plaintiff can also allege a breach of the duty of care to manufacture a reasonably safe product—a manufacturing-defect claim. (*Sheward v. Virtue* (1942) 20 Cal.2d 410, 412, 414-

15.) And a plaintiff can allege a breach of the duty of care by alleging that the design of the product is not reasonably safe—a design-defect claim. (*Pike v. Frank G. Hough Co.* (1970) 2 Cal.3d 465, 470.)

Regarding a product's design—what is at issue here[2]—the "general duty [is] to produce defect-free products." (*Milwaukee Electric Tool Corp.*, *supra*, 15 Cal.App.4th at p. 551.) That legal obligation "translates into a duty similar to that in negligence law not to depart from the appropriate standards of care in manufacturing its product." (*Ibid.*; *see Merrill, supra*, 26 Cal.4th at p. 480 ["[T]o say that a product was 'negligently designed' is to say it was defective, for purposes of establishing liability under a theory of negligence." (quotation marks omitted)].) Critically, however, the specific duty is to produce "defect-free products," (*Milwaukee Electric Tool Corp.*, *supra*, 15 Cal.App.4th at p. 551); there is no alternative, free-floating obligation separate from the duty that the product be free of defects. As the Supreme Court has said: "The rules of products liability *focus responsibility for defects* … on the manufacturer of the completed product." (*See Merrill*, *supra*, 26 Cal.4th at pp. 478-79 [italics added].)

As is obvious from the above, manufacturers—including "drug manufacturers[—]are not free of all liability for defective drugs." (*Brown*, *supra*, 44 Cal.3d at p. 1069, fn. 12.) As the Supreme Court explained, when a product is "defective," there can be liability for "manufacturing defects," defects in the warning

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[2] Plaintiffs have dismissed their failure-to-warn claims (*supra* at 18) and do not allege any manufacturing defects.

label (*i.e.*, "failure to warn of known or reasonably knowable side effects"), and "negligence" in the design of the drug (*i.e.*, negligent design defect). (*Ibid.*) Moreover, other claims may exist too, such as breach of express and implied warranties—both of which Plaintiffs voluntarily dismissed here (App. 107 [Stip. & Order, ¶¶ 1-2])—and common-law fraud based on representations and omissions regarding the product (so long as the plaintiff establishes the elements of such a claim). In the context of a consumer alleging injury from using a product, though, the duty is clear: The manufacturer has a duty to make a reasonably safe product and warn of all known or reasonably knowable risks. The duty is not a free-floating legal obligation to produce any and all products that show some initial promise of being a marginal improvement over an existing product. (*Contra* App. 3011 [Pls.' MSJ Opp'n at 2:11-12] [asserting liability on the ground that TDF is, in Plaintiffs' word, "inferior" to TAF].)

The non-viability of any free-floating negligence claim, divorced from a defect, is evident in the legal standard applicable to prescription medications. For most products, the manufacturer is strictly liable for an injury caused by a defect in the product's design, no matter what degree of care the manufacturer exercised in designing the product. (*Brown, supra,* 44 Cal.3d at p. 1057.) In *Brown*, however, the Supreme Court concluded that strict liability for prescription drugs would be contrary to public policy. (*Id.* at pp. 1061-63 [explaining that prescription drugs "may be necessary to alleviate pain and suffering or to sustain life," that "strict liability" might make drug manufacturers "reluctant to undertake research

programs to develop" new medications, and that the costs associated with strict liability would increase the price of medications and put them "beyond the reach of those who need [them] most"].) Accordingly, the Supreme Court concluded that a greater showing would be required to establish liability for design defects in medications—not just a defect, which would be strict liability, but negligence as well as a defect (*i.e.*, negligent design defect). (*Id.* at 1065.)

To make out a negligent-design-defect claim, "the plaintiff must prove a defect caused injury" and must prove the "additional element" that "the defect in the product was due to negligence of the defendant." (*Chavez*, *supra*, 207 Cal.App.4th at pp. 1304-05 [quotation marks omitted].) Thus, as the Supreme Court intended, the test is more stringent than strict liability. (*Ibid.*; *see Brown*, *supra,* 44 Cal.3d at p. 1065). It is also more stringent than negligence alone because it requires proof of negligence *and* a defect—not *instead* of a defect. The additional level of proof comports with the common-sense principle in the caselaw that "manufacturers are not insurers of their products"—they "are liable in tort only when 'defects' in their products cause injury." (*Soule v. Gen. Motors Corp*. (1994), 8 Cal.4th 548, 568 fn. 5; *accord infra* at 54-55.)

2. Neither Civil Code Section 1714, nor the cases cited by the Superior Court, supports Plaintiffs' free-floating negligence theory.

Throughout the extensive briefing and oral argument below, Plaintiffs have not once cited a case—not in California, not elsewhere—that allows a plaintiff allegedly injured from using a

non-defective product to sue in negligence to recover for their injuries. (*See, e.g.*, App. 3165 [MSJ Hr'g Tr. at 27:22-28:4].) Indeed, Gilead specifically challenged Plaintiffs to do so at oral argument, and they had no answer. (*Ibid.*)

It is no wonder why. The consensus is clear: Manufacturers are not insurers for customers' injuries—there is no "*absolute* liability" just because a product causes injury. (*O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 362 [emphasis in original].) There must be something wrong with the product—some defect—before a plaintiff can recover for injuries caused by the product. That is why it is the law in California, and "in every other state" and "*every jurisdiction*," that "[t]he plaintiff must, *in every case* … show that the product was defective." (*Prentis*, *supra*, 365 N.W.2d at pp. 181-82 [emphasis in original]; *see also* App. 3147 [MSJ Reply at 6:27-7:10 & fn.3] [collecting dozens of cases from around the country].)

The authority foreclosing Plaintiffs' negligence claim should have been the end of the matter. Instead, Plaintiffs pointed to Civil Code Section 1714, insisting that the statute makes Gilead liable for *any* purported negligence that leads to injury from a product, even if there is no defect in the product. But as explained above (at 40-42), where a plaintiff alleges injury from a product, a manufacturer's duties to its consumers *are* the more specific duties embodied by the products-liability law, which require a defect in the product that is concededly absent here. As the Supreme Court held in *Merrill*, a plaintiff cannot simply recast a product-defect claim as one for negligence. (*Supra*, 26 Cal.4th at pp. 478-81.)

Merrill arose from a horrific mass shooting. The California statute at the time foreclosed a products-liability claim because it barred the plaintiffs from arguing that guns were defective products whose risks outweighed their benefits. (*Id.* at p. 470 [discussing Civ. Code, § 1714.4(a)].) Just as here, then, the *Merrill* plaintiffs knew they could not prevail on a design-defect claim, and so they recharacterized their claim as a negligence claim, completely divorced from a design defect and focused instead on the defendant's allegedly negligent *conduct*. (*Id.* at pp. 470, 478-81.)

The Supreme Court rejected the plaintiffs' gambit, holding that, regardless of how they characterized it, their claim was still a products-liability claim for injury from a product and thus required proof of a defect. (*Id.* at pp. 480-81.) It did not matter that the plaintiffs focused their claim on the manufacturer's allegedly "negligent conduct" because ultimately, the Supreme Court reasoned, the claim required a showing that the product was defective, which the plaintiffs could not make. (*Ibid.*)

The same is true here: Plaintiffs allege that the TDF medications injured them. As in *Merrill*, Plaintiffs cannot prove that the products that allegedly injured them are defective (because Plaintiffs conceded that the TDF medications are not defective). Plaintiffs are thus left to assert, as in *Merrill*, a negligence claim for injury from a product they are not claiming is defective. But as *Merrill* held, plaintiffs cannot prevail on a negligence claim for injury from the product without proving a defect. Here, that means Plaintiffs cannot prevail on a claim

premised on Gilead's allegedly negligent conduct in delaying TAF development without proving that the TDF medications that they took are defective.

The Superior Court was clearly unmoved by Plaintiffs' exclusive reliance on Section 1714—after all, it did not rely on Section 1714 in its analysis. (App. 3246 [Op. 10:15-28].) In the absence of Plaintiffs "cit[ing] any authority where a claim like theirs had proceeded," (*id.* 10:12-13), the Superior Court attempted to fill the doctrinal void in Plaintiffs' argument with a handful of cases that Plaintiffs never cited. (*Id.* at 10:16-21.)[3] None of the cases supports a free-floating negligence claim based on purported withholding of TAF; in fact, most of the cases say the exact opposite. The cases explain, for example, that negligence and strict liability are two separate ways of proceeding on a *defect* claim, and reiterate that a negligence claim, in this context, still requires proving the product that caused the injury is defective. (*See also Merrill*, *supra*, 26 Cal.4th at p. 483 ["[P]laintiffs incorrectly assume that an action based on negligence is necessarily not a products liability action."].)

Brown is a prime example. As noted, *Brown* rejected strict liability for design defects in prescription medications in favor of

[3] The Superior Court also held it against Gilead that *Plaintiffs* had cited no authority, noting that "Gilead bears the initial burden of establishing" that Plaintiffs' claim for relief is not cognizable. (*Id.* at 10:13-15.) Certainly, Plaintiffs must bear the burden of showing that their claim is cognizable. In any event, Gilead plainly met its burden with the numerous authorities it presented, including those cited herein. (*See* App. 131-134 [MSJ Op. Br. at 12:6-15:20]; App. 3145-3148 [MSJ Reply at 5:6-8:13].)

negligent design defect instead. (*Supra*, 44 Cal.3d at pp. 1061-66.) As discussed above, *Brown* noted that drug manufacturers would still be subject to "liability for manufacturing defects, as well as under general principles of negligence, and for failure to warn of known or reasonably knowable side effects." (*Id.* at p. 1069, fn. 12.) The Superior Court seemingly believed, however, that by referencing "general principles of negligence," the Supreme Court meant that companies could be sued for negligence, regardless of any defect in the product. That is wrong. In the sentence immediately preceding the quote, *Brown* makes clear that a defect is a necessary precondition of any such suit: Drug companies, it holds, are not "free of all liability for *defective drugs*," but rather when there is a "defect[]," they can be sued for manufacturing defect, failure to warn, or negligent design defect. (*Ibid.* [italics added].) "Negligence," in that context, presupposes a defect, and asks additionally whether "'the defect in the product was due to negligence of the defendant.'" (*Chavez*, *supra*, 207 Cal.App.4th at pp. 1304-05; *see also Scott v. C.R. Bard, Inc.* (2014) 231 Cal.App.4th 763, 773 [cited by App. 3246 [Op. 10:21]] [Under either strict liability or negligence, a "plaintiff must prove that a defect caused the injury …. However, under a negligence theory, the plaintiff must also prove that the product defect was due to negligence of the defendant."].)[4]

[4] The Superior Court made the same error in referencing *Milwaukee Electric Tool*, which says that "a plaintiff injured by an allegedly *defective product* may seek recovery … on alternative theories of strict liability in tort and in negligence." (*Supra*, 15

Similarly unhelpful to Plaintiffs is *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89, another case cited by the Superior Court but not Plaintiffs. In *Conte*, the Court of Appeal addressed a negligent-misrepresentation claim—a form of common-law fraud, (*id.* at p. 101, fn. 7)—and asked whether a brand-name drug manufacturer owed consumers of the generic version a duty to avoid misrepresentations about the product. (*Id.* at pp. 94-95.) Because it is the brand-name manufacturer that "authors and disseminates information" about the brand-name drug and its generic versions, the court held that the brand-name manufacturer could be liable for fraud in that information. (*Id.* at pp. 101-102.) *Conte* was thus doubly removed from Plaintiffs' unprecedented negligence claim. *First*, the holding of *Conte* is about liability when the injurious product was not the defendant's product. That issue is inapposite here. *Second*, there is nothing significant or groundbreaking about *Conte* permitting a claim for fraud—a claim that focuses on representations about the product rather than injuries from the product itself. Plaintiffs here also bring a fraud claim, and Gilead does not argue that Plaintiffs are precluded from doing so (rather, Gilead argues that Plaintiffs' fraud claim fails on the merits (*infra* § II)). It is therefore unsurprising that *Conte* perceived "no logical or legal inconsistency between allowing the suit for [fraud (*i.e.*, negligent misrepresentation)] and disallowing the suit for strict products liability." (App. 3246 [(Op. 10:16-18] [quoting *Conte*, *supra*, 168

Cal.App.4th at p. 557 [italics added].) Again, a "defective product" is a prerequisite to negligence. (*Ibid.*)

Cal.App.4th at p. 102].) In any event, *Conte* is not a design-defect case nor is it a free-floating negligence case. And nothing about *Conte* supports the radical theory advanced by Plaintiffs here that people injured when using a product hold the manufacturer liable without proving that the product that allegedly injured them is defective.[5]

3. Allowing Plaintiffs' unprecedented negligence claim to proceed to trial would have disastrous consequences for tort litigation, medical innovation, and manufacturers across industries.

Authorizing liability for injuries caused by non-defective products would radically transform mass tort litigation, eviscerating decades-old protections in the common law and wreaking havoc in the pharmaceutical industry and beyond.

Destabilizing products-liability law. Negligent design defect is a products-liability claim that the Supreme Court has long recognized. (*See Merrill*, *supra*, 26 Cal.4th at pp. 478-80 [collecting cases and treatises].) As discussed, it requires proof of

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[5] The Superior Court also cited *T.H.*, *supra*, 4 Cal.5th at pp. 162, 175-80, for the proposition that the Court of Appeal sometimes disagrees with "out-of-state authority." (App. 3246 [Op. 10:19-20].) While not controlling, it cannot be overstated that the Superior Court's decision conflicts with the law in *every state*, in *every jurisdiction*, in the country. (*See Prentis*, *supra*, 365 N.W.2d at pp. 181-82.) On the merits, as discussed above (at 40), *T.H.* favors Gilead; it recognizes that products-liability law is a specific expression of the general duty of care in Section 1714. Moreover, like *Conte*, *T.H.* is about liability for brand-name manufacturers for injuries caused by inadequate warnings on generic versions manufactured by another company. (*Supra*, 4 Cal.5th at p. 164.)

both a defect and, additionally, negligence. (*Id.* at 479.) But under Plaintiffs' theory of free-floating negligence, a plaintiff can prevail by proving only negligence, without proving the product was defective. With fewer elements required to reach the same result, no plaintiff would ever claim negligent design defect. The consequence would be to effectively write the tort out of the law—a particularly alarming result in the prescription-drug context, where the Supreme Court eliminated strict liability precisely because it feared that too relaxed a standard of liability would undermine the development and availability of lifesaving and pain-reducing medications. (*See Brown*, *supra*, 44 Cal.3d at p. 1063.)

Eviscerating the protections in products-liability law. The appropriate boundaries on liability embodied in the products-liability laws exist for a reason: They balance the incentives to ensure that manufacturers develop reasonably safe products with adequate warnings, while recognizing that there are no perfect products. Indeed, every product contains risks. For prescription drugs, this balance ensures that drug manufacturers continue to develop life-saving medications, like those at issue here, and that the cost of crushing liability does not make those medications inaccessible to those who need them most.

Eliminating the requirement that a plaintiff must prove the product is defective—and that the defendant is not liable if the product is not defective—threatens to create virtually limitless and unpredictable liability with no additional incentive for safety. Under Plaintiffs' theory, a manufacturer could be sued anytime it

pauses development of a product that, in hindsight, could have been slightly better than an existing product. The manufacturer cannot know for certain that the product being developed will be better than the existing product or that its reasons for pausing development might be considered unreasonable years later. The unpredictability of future liability makes it impossible for the manufacturer to conform its conduct or to enhance safety. In fact, such "failure to innovate" liability is likely to have the opposite effect: Because a manufacturer will fear that pausing development of a product could lead to future liability, the manufacturer will be incentivized to avoid beginning development of a product unless it is prepared to take it to market. For prescription medications, that means manufacturers drastically reducing the number of compounds they begin to investigate to avoid later liability for not bringing them to market. It also means manufacturers across industries having little incentive, even when circumstances change, to investigate improvements for a product that could risk creating liability where none currently exists.

The liability is limitless in another respect as well: Here, Plaintiffs are claiming to have been injured by one of Gilead's products, but nothing about the Superior Court's order or reasoning requires that injury from a company's product is a necessary element of a free-floating negligence claim. Imagine a person afflicted with an excruciatingly painful but exceedingly rare illness. Under the Superior Court's order, that person could sue, in negligence, a drug manufacturer that briefly investigated a treatment for the illness but declined to pursue it, reasoning that

the illness was rare and choosing to focus on more common illnesses. Because there would no longer be a requirement that the plaintiff's injury be caused by a defect in the manufacturer's product, such a negligence claim alleging failure to develop a beneficial medication would be cognizable under the Superior Court's ruling.

Cascading consequences beyond the prescription-drug industry. Though the disastrous consequences are most vivid in drug development, the impacts are not limited there. Imagine a car company that develops a better airbag for next year's model. That company could be sued, not because this year's airbag is defective, but because next year's model is marginally better and the car company was too slow in developing it. Imagine, too, a startup medical device company that has two different approaches to the design of a particular medical device but the resources to pursue only one. That company could be sued later for not developing the other device (even if the one it developed was best for the vast majority of users), on the theory that the other device would have been better for the particular plaintiff bringing the suit. And imagine a personal device company that is aware of some additional features for its product but decides they are not attractive enough and omits them. That company could be sued later in negligence for not including those features.

On top of all of that, this new free-floating negligence standard would prove entirely unworkable in individual cases. As the Superior Court made clear in its recent *Sargon* decision, this is not a case of "[p]rofessional negligence" or "malpractice"; the

duty is not "compliance with standards for clinical trials, compliance with FDA regulations, or the safety of an assertedly defective product." Instead, the question of liability all comes down to the jury's view of the reasonableness of "a business decision ... possibly informed by medical and financial concepts." App. 3274-3275 (*Sargon* Order at 13:16-19, 14:9-14.) How is the jury to consider the "financial concepts" inherent in a manufacturer's decision? Can a manufacturer ever make decisions based on profit without risking negligence liability? How is the jury to judge the free-floating "reasonableness" of a manufacturer's decisions when the manufacturer was choosing between several *sui generis* products or treatments? These are only a few of the questions that this newfound standard raises.

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In sum, without the protection against liability afforded to a manufacturer that develops a defect-free product, defendants are at the whim of a jury to decide years later whether it disagrees with the product-development decisions the manufacturer made. This is not the law in California or anywhere else. Nor should it be. The result would be less innovation, fewer products that are more expensive, and substantial, unpredictable damages verdicts that do nothing to make the products on the market any better or any safer—precisely the opposite of what the careful balance in products-liability law currently achieves.

B. No actionable claim for design defect exists when the product that allegedly caused the injury is admittedly not defective.

Not much more is necessary to address the Superior Court's second error: failing to dismiss a negligent-design-defect claim without a design defect. As mentioned (at 22-23), the Superior Court accepted Plaintiffs' concession that they are not alleging that the TDF medications are defective. (App. 3247 [Op. 11:19-25].) The Superior Court also recognized that Plaintiffs' concession was fatal to their claim. (App. 3248-3250 [Op. 12:8-14:10 ["Under a negligence theory, a plaintiff must prove that a product defect caused injury and that the defect arose from negligence." [citing *Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110]]; *ibid.* ["[A] product defect seems to necessarily be part and parcel of a negligent design claim." [discussing *Merrill, supra,* 26 Cal.4th at 481]].) And yet, despite spending pages explaining that a product defect is critical—and thus, that Plaintiffs had conceded away an essential element of their claim—the Superior Court decided "[n]onetheless" not to dismiss Plaintiffs' design-defect claim. (App. 3250 [Op. 14:14-16].)

That was error. As courts since *Brown* have made clear, a plaintiff who brings a negligent-design-defect claim must prove not only that there is a "defect" in the product that "caused injury"—which would be strict liability—but also that "the defect in the product was due to negligence of the defendant." (*Merrill*, *supra*, 26 Cal.4th at p. 479; *accord Chavez*, *supra*, 207 Cal.App.4th at pp. 1304-05 [describing negligence as an "additional element" a

plaintiff must prove on top of a design defect in a negligent-design-defect claim].)

In determining whether there is a design defect, it is not enough to simply show that the product caused an injury, even a foreseeable injury. (*Garcia v. Joseph Vince Co.* (1978) 84 Cal.App.3d 868, 879; *O'Neil*, *supra*, 53 Cal.4th at p. 362.) When the product is complex, like a medication, courts apply the risk-benefit test, evaluating whether the magnitude of the reasonably foreseeable harm from the product outweighs the product's utility. (*See Brown, supra*, 44 Cal.3d at p. 1061 [rejecting "the 'consumer expectation'" test as "inappropriate to prescription drugs"]; *Trejo, supra*, 13 Cal.App.5th at pp. 156-58 [accepting risk-benefit test for over-the-counter medication].) Plaintiffs here, however, concede that they are not alleging that the risks of the TDF medications outweigh their benefits. (*Supra* at 38-39.)

Given that Plaintiffs are no longer alleging a defect and the Superior Court agreed that a defect is an essential element of a negligent-design-defect claim, it is unclear why the court denied Gilead's Motion. It seemed to conclude that because courts have construed negligence claims, in this context, to require proof of a product defect (App. 3250 [Op. 14:12-14] [citing, *e.g.*, *Merrill*, *supra,* 26 Cal.4th at p. 481]), Plaintiffs *must* be alleging either a defect or a theory that would establish a defect, notwithstanding Plaintiffs' insistence that they are not. That argument is foreclosed twice over.

First, as a doctrinal matter, it is foreclosed by the elements of a negligent-design-defect claim, which require both a design

defect and negligence. (*Supra* at 43.) If, as the Superior Court seemed to assume, negligence alone can satisfy both elements without proof of a defect in the product's design, the design-defect element of a negligent-design-defect claim would be written out of the claim. *Second*, it is foreclosed by Plaintiffs' repeated concessions that they are not alleging that the TDF medications are defective or that the risks of the TDF medications outweigh their benefits. Plaintiffs must be taken at their word when they say, over and over, that they are not alleging a design defect. And because they are not, their negligent-design-defect claim is fatally flawed and should have been dismissed.

The Court suggested that dismissal was not warranted because a motion for "summary judgment or summary adjudication must dispose of the entire action or cause of action, respectively" and Gilead's design-defect argument "focuses on [only] a facet of" Plaintiffs' negligence count. (App. 3248 [(Op. 12:3-7].) But Gilead moved as to other portion of Plaintiffs' negligence count too—the free-floating negligence theory—making its motion dispositive of the entire negligence cause of action. (*Supra* § I.A.) Moreover, "a cause of action for purposes of a summary adjudication motion means a group of related paragraphs in the complaint reflecting a *separate theory* of liability." (*Silva v. See's Candy Shops, Inc.* (2016) 7 Cal.App.5th 235, 257 [quotation marks omitted], *disapproved of on other grounds by Donohue v. AMN Services, LLC* (2021) 11 Cal.5th 58.) So, even where multiple claims or theories of liability appear in the same count of a complaint, it is appropriate to grant summary

adjudication with respect to one claim or theory but not the other. (*Ibid.*; *compare* App. 68-70 [Master Longform Compl. ¶¶ 136-143, 147, 149] [focusing on purported defects with TDF] *with* App. 69-71 [Master Longform Compl. ¶¶ 144-146, 148, 150] [focusing on purported withholding of TAF].)

The Superior Court's refusal to dismiss negligent design defect means that, without this Court's intervention, Gilead must spend extensive time and resources defending at trial a claim that cannot succeed, and that Plaintiffs even have no intention of proving under established law. This error should be corrected now, before Plaintiffs' conceded-away claim is allowed to go any further.

II. This Court's Immediate Intervention Is Necessary To Prevent Needless Trials Of A Non-Actionable Fraud-And-Concealment Claim Premised On Information About A Product That Plaintiffs Were Not Using And Was Not On The Market.

This Court should also grant the writ to review and direct the dismissal of Plaintiffs' fraud-and-concealment claim. A "cause of action for fraud based on concealment" requires a plaintiff to establish that "the defendant must have been under a duty to disclose [a certain] fact to the plaintiff." (App. 3250 [Op. 14:18-23] [quotation marks omitted].) The Superior Court, however, identified no such duty. It asserted in a footnote that Gilead's obligation to disclose information about TAF was based on "established law," App. 3251 (Op. 15 n.7), but it did not cite a single case (nor did Plaintiffs) establishing such a duty. Indeed, no such case exists. It is quite literally unprecedented to require that a manufacturer disclose information about a product still in

development and years from entering the market—simply because the plaintiff was using one of the manufacturer's other products. Yet that is precisely what the Superior Court did here: It held that a plaintiff allegedly injured from one medication can hold a drug company liable for failing to disclose to them information about a different medication that was years away from the market.[6] That is not a cognizable claim.

To make out a fraud claim based on concealment, a plaintiff must show five elements:

> (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 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 (as modified) [quoting *Roddenberry v. Roddenberry* (1996) 44 Cal.App.4th 634, 665].)

Only the second element (legal duty to disclose) is at issue in this Petition. Whether a defendant has a "duty to disclose" is a

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[6] We say "years away from the market" because it is undisputed that Gilead *did* disclose the information at issue about TAF four years before a TAF-containing medication was sold. *Supra* at 21. Plaintiffs' claim is that Gilead was obligated to disclose that information even earlier.

"threshold question" of law for the court to decide. (*Bank of America*, *supra*, 198 Cal.App.4th at pp. 870-73 [collecting cases].) Where, as here, there is no "fiduciary relationship" between the parties, a duty to disclose may arise only if "there is some relationship between the parties" that is "created by *transactions* between [them]." (*LiMandri*, *supra*, 52 Cal.App.4th at pp. 336-37 [italics added].) The "duty" that arises in a transactional "relationship[]" is one to "disclose facts *material to the transaction*." (*Ibid.* [italics added].) Furthermore, in the prescription-drug context, the defendant's duty to disclose to the plaintiff is modified such that the duty "to warn of risks associated with [a drug's] usage runs to the physician, not the patient." (*Conte*, *supra*, 168 Cal.App.4th at p. 98, fn. 5.)

One would have expected Plaintiffs' claim to focus on purported concealment of information about the prescribed medication that allegedly injured them—information about *TDF*'s dangers or risks. Not so. As Plaintiffs have made clear, their claim is that Gilead failed to disclose information about *TAF*—not TDF—from a single study (the 1101 Study). (App. 3032 [Pls.' MSJ Opp'n at 23:22-23] [arguing Gilead failed to "present[] or publish[] the results of [the 1101] study prior to completing Phase III studies a decade later"].) Plaintiffs do not contend that Gilead withheld any information about the TDF medications they were taking. (*See* App. 3251-3252 [Op. 15:26-16:3] [observing that Gilead is alleged to have concealed only "information about TAF" and "TAF medication information"].) Indeed, Plaintiffs dismissed all their

failure-to-warn allegations, theories, and claims—including, everything related to TDF. (App. 100 [Stip. & Order, ¶¶ 1-2].)

As for the allegedly concealed information, Plaintiffs concede that Gilead disclosed the information about TAF from the 1101 Study in 2011—four years before FDA approved the first TAF medication. (App. 3032 [Pls.' MSJ Opp'n at 23:24-26] [citing App. 3092 [Pls.' Sep. Stmt. of Facts ¶ 116]].) The 1101 Study was an early Phase I/II study of only 30 people, 20 of whom took TAF for 14 days—it was not a full-blown Phase III study of a large number of people for an extended period of time. (App. 3051 [Pls.' SUMF Resp. ¶ 32].) Significantly, that preliminary study concluded that TAF "showed a safety profile *similar to that of [TDF]*." (App. 2290 [1101 Study] [italics added].) Accordingly, there is no allegation that Gilead withheld information about unapproved TAF being safer than the approved TDF that Plaintiffs took.

The Superior Court held that Gilead had a duty to disclose the results of the 1101 Study about TAF to Plaintiffs' TDF-prescribing doctors even earlier than 2011—even though TAF was still four years from FDA approval at the time. In the absence of a fiduciary relationship, however, Gilead's duty to disclose arose, if at all, from a "transaction" between it and the plaintiff, with the duty to disclose facts material to *that* transaction. (*LiMandri*, *supra*, 52 Cal.App.4th at pp. 336-37.) Accordingly, just as there can be no duty to disclose information in the absence of a relationship between the parties, there is no duty to disclose information about a different product that is not a part of, or has no bearing on, the transaction from which a duty to disclose could have arisen.

Here, it is undisputed that there was no TAF-related transaction between the parties during the relevant period. Nor could there have been. Gilead could not have sold TAF, and Plaintiffs' doctors could not have prescribed TAF, until *after* FDA approval—which did not happen until four years after Gilead already had disclosed the information from the study. (*See* 21 U.S.C. § 355(a) [requiring FDA approval of medications before they enter the market and are prescribed].) The only transactions between Gilead and Plaintiffs prior to 2011 were transactions "related to the prescription of [Gilead's] TDF medication." (App. 3034 [Pls.' MSJ Opp'n at 25:5-7].) Because there was no transaction between Gilead and Plaintiffs' doctors from which a duty to disclose information about *TAF* could have arisen, Gilead had no duty to disclose information to Plaintiffs' doctors about TAF before it was approved and available to be prescribed.

In cases where the duty to disclose is created by a transaction for sale and purchase of a product, the information purportedly concealed invariably concerns the product at issue in the transaction—not some other hypothetical product that the consumer is unable to access or purchase because it is not on the market. In *Collins v. eMachines, Inc.*, for example, a class of plaintiffs that purchased defective computers sued the manufacturer for marketing and selling the computers with a defective microchip, plausibly alleging that the manufacturer "actively concealed the existence of the [defect] from purchasers" to "continue to sell the defective computers." ((2011) 202 Cal.App.4th 249, 253.) Similarly, in *Snow v. A.H. Robins* Co., a

plaintiff who "suffered from an unwanted pregnancy and resulting therapeutic abortion after having a [particular] [IUD] device … inserted for contraception" stated a valid claim of fraudulent concealment against the IUD's manufacturer for having "wrongfully concealed actual higher pregnancy rates" with that IUD. ((1985) 165 Cal.App.3d 120, 125.) Many other examples abound: Imagine, for instance, a lawsuit against a cigarette or a lead-paint manufacturer for intentionally concealing information about the dangers of their products. (*See generally Bullock v. Philip Morris USA, Inc.* (2008) 159 Cal.App.4th 655, 677-79; *County of Santa Clara v. Atlantic Richfield Co.* (2006) 137 Cal.App.4th 292, 326-31.)

Gilead is not aware of a single case that establishes a duty for a manufacturer to disclose information about a product that is not on the market and that is not a part of the parties' existing transaction. Neither Plaintiffs nor the Superior Court cited any such case. And that is for good reason. It is beyond dispute that a car manufacturer is not obligated to tell a current customer that a future year's model contains enhanced safety features that are still undergoing testing but could be an improvement over the current model. Similarly, a technology company is not required to tell its customers that it is developing new software that is a quantum leap over the current product but is years away from being launched. Likewise, a drug manufacturer is not required to tell prescribing doctors about a promising new medication that it is researching and that might one day make it to market.

The Superior Court nonetheless allowed this unprecedented fraud-and-concealment claim to proceed to multiple trials in this JCCP. Unable to explain how a duty to disclose could possibly exist in these circumstances, the court inexplicably said that Gilead was "not challenging the existence of a duty to disclose." (App. 3251 [Op. 15:23-26].) But, of course, Gilead challenged the existence of any such duty. It did so repeatedly and unmistakably. Gilead's principal argument on the fraud-and-concealment claim in its opening brief was that Gilead had no duty to disclose information about unapproved TAF to Plaintiffs or their doctors. (App. 140-142 [MSJ Op. Br. at 21:4-23:3] [section entitled, "Plaintiffs' fraud-and-concealment claim fails as a matter of law because there was no duty to disclose …."].) Gilead did so again in its reply brief. (App. 3153-3154 [MSJ Reply at 13:20-14:16] [section entitled, "Plaintiffs cannot show that Gilead had a duty to disclose to Plaintiffs' doctors information concerning an unapproved medication"].) Gilead reiterated the argument in the motion hearing, (App. 3162, 3166 [MSJ Hr'g Tr. at 16:20-17:15, 30:17-31:5]), and dedicated an entire section in its proposed order to the lack of duty, (App. 3213-3214 [Gilead Proposed Order at 15:1-16:3] [section entitled, "Gilead had no duty to disclose information about TAF years before its approval"].)

Separately, in a footnote, the court added: "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." (App. 3251 [Op. 15 fn. 7].) The court never explained what about Gilead's view of the

"transaction giving rise to a duty to disclose" is "too granular." (*Ibid.*) Presumably, the court meant that it was "established law" that a transaction for a manufacturer's product gives rise to a duty to disclose information about its other products too, even when those products are not on the market (and thus could not be relevant to the transaction). But, as just discussed, the Superior Court cited no law—certainly no "established law"—recognizing any such duty, and Gilead is unaware of any. The only transactions that could give rise to a duty to disclose involved TDF, and it is undisputed that Gilead disclosed all known or knowable adverse effects from TDF. (App. 3251 [Op. 15:17-19].) Nothing about a TDF-related transaction, however, imposed upon Gilead a duty to disclose information about a different product (TAF), still in development and years away from being available to Plaintiffs and their doctors. Indeed, Gilead had no legal obligation to disclose information to doctors about TAF long before it was approved for the simple reason that the doctors could not have prescribed TAF.

Because there can be no fraud-and-concealment claim without a duty to disclose, Plaintiffs' claim cannot be maintained as a matter of law. The Superior Court's failure to grant summary judgment or adjudication was a fundamental error that warrants this Court's immediate review and direction of dismissal.

CONCLUSION

For the foregoing reasons, the Court should grant a writ of mandate, prohibition, or other appropriate relief as requested in this petition.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

The undersigned counsel for Petitioner, pursuant to Rule 8.204(c)(1) of the California Rules of Court, certifies that Petitioner's Petition for Writ of Mandate contains 13,676 words, as counted by the word count of the computer program used to prepare the brief.

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