Case No. A165558

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

REPLY MEMORANDUM OF POINTS AND AUTHORITIES IN SUPPORT OF PETITION FOR WRIT OF MANDATE, PROHIBITION, OR OTHER APPROPRIATE RELIEF

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TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Cases

Statutes

INTRODUCTION

Gilead's Petition explained that the Superior Court's adoption of Plaintiffs' radical theories of liability was so unprecedented—and threatened to inflict such far-reaching and disastrous consequences across industries—that this Court's immediate review is warranted and required. Plaintiffs' response is remarkable for how few of Gilead's points it addresses and how little it disputes.

Start with the Superior Court's unprecedented decision. No case in California or in any other jurisdiction has ever held that a manufacturer could be liable for injuries allegedly caused by a non-defective product. Nor has any case anywhere held that a manufacturer can be liable for a design defect when there is no defect, or for fraudulent concealment when the allegedly omitted information is about a product that was years from ever being purchased or used by a consumer. Plaintiffs' Opposition marks their fourth opportunity to cite a single case supporting any one of their claims, and they have cited none.

The lack of caselaw supporting Plaintiffs' claims is not surprising. The law does not obligate a manufacturer to make a perfect product—one that carries no risk of injury. Rather, a manufacturer's duty is to make a reasonably safe product—i.e., a product that is not defective. A manufacturer that does so is not liable for injuries that may nevertheless result from using that non-defective product, lest manufacturers become insurers for all injuries connected to their products. For the same reasons, no case holds that a manufacturer must develop a "slightly better"

product, or that failing to do so earlier subjects the manufacturer to liability for any injury from its earlier non-defective product.

This brings us to the far-reaching and disastrous policy ramifications. If making a non-defective product better or safer could result in the manufacturer being held liable for injuries from the original product, manufacturers would never innovate. Similarly, if a manufacturer could be second-guessed for not developing fast enough a product that showed early promise, manufacturers would have an incentive not to research potentially new products. This too would stifle innovation, resulting in less product development and fewer improvements—all to avoid the rule adopted by the Superior Court.

These policy consequences are not just Gilead's say-so. Gilead's Petition is supported by amicus briefs from the California and U.S. Chambers of Commerce, the Pharmaceutical Research and Manufacturers of America ("PhRMA"), and Washington Legal Foundation. They document how the Superior Court's decision strays from settled law and explain what the decision's negative impact would be across industries, especially in the biopharmaceutical industry. Plaintiffs do not respond to the amici either.

That leaves why this Court's immediate review is warranted. Plaintiffs do not dispute that the legal issues raised in Gilead's Petition apply to the more than 24,000 lawsuits in this JCCP. Plaintiffs also do not dispute that judicial economy favors immediate appellate resolution of these legal issues which are dispositive of Plaintiffs' claims. And Plaintiffs do not dispute that

Gilead will undergo multiple trials—including at least four bellwether trials—before the issues raised in this Petition could be resolved on a post-trial appeal from the first trial. That means subjecting Gilead to numerous trials and verdicts on potentially non-actionable claims, which, as the extensive authority collected in Gilead's Petition explains, makes a direct appeal wholly inadequate.

This Court should grant writ review to consider and decide these important and dispositive issues that pose tremendous consequences for the future of tort litigation and the State's manufacturing industry.

ARGUMENT

I. Gilead Has No Plain, Speedy, And Adequate Remedy Other Than Writ Relief.

There is no dispute that this Court's immediate review is permissible (Pet. 29-30); the only question Plaintiffs raise is whether this Court should exercise its "discretion[]" to do so. (Opp. 4.) The answer is yes.

Despite choosing to file a response in the first place, Plaintiffs have little to say, leaving the majority of Gilead's points unanswered and undisputed. This Court should see Plaintiffs' silence for what it is: confirmation of how urgently review is needed and how inadequate other remedies are. Were there any question remaining, even cursory review of Plaintiffs' arguments dispels any such doubt.

A. Gilead's Petition presents important questions of widespread interest that warrant this Court's immediate review to avoid multiple unnecessary trials.

The Superior Court's decision recognizing Plaintiffs' claims of negligence and fraudulent concealment is of widespread interest and substantial public importance. (Pet. 24-25, 33-34.) Plaintiffs' unprecedented theories are presented in more than 24,000 cases and are of significant importance to the pharmaceutical industry and manufacturers across the economy. (Pet. 25, 30, 33-34.) That is why the U.S. and California Chambers of Commerce, PhRMA, and the Washington Legal Foundation filed amicus letters supporting Gilead's Petition—each highlighting the importance of this Court's immediate review. Tellingly, Plaintiffs do not acknowledge, much less refute, these letters.

So what do Plaintiffs argue? Besides suggesting that Gilead should wait until the end of the first trial to appeal (addressed *infra* § I.B), Plaintiffs' principal argument is that "Gilead has not demonstrated any irreparable injury." (Opp. 3 [capitalization omitted]; *accord* Opp. 5.) Plaintiffs argue that writ review is "extraordinary" and that, in an "ordinary action," a defendant is not irreparably injured if it must undergo a trial. They contend that the asserted "error" might "be either mooted or cured by the time of judgment" or that "the case might settle in the interim." (Opp. 4 [citations and quotation marks omitted].) Plaintiffs' argument is wrong three times over.

First, this is no "ordinary action," and there is nothing "ordinary" about the Superior Court's decision. There are more

than 24,000 JCCP plaintiffs, and the non-viability of Plaintiffs' claims is a legal question presented in each case, which is why it was raised and decided in a common-issues summary-judgment motion. (Pet. 25.) Resolving common legal issues across numerous pending cases is a typical reason for writ review. (*See* Pet. 25, 30-32 [collecting cases].) The Superior Court's ruling also transcends this litigation, threatening to upend tort law in this State by imposing liability on manufacturers for injuries caused by non-defective products and non-disclosure of information about products still in development. (Pet. 24-25, 33-34.)

The Superior Court's endorsement of unprecedented theories of liability is itself a basis for writ review. (Pet. 33 [collecting authority].) Plaintiffs' claims are unprecedented, and the Superior Court's decision is erroneous, for the reasons discussed below (*infra* § II). At a minimum, though, that Plaintiffs can identify no case supporting their claims means that their theories are at least a matter of first impression—"novel," in the words of Plaintiffs and the Superior Court (Opp. 6 [citing App. 3247] (MSJ Op. 11:7-12))—which also warrants this Court's review (Pet. 31 [collecting authority].)

What's more, Plaintiffs do not contest Gilead's showing that the Superior Court's decision conflicts with the law in *every other state* and *every other jurisdiction* in the United States. (Pet. 27.) Plaintiffs downplay whether the unanimous view of the entire country resolves the matter on the merits (Opp. 3), but it is certainly extraordinary—and worthy of this Court's attention—

that the Superior Court's decision puts California so out of step with the view of every other jurisdiction.

Second, Plaintiffs are wrong that the Superior Court might, without this Court's intervention, "cure[]" its own error. (Opp. 4.) Far from signaling any intention to reverse its summary-judgment decision, the Superior Court has doubled down. Its *Sargon* ruling explains that the jury's job will be to evaluate the reasonableness of "a business decision … possibly informed by medical and financial concepts." (Pet. 20, 28, 51-52 [quoting App. 3275].) Unless the Superior Court completely reverses itself, the errors being presented here for review will not be "cured" before judgment. (*Contra* Opp. 4 [quotation marks omitted].) It is also incorrect that the non-viability of Plaintiffs' claims will somehow "diminish in importance" as the cases "proceed[] towards trial." (*Omaha Indem. Co. v. Superior Ct.* (1989) 209 Cal.App.3d 1266, 1273 [*cited in* Opp. 4-5].) To the contrary, those issues are the very essence of the more than 24,000 cases in the JCCP.

Third, Plaintiffs are wrong that writ review should be denied because multiple unnecessary trials might force Gilead to "settle" and therefore "moot[]" future appeals. (Opp. 4 [quotation marks omitted].) If anything, that is a reason why this Court's immediate review is so important: Gilead will be irreparably harmed by multiple trials on non-actionable claims—a circumstance that this Court has identified repeatedly as requiring writ relief. (Pet. 25-26, 30-31 [collecting cases].)

For the same reasons, Plaintiffs are wrong to say that a single trial will not irreparably harm Gilead. (Opp. 5 [discussing

the prospect of "a trial" and "a trial verdict"] [capitalization altered].) The issue here is not a single trial; it is multiple trials. As explained in the next section, there is no dispute that at least four trials (all of them lengthy) will have concluded before this Court adjudicates a direct appeal from the first trial. That is reason alone to grant review. (Pet. 25-26, 30-31 [collecting cases].)

B. An appeal from the first trial does not adequately protect Gilead, nor does it expeditiously resolve these critical legal issues.

Unable to refute the points above, Plaintiffs contend that writ relief is inappropriate because Gilead can take a post-judgment appeal after the first trial. (Opp. 3-5.) But in light of the showing above, this Court can grant writ review regardless of the adequacy of a direct appeal as a remedy. That is because "[w]rit review is appropriate" if "an [immediate direct] appeal would be inadequate *or* the issues presented are of great public importance and require prompt resolution." (*Henry M. Lee L. Corp. v. Superior Ct.* (2012) 204 Cal.App.4th 1375, 1383 [italics added]; Pet. 33-34 [collecting cases].)

In any event, it is beyond dispute that appealing from the first trial will not save Gilead from the irreversible injury of undergoing multiple unnecessary trials. Nor can an after-the-fact appeal secure this Court's speedy resolution of the important legal and policy consequences raised by Plaintiffs' novel theories. Plaintiffs twice insist that "Gilead offers no reason why such an appeal is inadequate" (Opp. 3, 5), but Plaintiffs can say that only by ignoring the many pages and long line of precedent cited in Gilead's Petition (*see* Pet. 23-26, 29-33.)

Gilead cited no less than a dozen cases explaining that writ review is the *only* adequate remedy where an erroneous ruling recognizing non-actionable claims would force the defendant to undergo multiple, costly, and potentially unnecessary trials, at the expense of limited judicial resources and needless burden on the jurors of this State. (Pet. 26, 30-31 [collecting authorities].) One trial is already scheduled for October 2022, and Plaintiffs are urging the Superior Court to hold three more trials before the end of July 2023—within eight months of the conclusion of the first trial. (*See* Jnt. Case Mgmt. Conf. Stmt., July 26, 2022 at 4 [Plaintiffs' Position].) Far from establishing the adequacy of a direct appeal from the first trial, Plaintiffs prove Gilead's point by insisting that all four bellwether trials occur before this Court could decide an appeal following the first trial.[1]

Plaintiffs take down a strawperson by arguing that a "verdict in an individual case will not render Gilead liable to more than 24,000 plaintiffs." (Opp. 5 [quotation marks omitted].) Obviously, that is true; but it is not the point. The point is that Gilead will face "trial" and a "verdict" in every "individual case" until the legal issues in the Petition are resolved. (*Ibid.*) At a minimum, that is multiple bellwether trials and an unknown

[1] At the same time that they are pushing for four quick trials, Plaintiffs fault Gilead for having not "requested a stay." (Opp. 3.) Plaintiffs' argument elides that Gilead filed this Petition to correct the Superior Court's errors and avoid those trials altogether, and there is ample time for this Court to do so before the first trial starts. Plaintiffs also ignore that Gilead's Petition expressly reserved the right to seek a stay as the trial date nears. (Pet. 35.)

number of other trials. Unless and until an appellate court correctly concludes that California law does not recognize Plaintiffs' unprecedented claims, Gilead faces the substantial expense of multiple trials and the risk of being found liable in one or more of those trials occurring before the first appeal is resolved. That is precisely the undue prejudice and harm that this Court has repeatedly found warrants writ relief.

Finally, Plaintiffs do not dispute that Gilead's Petition is an ideal vehicle to address these purely legal common issues. (Pet. 23-24, 33.) Plaintiffs contend that this Court should wait for a more "fulsome record" (Opp. 3, 5), but Plaintiffs never explain how and why the factual record could change the analysis of the purely legal issues presented here. Nor do Plaintiffs deny that writ review will avoid unnecessary evidentiary complications that will inevitably follow from a post-trial appeal. (Pet. 33.) By contrast, though the Petition arises from summary judgment, Plaintiffs do not once claim that there is a factual dispute that would impede this Court's review. Rather, the Petition catalogs Plaintiffs' critical concessions (Pet. 20-22), which Plaintiffs implicitly concede again in their Opposition. These concessions get to the heart of whether Plaintiffs' claims are "legally cognizable as a general matter." (Opp. 6 fn.3 [quoting App. 3246] (MSJ Op. 10:10-16); *accord infra* § II.) No more "fulsome record" is needed to address those issues, nor is it worthwhile for this Court to delay their consideration pending trial.

C. Plaintiffs' procedural objections are meritless and present no impediment to this Court's review.

Failing in the traditional writ analysis, Plaintiffs argue the Petition should be denied because Gilead's underlying motion was supposedly "procedurally deficient." (Opp. 3.) Plaintiffs even contend that "Gilead's Petition ignores the procedural errors plaguing its motion," (Opp. 6.), while completely overlooking that Gilead's Petition expressly addressed and refuted them (*see* Pet. 55-56.)

First, Plaintiffs argue that Gilead's common-issues motion for summary judgment and summary adjudication was improper because it was brought under Civil Procedure § 437c and supposedly "did not attack the entirety of Plaintiffs' negligence claim." (Opp. 3.) According to Plaintiffs, they "posit multiple theories of negligence"—both "general negligence and negligent design"— and a motion aimed at only one theory should have been brought under § 437c(t). (Opp. 6.) But, as is evident from Gilead's briefing below, its proposed order, the Superior Court's decision, and Gilead's Petition, Gilead clearly sought summary adjudication (on multiple grounds) as to both negligence theories—free-floating negligence (or, as Plaintiffs call it, general negligence) and negligent design defect. (*See* Pet. 55; *see also* App. 126-138 [MSJ Op. Br. 7:14-19:25]; App. 3142-3150 [MSJ Reply at 2:10-10:21]; App. 3202-3210 [Proposed Order at 4:20-12:18].)

In addition, nothing precluded the Superior Court from granting Gilead's motion as to either or both of Plaintiffs' negligence theories. Not only was Gilead's motion "dispositive of

the entire negligence cause of action," (Pet. 55), but each of Plaintiffs' theories is a separate cause of action for purposes of § 437c. That is because, as Plaintiffs do not dispute, each group of related paragraphs in the Complaint reflecting a separate theory of liability is a distinct cause of action for purposes of summary adjudication. (Pet. 55-56 [citing authorities and the Complaint].)

Second, Plaintiffs are wrong that there is some procedural infirmity with Gilead arguing that their "negligence claim is not legally cognizable" rather than "seek[ing] to disprove any essential elements of [the] negligence claim." (Opp. 6 fn.3 [quotation marks omitted].) That is obviously wrong as to negligent design defect, where Plaintiffs' concessions foreclose them from proving the "essential element[]" of design defect. (*Ibid.*) It is also wrong as to Plaintiffs' free-floating negligence claim. If the claim is not legally cognizable, it must be dismissed. Moreover, Gilead's argument that a plaintiff claiming an injury from a product must prove the product is defective is an argument that Plaintiffs cannot prove a breach here because of their concession that TDF is not defective. In other words, Gilead's argument, coupled with Plaintiffs' concession, "disprove[s] an[] essential element[] of [Plaintiffs'] negligence claim." (Opp. 6 fn.3 [quotation marks omitted].)

* * *

Plaintiffs ultimately have no meaningful response to Gilead's many arguments favoring this Court's immediate review, other than to rely on the generic refrain that writ relief is "extraordinary," (Opp. 4-5, 11)—all the while failing to recognize that such "relief, while extraordinary, exists precisely for

circumstances like this." (Pet. 25.) Writ relief is not just appropriate here; it is warranted, and it is necessary.

II. The Superior Court's Decision Was Wrong On The Merits.

A. This Court should review the Superior Court's decision on "general negligence."

As Gilead's Petition explained, the Superior Court has blessed Plaintiffs' radical theory of liability. Plaintiffs took TDF medications that they admit are not defective and sued because of alleged injuries from those medications. Because Gilead indisputably fulfilled its duty to design and produce a reasonably safe product—a specific duty, embodied by the products-liability caselaw—that should have been the end of the matter.

But it wasn't. The Superior Court held that Gilead could be liable for not more quickly developing entirely *different* medications that Plaintiffs allege would have avoided their injuries from admittedly non-defective TDF medications. This theory of liability is unprecedented; contradicted by decades of caselaw; and disastrous for manufacturers and consumers alike, as the amici make clear.

Plaintiffs hardly respond to anything in Gilead's Petition and wholly ignore the amici. Instead, Plaintiffs repeat their strategy from summary judgment: They trot out irrelevant purported facts; mischaracterize Gilead's argument; and dismiss as a "parade of horribles" (Opp. 2) the serious policy consequences that will result from the Superior Court's order. While there are numerous problems with Plaintiffs' theory of liability—all explained in the Petition (at 37-52)—Gilead focuses on two here:

the complete absence of legal support for Plaintiffs' theory, § II.A.1, and the significant negative ramifications of the Superior Court's ruling, § II.A.2.

1. Despite yet another opportunity to do so, Plaintiffs cite no caselaw supporting their unprecedented theory of liability.

Plaintiffs have now had four opportunities to identify any case recognizing a free-floating (or, as Plaintiffs say, "general") negligence claim where a consumer has been purportedly injured by a product. And they have failed to do so. That bears repeating: In their MSJ Opposition, oral argument, proposed order, and the Opposition here, Plaintiffs have never identified a single case, in any jurisdiction, allowing their claim to proceed.

Plaintiffs represent that there is "a long history" of cases establishing that manufacturers have a duty to a consumer injured by a product, beyond the duty to ensure that the product is free of defects. (Opp. 9.) But Plaintiffs never cite any such case. And they ignore the overwhelming caselaw collected throughout Gilead's Petition showing that the duty of a manufacturer is to develop a non-defective product—no more, no less. (*See* Pet. 40-46.)

As Gilead has explained (Pet. 35-40), courts in California, and across the country, universally hold that a manufacturer's duty is only to design and produce a non-defective product. (*See, e.g.*, *Soule v. Gen. Motors Corp.* (1994) 8 Cal.4th 548, 568 fn.5; *Milwaukee Electric Tool Corp. v. Superior Ct.* (1993) 15 Cal.App.4th 547, 551; *see also Prentis v. Yale Manufacturing Co.* (Mich. 1984) 365 N.W.2d 176, 181-82; App. 3146-47 [MSJ Reply at 6:27-7:10 & fn.3] [collecting dozens of cases from around the

country].) *That* is the duty that applies under these circumstances. And while Plaintiffs criticize Gilead for citing out-of-state caselaw (Opp. 3), they have little answer to the California cases Gilead cited. Nor do Plaintiffs address *why* Gilead pointed to the unanimous view of courts around the country: Plaintiffs in this JCCP hail from all 50 states and those cases show just how out of step the Superior Court's decision is with every other jurisdiction in the United States.

Courts have also rejected plaintiffs' efforts to avoid products-liability law by alleging that an injury from a product is actually from the manufacturer's wrongful "conduct"—the same type of semantic ploy Plaintiffs attempt here. (*See* Opp. 7 [claiming that a plaintiff can hold a manufacturer "liable for injury caused by its unreasonable *conduct*"] [italics in original].) As one court put it, insisting that "[a manufacturer's] conduct, rather than a defective product, caused damages" is nothing but "sophistry" repeatedly rejected by the courts. (*Hill v. Forest Laboratories, Inc.* (S.D. Miss. 2014, June 6, 2014, No. 2:06-CV-244) 2014 WL 2558756, at *2.) At bottom, a consumer alleging injury from a product challenges the product itself and cannot avoid the requirement to prove a defect in the product. (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 480-81.)[2]

[2] Plaintiffs emphasize that the *Merrill* plaintiffs were barred from claiming that the guns were defective by a "very specific legislatively-created statutory exception" that has since been "repealed." (Opp. 7 [italics omitted].) That repeal does not cast doubt on *Merrill*'s holding that a plaintiff's claim for injury from a product must be brought as a products-liability claim with proof of a defect, not as a claim aimed at the defendant's conduct.

In the face of that authority, Plaintiffs cite only Civil Code Section 1714—California's general duty-of-care statute. But as Gilead (and this State's courts) have repeatedly explained, Section 1714's general duty of ordinary care takes on a specific shape depending on the circumstances. That is, the contours of the duty of care applicable to a school district charged with protecting a student from sexual abuse (*see* Opp. 8 [citing *Doe v. Lawndale Elementary School District* (2021) 72 Cal.App.5th 113, 127]) are different from those of the duty applicable to a product manufacturer (*see, e.g.*, *T.H. v. Novartis Pharmaceuticals. Corp.* (2017) 4 Cal.5th 145, 163-64 [explaining the duty that applies where a consumer challenges a product's label].) Where a consumer alleges injury from a product, the manufacturer's duty is clear: to design and produce a reasonably safe (i.e., non-defective) product. (*See Merrill*, *supra*, 26 Cal.4th at pp. 478-79.)

For those reasons, Gilead is not demanding an "exception" from its duty of care, such that Gilead would need to resort to the California Supreme Court's decision in *Rowland v. Christian* (1968) 69 Cal.2d 108. (Opp. 2, 6, 8.) Plaintiffs inadvertently acknowledge as much when they add the hedge: "*If* [Gilead] sought to create an exception, Gilead should have proposed that exception and met its burden of establishing factors weighed in its favor." (Opp. 8 [italics added].) As Plaintiffs know, Gilead does not seek to create an exception, but rather asks this Court to enforce what the duty of care *is* in the context of a suit like this one: Not a free-floating duty to act "reasonably," but instead a more particularized duty to develop a medication that is reasonably safe for consumers.

At bottom, by seeking to hold Gilead responsible for not releasing a "slightly better" medication than TDF (Pet. 36 [quoting Plaintiffs' expert]), Plaintiffs are demanding far more than a reasonably safe product. They are demanding a perfect product—one that will never be surpassed by a safer or more effective one. "[N]egligence law," however, does not require a manufacturer "to develop the 'safest' alternative product." (U.S. Chamber of Commerce Amicus Ltr. at 5.) As discussed below, that is for good reason: "manufacturers must frequently balance and trade-off safety with efficacy, costs, and feasibility," and "[t]he flexibility to make these choices is essential to ensuring the availability and development of innovative and existing treatments." (*Id.* at 4.)

2. Amici further highlight the consequences of the Superior Court's ruling.

To understand the impact of this case, one need only look to the amici: Four different entities, including the U.S. and California Chambers of Commerce, attest that the Superior Court's free-floating negligence theory will have far-reaching consequences across industries. As the Washington Legal Foundation explained, "Innovative companies face endless choices in product development—the age-old Betamax-versus-VHS question. Choosing one product over the other must not be turned into a legal wrong, particularly when the product chosen has proven to be beneficial and not defective." (WLF Amicus Ltr. at 3.)

Exploring different products—and bringing to market products that are reasonably safe *and* efficient to produce—is essential for maximizing consumer safety and choice. Hindsight

liability for preferring one non-defective product over another would discourage manufacturers from innovating. After all, the perfect often comes at the expense of the good.

As one amicus points out, during the COVID-19 pandemic, manufacturers have "developed varied masks, from cloth masks to disposable surgical masks to N95 respirators," a choice that enabled consumers to access masks during a fast-moving pandemic that spiked demand. (WLF Amicus Ltr. at 4.) Scientists now know "that N95 respirators provide the highest level of protection." (*Ibid.*) But "[t]hat does not mean that manufacturers of non-defective surgical and cloth masks can or should be liable—retroactively or today—for the spread of COVID-19 among individuals wearing those face coverings." (*Ibid.*) And yet that is precisely the result the Superior Court's decision countenances. If manufacturers considered making N95s but settled on slightly less effective surgical models, they could be sued for negligence. That is especially so if the manufacturer considered relative profits and losses in making that decision—as all manufacturers do.

Gilead explained these consequences in its Petition (at 48-52). It presented hypothetical, real-world examples illustrating that, under Plaintiffs' theory, manufacturers could be sued for pausing development of a product or not including every possible feature in a product. (Pet. 50-51.) They could even be sued by consumers who did not use the manufacturer's product. (*Ibid.*) Plaintiffs' response confirms these concerns: They seem to agree that these hypothetical claims are actionable as a matter of law, such that they would have to go to "a jury [to] find [whether] the

manufacturer's conduct was reasonable and that there was no breach of a duty." (Opp. 9.) This means actionable "negligence" claims on everything—from year-over-year airbag improvements, to N95 masks, to the absence of treatment for an illness. Regardless of whether the manufacturer could ultimately prevail on the "specific … facts" and "unique circumstances" of individual cases (Opp. 9), the risks of liability and the price associated with such litigation would be calamitous across industries—especially in the biopharmaceutical industry, where drug development is already so expensive and the results so uncertain. (*See* PhRMA Amicus Ltr. at 3-4.)

The consequences of Plaintiffs' theory are so extraordinary that Plaintiffs are forced to say that they "are not arguing for liability based on 'non-defective products.'" (Opp. 8.) But that is disingenuous, if not flatly wrong. Clearly Plaintiffs do not mean that a manufacturer satisfies its legal duty by producing a non-defective product—otherwise, Plaintiffs would agree that Gilead is entitled to summary judgment. What Plaintiffs mean is that a manufacturer can still be liable for an injury from a non-defective product "based on" its "conduct" in the development process. (Opp. 7-8.) Whether that liability is characterized as "absolute" or "infinite" (Opp. 8-9), the result is the same: Permitting liability for an injury caused by a non-defective product eliminates the carefully calibrated protections in products-liability law, at the risk of disastrous consequences to manufacturers and consumers alike. (*See* Pet. 48-52; Chamber of Commerce Amicus Ltr. 4-5, WLF Amicus Ltr. 3-4; PhRMA Amicus Ltr. 3-6.)

Finally, Plaintiffs resist the public-policy implications of the Superior Court's ruling by claiming that "Gilead asks for … immunity for all manufacturers from the duty of ordinary care for any conduct not directly involving a product." (Opp. 9.) Gilead's position is the exact opposite. It has nothing to do with claims "not directly involving a product." (*Ibid.*) Where, for example, a manufacturer causes a fire, pollutes the environment, or takes an action unrelated to selling a product that injures members of the public, the manufacturer can and should be held liable. But where, as here, a plaintiff alleges injury from a product—and seeks to recover damages for that injury—the manufacturer's duty is only to design and produce a defect-free product.

B. This Court should review the Superior Court's decision on design defect.

As explained in Gilead's Petition (at 53-55), the Superior Court erred in allowing a defect-free design-defect claim to proceed to trial. The Superior Court recognized that Plaintiffs had conceded that they could not prove a defect in the TDF medications and agreed that the absence of a defect in the TDF medications is fatal to any design-defect claim. (App. 3247-3250 [MSJ Op. 11:19-25, 12:8-14:10].) And yet the Court allowed the claim to proceed to trial—in essence eliminating, across all the JCCP cases, the requirement that Plaintiffs prove a design defect.

Plaintiffs have little to say in defense of the Superior Court's ruling—only a few lines in a single paragraph. (*See* Opp. 10.) And what they *do* say underscores the importance of writ review. Plaintiffs concede that they "cannot argue … that [the] design of

TDF ... was defective." (*Ibid.*; *see also* Pet. 22, 37 [collecting Plaintiffs' concessions that TDF is not defective].) They instead fault Gilead for not addressing "any other aspect of Plaintiffs' claim." (Opp. 10.) But why would Gilead need to prove that Plaintiffs' design-defect claim fails on other elements when Plaintiffs cannot satisfy *the* critical element of a design-defect claim? (Pet. 53-55.) Plaintiffs never say.

Finally, Plaintiffs insist that this Court should await "a fulsome record after trial and a determination by the jury of whether a defect exists." (Opp. 10.) But no trial record will change what Plaintiffs have conceded: The TDF medications are not defective. What Plaintiffs' argument reveals is that they hope the jury will somehow find "a defect exists," even though Plaintiffs have conceded that it does not. (*Ibid.*) Given Plaintiffs' concession, this Petition cleanly tees up the purely legal question of whether a design-defect claim requires a design defect.

C. This Court should review the Superior Court's decision on fraudulent concealment.

Plaintiffs' Opposition also confirms the suitability of writ review of the Superior Court's decision on fraudulent concealment. The common ground between the parties is pervasive, teeing up a crisp, narrow, and dispositive legal question for this Court's consideration.

Plaintiffs agree that the "[o]nly" issue before this Court is whether Gilead had a "legal duty to disclose." (Opp. 10.) As to that legal duty, it is undisputed that Plaintiffs' claim is *not* about the concealment of information concerning *TDF*—the medication that

Plaintiffs were prescribed and allegedly injured them. (*See* Pet. 58.) Rather, Plaintiffs allege that the "omitted facts [are] about TAF." (Opp. 10.) The parties also agree that, if Gilead had any duty to disclose to Plaintiffs, it would need to be a "transaction [with them] … that gives rise to a duty to disclose." (*Ibid.*) And it is undisputed that there were no transactions between the parties about TAF, which was not on the market and could not have been prescribed. Finally, the parties agree that the only transaction between them was "the prescription of [Gilead's] TDF medication[s]." (*Ibid.*)

The sum total of the parties' agreement is that it sets up perfectly for this Court the question of whether a manufacturer has a legal duty to disclose to a consumer information about a product that the consumer did not use and could not have used because the product was not on the market. On this important question, it is notable—albeit not surprising—that Plaintiffs do not defend the Superior Court's statement that "established law" imposed a duty on Gilead to disclose information about unapproved TAF to Plaintiffs' TDF-prescribing doctors. (App. 3251 [MSJ Op. 15 fn.7].) It is understandable that Plaintiffs do not defend this point given that they have not been able to locate "a single case" in California or anywhere else imposing a duty on "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." (Pet. 61.)

Plaintiffs never explain why information about TAF could possibly "have influenced Plaintiffs' decision" to take TDF years

before TAF was approved. (Opp. 10 [italics omitted].) Nor could they. In fact, Plaintiffs are careful to never tell this Court the allegedly concealed information about TAF. That is because the information was merely that, according to an early 14-day study, TDF and TAF have a "similar" "safety profile." (Pet. 59 [quoting App. 2290 [1101 Study]].) And still, all agree that Gilead publicly disclosed the study results at least four years before TAF was approved and available to be prescribed. (Pet. 56-57 & fn.6.)

Plaintiffs respond by criticizing Gilead for "cit[ing] no support or case law for the proposition that the material fact … must be about TDF." (Opp. 10.) But Plaintiffs ignore Gilead's explanation (and cited caselaw) for why the TDF prescriptions created no duty for Gilead to disclose information about unapproved TAF: "[W]here 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." (Pet. 60-61 [collecting authorities].)

As one court aptly put it, "a retail consumer can sue the retail seller of a product for fraud if that seller conceals material information *about the product in connection with the sale* because the direct sales transaction between the consumer and the seller constitutes the 'some other relationship' described by the California Court of Appeal." (*Glassburg v. Ford Motor Co.* (C.D. Cal., Nov. 2, 2021, No. 2:21-cv-01333) 2021 WL 5086358, at *8 [italics added] [citing *Hoffman v. 162 N. Wolfe LLC* (2014) 228

Cal.App.4th 1178, 1187].) The same is true with a manufacturer: A consumer can sue for fraud if the manufacturer conceals information "about the product in connection with the [transaction]," or about a "safety-related defect" in that product. (*Id.* at pp.*8-9; *see also* Pet. 60-61.) Here, the information did not involve the product at issue in the transaction, or any safety-related defect in any Gilead medication.

Plaintiffs conclude by arguing that the real question surrounding their claim is one for the jury—whether information about unapproved TAF is material to the prescription of TDF to Plaintiffs. (Opp. 10.) That argument is meritless. Merely recasting the issue as one of materiality and calling it a question of fact does not make it so. This Court is presented with a "threshold question" of law about what sort of transaction can create a "duty to disclose," particularly where the allegedly concealed information concerns a product that is years away from the market and is not implicated by the relevant transaction from which a duty to disclose could arise. (*Bank of America Corp. v. Superior Ct.* (2011) 198 Cal.App.4th 862, 870-73.) No more "fulsome record" after a trial (Opp. 11) will change the answer to that *legal* question.

CONCLUSION

For the foregoing reasons, the Court should grant a writ of mandate, prohibition, or other appropriate relief as requested in Gilead's 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 5,816 words, as counted by the word count of the computer program used to prepare the brief.

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