No. S283862

IN THE SUPREME COURT OF CALIFORNIA

GILEAD TENOFOVIR CASES

GILEAD SCIENCES, INC.,
Petitioner,
v.
SUPERIOR COURT OF THE CITY AND COUNTY OF SAN FRANCISCO,
Respondent;
and
PLAINTIFFS IN JCCP NO. 5043,
Real Parties in Interest.

Review of a decision from the Court of Appeal, First Appellate District, Division Four, No. A165558
San Francisco County Superior Court No. CJC-19-005043
Hon. Andrew Y.S. Cheng

PETITIONER'S REPLY BRIEF ON THE MERITS

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INTRODUCTION

Plaintiffs' brief is a tangle of incongruities. They seek to impose liability for purported injuries from a medicine, but concede that medicine is reasonably safe. They claim injury from one product, but challenge decisions about another. They insist the duty to develop an even-safer alternative product has been established for 150 years, while admitting no court or plaintiff has ever recognized it. They ask this Court to override centuries of common law establishing a finely reticulated standard of care to address a situation that, even by their telling, is "rare." (Plaintiffs' Response Brief ("RB") 20.) They base the duty on a statute that applies to "[e]veryone" and everything they do (Civ. Code, § 1714), yet characterize the duty as "narrow[]." (RB9.)

Plaintiffs exploit this last incongruity as an excuse for presenting only a partial defense of the duty. The upshot of Plaintiffs' arguments is clear: All manufacturers would have a duty to develop and sell, without delay, alternatives to existing reasonably safe products. That duty would apply to any phase of product development, and whether the manufacturer knows or, in hindsight, merely should have known the alternative product is safer. But Plaintiffs shirk any responsibility to defend the duty's full scope. They defend only a duty tailored to the specific industry and scenario they allege here. Yet they do not explain how any court could adopt their ad hoc limits going forward. Plaintiffs' limited defense of a limitless duty is reason enough to reverse.

Regardless, Plaintiffs' effort at narrowing is for naught. Even the truncated duty Plaintiffs are willing to defend constitutes a profound legal sea change. And their defense is fundamentally flawed along three dimensions.

First, at every turn, Plaintiffs invoke their allegations in this case as the only basis for asserting that this duty is needed to prevent drug manufacturers from promoting profits over patient safety. Plaintiffs embrace the Court of Appeal's erroneous reliance on allegations rather than record evidence, even though they offered 116 exhibits opposing summary judgment. Why they must do so is obvious: The undisputed record—largely of their creation—disproves their narrative. This Court should not craft a duty, or discard entire products-liability doctrines, based on pure fiction.

Second, in an effort to harmonize this duty with the common law, Plaintiffs ignore the reams of history explaining that a defect is required where a consumer alleges injury from a product—whether asserting strict liability *or* negligence. Plaintiffs must justify any departure from this carefully calibrated rule. But other than pointing to the (false) claims in this case, Plaintiffs offer no rationale for abandoning the defect requirement.

Third, Plaintiffs scarcely address the duty's disastrous policy consequences: less innovation, fewer affordable products, and diminished consumer safety overall. Plaintiffs brush all this aside mainly by arguing that the duty targets only "unreasonable" decisions. But the notion that a jury might

ultimately rule in favor of some defendants does not prevent the harmful effects of this new, expansive threat of liability. This is a case in point: If Plaintiffs can reach a jury and threaten billions of dollars of exposure on a record like this, manufacturers will undoubtedly alter their behavior to avoid similar lawsuits.

This Court should reverse.

ARGUMENT

I. Plaintiffs' Case Depends On Mischaracterizing The Undisputed Material Facts.

Plaintiffs' entire argument collapses because it is based on three false premises: (A) that Plaintiffs can oppose an evidence-based summary-judgment motion with allegations; (B) that Gilead "knew" in 2004 that TAF was safer than TDF; and (C) that Gilead delayed TAF to make more money.

A. Summary judgment demands evidence, not allegations.

The first sign that something is amiss comes from Plaintiffs' "Statement of Facts," a three-page blockquote of the Court of Appeal's summary of "'allegations of the complaint.'" (RB12-14.)

Gilead explained that this is improper on summary judgment. (Gilead's Opening Brief ("OB") 20.) Plaintiffs hide their response in a footnote (RB12 fn.2), arguing that this Court should treat Gilead's motion like a demurrer, under *American Airlines, Inc. v. County of San Mateo* (1996) 12 Cal.4th 1110, 1118. But in *American Airlines*, the summary-judgment motion *was* essentially a demurrer, with the moving party conceding the

allegations to determine "whether the [plaintiffs] had stated a cause of action." (*Id.* at 1117; see Code Civ. Proc., § 438(d) [motion for judgment on the pleadings may not rely on extrinsic facts].) Gilead's motion did not concede the allegations in Plaintiffs' complaint; instead, Gilead supported its motion with evidence (see 1App.145-3App.1062)—including concessions from Plaintiffs' experts that Gilead did not "know[]" TAF was safer in 2004 because TAF had not undergone adequate clinical testing (2App.443-46; see 2App.410-15, 419-21.)

Nor did Plaintiffs' opposition rest on allegations: They appended 2,000 pages of exhibits. (3App.1067-10App.3005; 10App.3036-94.) Plaintiffs cannot now rely on unproven allegations—much less allegations *dis*proven by an evidentiary record. (*College Hosp., Inc. v. Super. Ct.* (1994) 8 Cal.4th 704, 720 fn.7; *Aguilar v. Atlantic Richfield Co.* (2001) 25 Cal.4th 826, 843-44.)

Plaintiffs try to create the misimpression that the Court of Appeal was relying on evidence by sprinkling bracketed appendix cites throughout the blockquote. Those insertions cannot change the reality that the court stated explicitly that it was relying on "allegations" from the "complaint" and quoted only the complaint—not the documents Plaintiffs insinuate into the blockquote. (Op.4-6, 10.)

Plaintiffs try to evade basic procedural rules by asserting that Gilead "'did not seek summary judgment on the ground that … it lacked actual knowledge that TAF was safer … [than] TDF.'" (RB12, quoting Op.11 fn.4.) But Gilead did argue that it lacked

knowledge and proved it, including with concessions from Plaintiffs' experts. (See 1App.138.) Moreover, it would have been senseless to seek summary judgment on knowledge at that point: Knowledge is not an element of *negligence*, and Plaintiffs did not propose a duty that depended on knowledge; that was the Court of Appeal's creation.

B. The undisputed record proves Gilead did not know TAF was safer for patients in 2004.

Since the Court of Appeal premised the duty on the proposition that Gilead knew in 2004 that TAF was "safer than" TDF (see Op.43), Plaintiffs must support that premise with actual evidence. Plaintiffs' claim fails as a matter of law because they have no evidence Gilead knew that in 2004. It didn't.

Start with what Plaintiffs don't dispute:

- No one can even legally claim one medicine is safer than, and equally effective as, another without conducting large-scale, head-to-head studies in humans. (OB60-62.)

- By 2004, there was only one study of TAF in humans (Study 1101)—where 20 people took TAF for just 14 days—and it found that TAF and TDF had a "'similar'" "'safety profile.'" (OB15.)

- Plaintiffs' own experts concede that Gilead did not know in 2004 that TAF was safer than TDF. (OB18, 61.)

- By 2004, Gilead also had multiple studies raising questions about whether TAF might be *less* safe due to unpredictable distribution, potential toxicity, and different adverse effects. (OB13, 15-16.)

Plaintiffs do not even try to reconcile the above with their claim that Gilead knew TAF to be safer.

Tellingly, the best Plaintiffs can do is resort to an assertion about Study 1101 that they have already conceded is false. (RB50.) Study 1101 found that no patient experienced any "clinically significant change in laboratory values" related to safety. (7App.2300.) Yet Plaintiffs declare that "[Study 1101] showed that compared with those receiving TDF, patients on TAF 'experienced significantly smaller changes in'" certain safety-related laboratory values (RB50-51, quoting 9App.2835-41), falsely attributing that quote to the "Phase I/Phase II [1101] trial" "in 2002." (RB50.) In truth, that quote is from 12 years later—the results of Study 292-0102, which did not *begin* until 2011. That obviously cannot show what Gilead knew in 2004.

Plaintiffs made this same misstatement to the Court of Appeal. (Pls.' Supp. Resp. Br. 28.) When Gilead protested and demanded a correction, Plaintiffs apologized and filed a corrected brief. (Pls.' Corrected Supp. Resp. Br. 28.) Now Plaintiffs reprise the same misrepresentation as their *only* clinical evidence that Gilead knew TAF was safer in patients in 2004.

Plaintiffs' only other pre-2004 evidence comes from *pre*clinical studies of TAF—not human studies. At best, preclinical evidence can lead to optimism and "initial excitement" (RB8), but it cannot prove the knowledge of superior safety in humans that is critical to Plaintiffs' theory. To compensate, Plaintiffs repeatedly describe the "spectacular success" of some preclinical research without acknowledging that these were studies in rats, dogs, and plasma. (RB8.) Plaintiffs quote Gilead's research, but excise words like "*in vitro*" (test tube) and explicit

uncertainty about what might "translate[] to the *in vivo* [in body] case." (Compare 5App.1678 with RB50; compare 6App.1907-08, 1911 with RB8, 50 [presenting interim results as final]; see, e.g., RB50, citing 5App.1662-63 [preclinical TAF testing].) And, of course, they omit all of TAF's more equivocal preclinical safety data. (OB13, 15.)

This is all the evidence that Plaintiffs have. None creates even a triable issue that Gilead knew in 2004 that TAF was safer than TDF.

C. The record forecloses Plaintiffs' profit-motivation theory.

Also at the heart of Plaintiffs' claims—and narrative—is their insistence that Gilead stopped TAF development to maximize profits. (RB8-9.) If there is no evidence that Gilead knew TAF was safer, the motive theory collapses. Independently, Plaintiffs present no evidence of motive. Here, again, they blockquote the court's summary of allegations and backfill citations. (RB13-14.) But the citations do not support them.

Gilead detailed the evidence, in context and in chronological order, to demonstrate that the documents on which Plaintiffs rely categorically disprove their narrative. (OB13-14, 18-19.) To summarize, the documents prove Gilead hoped TAF would prove materially better than TDF, in which case the most profitable path would be to prioritize development of TAF and bring it to market as quickly as possible. (6App.1901, 1922; 7App.2314.) In that scenario, Gilead would intentionally "cannibalize" TDF by shifting patients to TAF. (6App.1901, 1922.)

But the 2004 evidence showed TAF was *not* materially better than TDF. (*Ante* 11-13; OB19.)

Plaintiffs scramble the scenarios in the documents to suit their narrative. They say, "Gilead laid out a detailed schedule for getting TAF to market in 2006" (RB8, citing 6App.1970-82), without acknowledging that draft schedule was premised on TAF proving to be superior. They say Gilead rejected TAF because it would "'cannibalize'" TDF (RB8), without acknowledging that Gilead was planning to do just that *if* TAF was superior. (6App.1901, 1922.) They reorder words in a sentence to insist that "Gilead decided that 'regardless' of TAF's 'efficacy and safety profile,' it would intentionally delay the release of TAF to coincide with the expiration of TDF's patent in 2017." (RB9, quoting 7App.2151-54.) But the sentence actually says that a new medicine like TAF will always cannibalize the earlier one, "regardless" of whether it is superior. Only if the new medicine is superior (which TAF appeared not to be) would it benefit patients and the manufacturer because it would switch over existing patients and attract new ones.

II. This Court Should Not Abolish The Century-Old Rule That A Consumer Claiming Injury From A Product Must Prove A Defect.

For nearly a century, courts in California—and everywhere else—have subscribed to a simple rule: A plaintiff alleging injury from a product must prove a defect. This rule is a crucial limitation on manufacturer liability. (II.A.) Eliminating it would destabilize the intricate balance the courts have struck, for no

good reason. (II.B.) None of this Court's precedents justify eliminating the defect requirement. (II.C.)

A. The defect requirement is a critical, longstanding limitation on manufacturer liability, including in negligence.

Plaintiffs do not dispute that this Court has repeatedly treated the defect standard as a core requirement. It has declared that manufacturers "are liable in tort *only* when 'defects' in their products cause injury" (*Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 568 fn.5, italics added), and that "under either a negligence or a strict liability theory of products liability, to recover from a manufacturer, a plaintiff *must* prove that a defect caused injury." (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 479, italics added; see OB24.)

Plaintiffs insist that all those opinions silently limited the defect requirement to strict liability (RB20), even though the *Merrill* quote explicitly referenced "negligence" too, and Plaintiffs never resist the Court of Appeal's observation that Plaintiffs' claim is a "products liability action[]." (OB40, quoting Op.26.) Nor could they, as "[P]laintiffs are seeking compensation for injuries caused by their use of TDF." (Op.2.)

Plaintiffs instead echo the Court of Appeal's assertion that the defect requirement evolved to limit only "the circumstances under which strict products liability applies." (RB18.) Gilead explained why that is wrong (OB25-27): Before the 1930s, the law generally "exonerat[ed] manufacturers from third party claims" for personal injury not rooted in contract or warranty. (*Beacon Residential Cmty. Assn. v. Skidmore, Owings & Merrill LLP*

(2014) 59 Cal.4th 568, 574.) This Court relaxed the prohibition in *Kalash v. Los Angeles Ladder Co.* (1934) 1 Cal.2d 229, allowing a plaintiff injured by a product to sue the manufacturer in negligence. To ensure this new negligence claim was constrained, *Kalash* limited it to products rendered dangerous because of "defective construction or assembling." (*Id.* at 233.) This Court adopted that defect limitation decades before it recognized strict liability. (OB26.)

Plaintiffs defy this history with bold historical revisionism. They posit there never actually was a prohibition against all negligence claims, but only against tort liability for injuries "'sustained by reason of defects.'" (RB27, quoting *Dahms v. General Elevator Co.* (1932) 214 Cal.733, 738, italics omitted.) They insist that negligence claims *not* involving a defect were always allowed—and therefore unaffected by the defect requirement.

That is wrong. There would have been no need to authorize defect-based negligence claims if plaintiffs could always have brought general negligence claims. And it would have been backwards to *bar* negligence liability against manufacturers whose products were defective—but allow negligence claims against manufacturers with non-defective products. *Kalash* makes that clear: It explained that the blanket prohibition it was overruling applied to all "claims of third persons, not direct purchasers, *for personal injuries sustained* from use of articles so manufactured and sold"—whether or not "defect[ive]." (1 Cal.2d

at 231, italics added.) The *exception* this Court carved out permitted negligence suits *only* where there was a defect.

B. Eliminating the defect requirement would destabilize the intricate balance the courts have struck and for no good reason.

Plaintiffs do not dispute the seismic consequences of eliminating the defect requirement. (OB27-31.) Here, Plaintiffs claim to have been injured by one product, but are incongruously suing over the manufacturer's decisions about another. But the incongruity goes much further: In Plaintiffs' view, once a manufacturer sells a product, it is subject to liability for just about any corporate decision that can conceivably implicate the product's users—product distribution, pricing, whether to advertise a competitor's product, etc. (RB10, 31; see OB28.) If anything, Plaintiffs would say the list is underinclusive, because the "'circumstances under which a manufacturer might … be held liable … are simply too varied to be so constrained.'" (RB10, quoting Op.20.) That is a sea change in tort law.

Plaintiffs do not explain how businesses are supposed to navigate this. They say that juries will have "[]workable" standards by which to judge all these decisions because juries are used to applying reasonableness. (RB31.) We explain later how wrong that is. (III.C.) The key point here is that manufacturers cannot predict outcomes based on—or plan their business around—how a jury decades later will evaluate whether a business decision reflected "'due care commensurate with the risk posed by the conduct taking into consideration all relevant considerations.'" (RB32.) This is a recipe for chaos.

Plaintiffs do not dispute that the defect requirement was designed to "strike a balance between safety and access." (RB32, quoting OB29.) Yet they scarcely explain why that was the *wrong* balance. On one side of the ledger, Plaintiffs do not contest that the defect requirement provides businesses, litigants, courts, and juries with essential clarity and guidance. (OB27-28.) The defect requirement ensures manufacturers continue making products consumers want and need without overcorrecting based on safety considerations. (OB30.)

Plaintiffs do not refute this Court's admonition that this balance is especially critical in the pharmaceutical context. (OB30, discussing *Brown v. Superior Court* (1988) 44 Cal.3d 1049.) That is why this Court eliminated strict liability for pharmaceuticals. So it is especially dissonant for Plaintiffs to cite the elimination of "strict liability design defect claims" to justify the far more disruptive step of eliminating the defect requirement entirely. (RB32.) Plaintiffs also do not dispute that FDA provides an added layer of protection in ensuring safety, efficacy, and fair warnings, further diminishing the need for more expansive tort protection. (OB30.)

On the other side of the ledger, Plaintiffs have no argument as to why the defect requirement has so disserved consumers as to warrant all the mischief they invite. Given Plaintiffs' acknowledgement that "section 1714 has not been previously applied" like this (RB21), why are existing tort protections inadequate? Plaintiffs do not dispute that existing negligence law, with the defect requirement, ensures that products on the

market are reasonably safe. Nor do they dispute that the defect standard entails a robust analysis of safer feasible alternatives. (OB29.) So what is missing?

Plaintiffs do not say it is necessary to abolish the defect requirement because manufacturers are routinely withholding safer products to make more money on non-defective products. Quite the opposite: They concede it is "rare" that a manufacturer has "a safer … drug but cho[oses] not to proceed with [it]." (RB20.) Plaintiffs' only basis for their assertion that this has *ever* happened is this case, invoking nothing but allegations the undisputed record disproves. (*Ante* 9-14.) False allegations in one case cannot support such a sea change. Even if Plaintiffs had proof of some other case where that happened, that would not suffice. Tort law is not supposed to insure against every conceivable injury; rather, "meaningful limits on liability" are necessary to "safeguard the efficacy of tort law." (*S. Cal. Gas Leak Cases* (2019) 7 Cal.5th 391, 401.) That is all the more resonant in the pharmaceutical context, where this Court has found "the broader public interest in the availability of drugs at an affordable price" outweighs additional consumer protection from expanded liability. (*Brown, supra*, 44 Cal.3d at 1063.)

Plaintiffs assert that, in the pharmaceutical context, federal preemption provides "near blanket immunity" from state tort actions. (RB46.) The headlines of massive products-liability verdicts prove otherwise. In just the past few years, plenty of courts have found pharmaceutical design-defect claims not preempted. (See, e.g., *In re Zostavax (Zoster Vaccine Live)*

Products Liability Litigation (E.D.Pa. Nov. 10, 2021, No. 18-MD-2848) 2021 WL 5235225, at *3-4 [citing eight recent cases].) Regardless, Plaintiffs do not explain why eliminating the defect requirement will resuscitate otherwise preempted claims.

Finally, Plaintiffs ignore the "doctrinal paradox" that would arise from eliminating the defect requirement: essentially abolishing the claim of negligent design defect, which this Court and others spent decades refining. (OB30-31.)

C. No precedents justify eliminating the defect requirement.

1. Plaintiffs present a string-cite of "many California cases," but none of them approve a negligence claim against a manufacturer for injury from a product without requiring a product defect. (RB22.) Plaintiffs only discuss two cases in any detail—neither of which support their novel claim.

Plaintiffs lead with *Mexicali Rose.* It is telling that Plaintiffs stretch to describe a *restaurant* as a "manufacturer of foodstuffs." (RB22.) Even the Court of Appeal conceded this made the case "atypical" as products-liability precedent. (Op.19.) Nevertheless, Plaintiffs emphasize a doctrinal technicality unique to that context (RB25 & fn.7): For reasons peculiar to natural contaminants in prepared foods, a bone in the food was not considered a defect. (*Mexicali Rose v. Superior Court* (1992) 1 Cal.4th 617, 630-32.) But Plaintiffs do not dispute that had this been in the manufacturing context, the bone would qualify as a manufacturing defect. The Court merely smoothed out that

doctrinal wrinkle to align the restaurant context with the products-liability requirement of a defect. (OB31-32.)

The other case Plaintiffs discuss is *T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145. Nothing in *T.H.* supports Plaintiffs' position that a negligence claim does not require a defect, because there *was* a defect: the failure "to warn … about the risks known or reasonably known to the manufacturer." (*Id.* at 164.) Everyone agreed that the manufacturer had a duty to warn its own consumers; the question was whether the duty extended to consumers of the generic version of its drug, made by a different manufacturer. *T.H.* held that it does, because "federal law explicitly conveys to the brand-name manufacturer … the responsibility to provide an adequate warning label for both [the] generic … and its brand-name equivalent." (*Id.* at 155.)

Plaintiffs do not contend that *T.H.* shows there can be negligence without a defect. They invoke *T.H.* for the unexceptionable proposition that "'[n]egligence and strict products liability are separate and distinct bases for liability.'" (RB25-26.) No one is saying they aren't—just that both require a defect. (OB26.) Nothing in *T.H.* says otherwise.

The remaining cases Plaintiffs string-cite also involved classic defects. Like the cases already discussed (OB32), *Hasson v. Ford Motor Co.* (1977) 19 Cal.3d 530, 543-44, recognized that a manufacturer can be negligent for failing to remedy a defect arising after sale. *Hasson* expressly declined to address whether

a negligence claim for injuries from a product requires proof of a defect. (*Id.* at 540; see Pet.19; Op.16-17.)

Stevens v. Parke, Davis & Co. (1973) 9 Cal.3d 51, 58, 66, involved a classic product defect: A manufacturer "negligently failed to provide an adequate warning" about a medication's risks by aggressively promoting the medicine without including "any warning whatsoever." And in *Scott v. C.R. Bard, Inc.* (2014) 231 Cal.App.4th 763, the claims included strict liability and negligent-design-defect as well as fraud (i.e., negligent misrepresentation). *Scott* recognized that when a plaintiff alleges injury from a product—as opposed to by fraud—"under either theory [negligence or strict liability], the plaintiff must prove that a defect caused the injury." (*Id.* at 773.)

2. Plaintiffs barely rebut Gilead's showing that other jurisdictions universally require a defect. (OB24-25.) They dismiss the Michigan Supreme Court's conclusion that "*in every case, in every jurisdiction*, … the plaintiff must … show that the product was defective," because it did not string-cite cases proving its point. (*Prentis v. Yale Mfg. Co.* (Mich. 1984) 365 N.W.2d 176, 181-82; see RB27-28.) And they ignore the Utah Supreme Court's similar conclusion. (See OB25.)

Plaintiffs instead claim to have "*multiple* decisions" *implying* that a defect is not required—three, to be precise. (RB28.) So right off the bat, Plaintiffs cede the other 46 states (and D.C.). And Plaintiffs are wrong about those three. A case from a Michigan lower court cannot override the Michigan Supreme Court's intervening pronouncement that a defect is

always required. (*Prentis*, *supra*, at 181-82.) Next is a Ninth Circuit case interpreting Idaho law, which Plaintiffs cite without mentioning the Idaho Supreme Court has since disavowed that view. (OB25 fn.2.) The last is a Pennsylvania case allowing a negligence claim, not where the product was reasonably safe but where it was unreasonably unsafe for unintended users (there, children). (*Phillips v. Cricket Lighters* (Pa. 2003) 841 A.2d 1000, 1007.)

In the end, whether the defect requirement is universal or near-universal, this veritable wall of precedent matters. This Court should not blithely dismiss the considered judgment of hundreds of judicial peers who have wrestled with these same considerations for a century—and, in the end, embraced the defect requirement as critical to the balance tort law strives to strike.

III. The Specific Duty The Court Of Appeal Recognized Is Unjustified As A Legal Matter And Untenable As A Policy Matter.

Whether or not this Court embraces the defect requirement, it should reverse by rejecting the specific duty the Court of Appeal recognized. Manufacturers have no duty to develop and commercialize safer alternatives to existing, non-defective products. Plaintiffs do not dispute that this duty would replace products-liability law (III.A.), and they fail to justify the Court of Appeal's framework (III.B.). Regardless, policy considerations fail to justify the duty. (III.C.) At the very least, any duty premised on a drug manufacturer's knowledge of a

"safer" alternative cannot attach this early in drug development. (III.D.) And Plaintiffs' waiver arguments are meritless. (III.E.)

A. This duty would replace the existing ordinary-care standard with a boundless standard.

Plaintiffs do not dispute that recognizing a broad duty to develop and commercialize safer alternatives to existing non-defective products would practically supersede products-liability law with perfect-product law, yielding the following consequences:

- A reasonably safe product will not be safe enough, if the manufacturer could have pursued a different path that would have avoided injury to *any* consumer. (OB35.)
- That will be true even if the risk of injury from the existing, non-defective product is extremely low, as it is here. (OB35.)

Instead, Plaintiffs assert that these consequences will not materialize because the duty is "narrow[er]" than Gilead depicts and only "unreasonable" manufacturers will ultimately be liable. (RB9-10, 41-42.) But those limits are illusory and will not mitigate this duty's breadth and consequences.

Types of manufacturers. Gilead presented numerous examples of manufacturers across industries whose product-development decisions would be subject to this duty. (OB36-37.) Plaintiffs respond that *this* case "involves a *pharmaceutical* manufacturer." (RB36; see RB38-39.) That is no limit. Plaintiffs take pains to emphasize that the duty derives from a statute that applies to "[e]veryone." (RB16, quoting § 1714.) And Plaintiffs

underscore that breadth by emphasizing that "manufacturers often"—even "*routinely*"—"have the knowledge necessary to develop and commercialize alternatives to their existing products that would *avoid harms* to some consumers." (RB37, quoting OB36, 47.)

Plaintiffs argue that *drug* manufacturers would be especially undeserving of an exception under *Rowland*. (RB32, 36-37, 46-47.) Those arguments are wrong, for reasons explained below. (*Post* 31-41.) Their arguments also cannot be harmonized with *Brown*, which rejected a standard that would have held drugmakers liable because a safer alternative existed. (OB37-38.) Far from being necessary to regulate drug manufacturers, the duty is uniquely inappropriate as applied to them. In any event, none of these pharmaceutical-specific arguments would absolve all other manufacturers of the duty.

Stage of development. Next, Plaintiffs assert that the duty requires a manufacturer "*not* 'to develop' a safer product," but only to market "a drug *already* 'developed.'" (RB11; Op.10-11 & fn.3.) Again, Plaintiffs' theory of duty permits no such limitation: Section 1714 applies to *any* decision a person makes "in the management of his or her property," whether characterized as a decision to "develop," "invent," or "commercialize."

Regardless, no company that reads the opinion below could find any comfort in that distinction. As the court recognized, Plaintiffs faulted Gilead for "discontinu[ing] *development* of TAF" in 2004. (Op.5, italics added; e.g., 1App.55, 58 [Complaint].) Even

after Gilead resumed TAF development, it took five years of further clinical studies to test TAF, secure FDA approval, and bring it to market. (1App.152-53.) Thus, whatever "already-developed" means, it encompasses an alternative product years and millions of dollars away from commercialization.

Reasonableness. Plaintiffs do not narrow the duty by repeatedly insisting that it addresses only "unreasonable" product-development decisions. (RB9-10, 36-37, 41-43.) Without meaningful standards for assessing reasonableness, plaintiffs can challenge *any* delay or failure to market an alternative product that would avoid injury to *some* consumers. (See OB45-47.)

In any event, Plaintiffs confuse duty with breach: The question of whether a particular manufacturer acted unreasonably would be for the jury. (See RB9.) This Court must decide whether to force manufacturers to litigate every product-development decision all the way to trial, even where a manufacturer behaved entirely reasonably with regard to the product *actually* marketed.

B. The Court of Appeal applied the wrong legal framework.

1. Everyone agrees that the duty under "section 1714 applies to a manufacturer of prescription drugs and is owed to the users of such drugs." (RB19.) The question is *what* does that duty entail. The parties present two alternatives:

> ***§ 1714 subsumes common law***: Gilead's position is that when the common law painstakingly defines the standard of care for a particular actor in a particular

context, § 1714 *subsumes* the common-law rule. (OB39.) So § 1714 incorporates the restrictions on duty established by products-liability law, and Gilead satisfied § 1714 by marketing a defect-free product. (OB23-27.)

§ 1714 supersedes common law: Plaintiffs' position is that § 1714 supplements the common law with a broader, independent duty that *supersedes* any common-law restrictions. (RB20.) It does not matter that courts have striven over decades to calibrate a workable standard of care for manufacturers. All that matters is a jury's hindsight assessment of the "reasonableness" of a manufacturer's conduct. (RB31-32.)

Plaintiffs' arguments against the defect requirement illustrate how extreme their position is. Plaintiffs gave short shrift to all the historical evidence, based on their view that "even if Gilead were right," common-law limits do not matter. (RB20.) They assert that § 1714 created an independent statutory duty that is insulated from—and "replace[s]"—common-law developments. (*Ibid*.)

If so, the California judiciary has wasted the past 150 years refining common-law duties. The reporter volumes are full of common-law limitations—assumption of risk, no duty to warn of open and obvious conditions, no duty to avoid some purely emotional or economic harms. On Plaintiffs' view, any plaintiff

can erase those limitations with a reasonableness standard by repleading her case under § 1714 for breach of "ordinary care."

Plaintiffs largely ignore the reasons Gilead marshaled as to why Plaintiffs' view is wrong. (OB38-42.) They ignore this Court's authority holding that § 1714 reflects "the intention of the Legislature to announce and formulate existing common law principles" (*Li v. Yellow Cab Co.* (1975) 13 Cal.3d 804, 814)—not to create an independent duty, immune from judicial development. And they ignore that § 1714 must be "construed in light of common-law decisions on the same subject," "incorporat[ing]" common law "developments." (*Id.* at 814-15, 822.)

Plaintiffs also fail to explain away *Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456. *Parsons* did not treat § 1714 as a free-floating reasonableness standard that supersedes the common law. (*Id.* at 465-68, 472-74.) Rather, it recognized that the situation *already* fell within an exception to § 1714's "general rule," based on "early cases" establishing "no liability" in such circumstances. (*Id.* at 472-44.) And it declined the "plaintiff's invitation to *expand* the limited duty of care imposed by the common law." (*Id.* at 472-78, italics added.) None of that is changed by Plaintiffs' observation that *Parsons* addressed the *Rowland* factors. (RB16-17.) Those factors inform any analysis of duty, regardless of whether the focus is on establishing a new duty or carving out an exception. (See OB41-42, 44-45.)

Rowland is also entirely consistent with Gilead's understanding of § 1714. (Contra RB20.) There, this Court took

full account of common-law limitations on a landowner's duty of care that had retained force long after § 1714 was enacted. (*Rowland v. Christian* (1968) 69 Cal.2d 108, 113-16.) *Rowland* did not assume that a boundless duty under § 1714 could coexist alongside those "common law rules"; it recognized that the common-law limitations would need to be abolished if the Court were to expand a landowner's duty of care. (*Id.* at 116-19.) This Court "replace[d] the common-law concept of landowner liability" (RB20) only after determining that "historical justifications" for the old rules were no longer compelling. (*Rowland*, *supra*, at 117-19.)

This is the Court's approach whenever a plaintiff invokes § 1714 to override longstanding common-law limitations. Plaintiffs argue otherwise by citing cases involving contexts the common law has *not* addressed—cases involving "novel applications" of § 1714. (RB20-21.) In those cases, courts naturally start with § 1714's default rule because there is no applicable common-law limitation to consider. (See *Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1015-21 [identifying no common-law limitation on negligence claim premised on defendant "violating a county health order"]; *Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1143 [same with the "use of asbestos in one's business or on one's premises"].) But those cases have no bearing where, as here, the common law has set a standard of care rejecting liability for the conduct at issue.

The proper framework has several consequences. First, if a plaintiff invokes § 1714 to overcome common-law limitations, the

court must grapple with the justifications for those limits and assess whether they are still valid; the plaintiff cannot simply override them with the facile assertion that § 1714 imposes a general duty of reasonableness. (OB41.) Second, where a plaintiff seeks to "increas[e] the burden" prescribed by common law, the plaintiff must justify the new standard of care. (OB41, quoting *Parsons*, *supra*, 15 Cal.4th at 474.) It is wrong to start with the assumption that a duty already exists and ask only whether Gilead justified carving out an exception. (OB31-42.)

2. Regardless of the new-duty-versus-exception framing, Plaintiffs confirm the Court of Appeal erred in limiting its duty analysis to cases involving "actual knowledge." (Op.11-12 fn.5.) The court thought that limitation appropriate because it believed Plaintiffs had abandoned a constructive-knowledge theory. (*Ibid.*) Plaintiffs rebuke that premise. Far from disclaiming constructive knowledge, Plaintiffs defend it. (RB37, 42.) Accordingly, this Court should decide one way or the other whether the duty extends to that theory.

Plaintiffs argue this Court need not address the full scope of their theory, because Gilead "never contested" that it "knew TAF was safer." (RB36-37.) That is false, as explained. (*Ante* 11-13.) It is also a non sequitur: Gilead indisputably contested any permutation of Plaintiffs' proposed duty, under any scienter. (OB44-60.)

Plaintiffs are wrong that this Court is powerless "to carve out an exception" for constructive knowledge because Gilead did not petition for it. (RB37 fn.10.) Gilead asserted that the

minimum this Court should do is reject a duty premised on constructive knowledge rather than leaving it unresolved. (Pet.29, 35; OB43-44.) This Court has the power to limit a duty in any way that sound policy requires. (*Kesner, supra*, 1 Cal.5th at 1154-55.) It should not, however, recognize a duty of undefined scope. (OB43-44.)

C. Policy considerations fall far short of justifying the duty under any framing.

Plaintiffs say little about several of this duty's negative consequences: It unsettles an equilibrium that protected consumers without overburdening manufacturers (see OB27-31, 34-38; *ante* 17-20), disrupts settled expectations (OB23-25, 27-30; *ante* 26-30), and unleashes doctrinal confusion with dueling standards of care. (OB29-30 [role of "safer alternative design"]; OB30-31 [abolishing negligent-design-defect claims].) Plaintiffs try to minimize the rest of the consequences by artificially cabining the duty. But for reasons already explained (*ante* 24-26), Plaintiffs cannot blink away the consequences of the duty by pretending it will never apply beyond the pharmaceutical context, or to cases where a safer alternative product still must be "developed," or to situations where the challenged decision is "reasonable." Nor will the duty be limited to cases involving bad-faith, profit-driven decisions (RB9, 11), because negligence depends on the "act," not on the "motive." (*Davis v. Hearst* (1911) 160 Cal.143, 162.)

Plaintiffs' entire policy analysis is inadequate because it is woefully incomplete along all these dimensions—and should be

rejected for that reason alone. Even as to the narrow context Plaintiffs do address, their own analysis reveals why the duty is unnecessary and harmful.

Workability and unpredictability. Gilead listed numerous foundational questions about *whether* or *when* manufacturers of a reasonably safe product must provide consumers with the choice of a safer alternative. (OB45-46.) Plaintiffs answer none of them. They just resort to a one-word answer to these, and all other questions, about this duty's scope: "reasonableness." (RB31.) That empty guidance dooms manufacturers to navigate a veritable minefield of potentially crushing liability blindfolded.

Plaintiffs do not dispute that a lack of guidance will lead manufacturers to be overly cautious in ways that decrease product affordability and customer safety. (OB47, 51-53.) Their only response is to quote *Ramirez v. Plough, Inc.* (1993) 6 Cal.4th 539, 546-47, for the proposition that juries regularly assess what a "reasonably prudent person under like circumstances" would do. (RB31.) They ignore *Ramirez*'s caution that certain cases involving complex decisionmaking are ill-adapted to this undefined "reasonableness" standard. (*Ramirez*, *supra*, at 552-53.) This is such a case.

Plaintiffs also undermine their point by citing design-defect cases as illustrative of juries' capability to decide complex issues. (RB31.) Plaintiffs do not dispute that a binary defect/no-defect determination is much more straightforward than intricate product-development decisions. (See OB45.) An expert can guide

a jury's analysis of defect by pinpointing, for example, the temperature at which brake fluid vaporizes. (*Hasson v. Ford Motor Co.* (1982) 32 Cal.3d 388, 397; see RB31-32.) But Plaintiffs do not explain how a jury could assess any of the questions Gilead identified, such as where a manufacturer should devote finite resources, whether a product with other safety risks is still safer, and how to assess prioritizing one segment of consumers over another. (See OB46.) Nor do they explain how juries would do it without expert testimony, as the trial court here directed. (OB47, discussing 10App.3275.) The inevitable results of this "fact-intensive, case-by-case standard" will be unacceptably "'arbitrary'" and "'inconsistent.'" (*S. Cal. Gas.*, *supra*, 7 Cal.5th at 410.)

Foreseeability of harm to plaintiffs & closeness of connection to defendant's conduct. A decision to stop developing a safer alternative will not necessarily injure any consumer years later. Gilead enumerated five illustrative contingencies that could break the causal chain. (OB48-49.) Plaintiffs do not dispute that each one makes injury contingent on events that are not knowable in advance. Instead, they respond with three non sequiturs.

First, they dismiss two of the contingencies as "reason[s] to conclude that a *particular* manufacturer was not *negligent*." (RB39.) Exactly—because if any of the contingencies comes to pass, the decision will not have caused an injury. Foreseeability is about what is known when the challenged decision is made—not what ends up happening. The problem is that the

manufacturer cannot know in advance whether any of those contingencies will occur.

Second, Plaintiffs assert that "pharmaceutical manufacturers are in the *best position* to understand the potential adverse effects of their products." (RB35-36.) That would be relevant in a suit challenging a manufacturer's failure to disclose (or anticipate) known adverse effects. But it has no bearing on whether injuries from not developing a *different* product are foreseeable, because manufacturers cannot predict the future. (See OB48-50; Op.41.)

Third, Plaintiffs argue that "unique patent protections afforded drug manufacturers … accentuate the foreseeability of harm" because Plaintiffs supposedly had "*no choice*" but to use TDF. (RB36.) But as discussed below (*post* 40), that premise is false. Besides, patent protection does not affect the likelihood of any of the other contingencies materializing. (OB49.)

Relatedly, everyone agrees that regulatory approval presents an additional contingency in this and other heavily regulated industries. (OB49-50; RB39-40.) Plaintiffs do not dispute that this hurdle further attenuates the causal chain, or that the clinical trial failure rate is 88%. (OB49.) Plaintiffs echo the Court of Appeal's speculation that the failure rate may drop somewhat below 88% where the manufacturer has "already secured" FDA approval of one medicine and is developing what is hoped to be a safer alternative. (RB39-40.) But prior approval of an analogue will never bring the failure rate to zero. That much

is evident from the sheer size and duration of the research program Gilead performed to secure TAF's approval. (OB13-17.)

Policy of preventing future harm. To justify such a tectonic shift away from the traditional duty, one would expect Plaintiffs to offer a comparably compelling justification—such as a proven, sustained epidemic of injuries inflicted because manufacturer incentives are misaligned. But Plaintiffs concede the opposite, acknowledging both that it will be "rare" for a manufacturer "not to proceed" with developing a safer alternative (RB20; see *ante* 19) and that "manufacturers have *ample* incentive to release safer products." (RB45.) All of which makes the duty even less necessary for consumer safety. (OB53-54.)

With regard to constructive knowledge, Plaintiffs also concede away any need for a duty by noting that "manufacturers with constructive knowledge … will have a strong argument before a jury that their conduct was not unreasonable." (RB42.) If it is generally reasonable not to develop and commercialize an alternative product absent *actual* knowledge that it is safer, no benefit outweighs the societal costs.

Whatever the scienter, Plaintiffs' argument reduces, again, to the assertion that the duty is necessary *in this case*—based on a stylized and false narrative. (RB32; *ante* 9-14.) But even "quite sympathetic" claims cannot form the basis of a duty with untenable policy consequences. (*S. Cal. Gas*, *supra*, 7 Cal.5th at 399; see *Kuciemba, supra,* 14 Cal.5th at 1031.)

Far outweighing the concededly minimal (even non-existent) harm this duty is designed to prevent is the massive

harm it will inflict—in deterred innovation, distorted development priorities, decreased affordability, and reduced overall consumer safety. (OB50-54.) Plaintiffs defy economic reality in contending that no manufacturer would resist investigating back-up candidates, hesitate to market improved products, or decline to prioritize under-served consumer markets solely "to protect themselves from liability." (RB44-46; see OB51-53.) This case illustrates why it is not enough to predict those activities could lead to greater profits. (Contra RB45-46.) Plaintiffs are seeking billions of dollars in damages for what they claim was an improper drug-development decision made in the throes of regulatory uncertainty years before any profit could be realized; that obviously will affect similar decisions going forward. (See 10App.3268.) This Court "*must* … account" for the resultant chilling effect. (*Vasilenko v. Grace Family Church* (2017) 3 Cal.5th 1077, 1089, italics added.)

Echoing their earlier theme about "reasonableness," Plaintiffs assert the duty will not distort manufacturers' behavior because only claims targeting *"negligent*" decisionmaking will be *"successful*[]." (RB45.) But the fact that some juries will ultimately find no breach does not diminish the degree to which manufacturers will alter their behavior to *avoid* litigation and potential liability. And given the nebulous "reasonableness" standard, those behavioral changes will be societally sub-optimal.

Plaintiffs argue, again, that unique features of the pharmaceutical industry enhance the need to protect consumers. They repeat that this duty is essential because preemption

provides "near blanket immunity" from tort actions (RB46), which is factually wrong and legally unpersuasive. (*Ante* 19-20.)

Plaintiffs also assert this duty is necessary to prevent manufacturers from "delaying the commercialization of an alternative product to maximize the patent protection of its existing product." (RB41.) That is patently false. Nothing about the development, commercialization, or patenting of a new compound (like TAF) affects the patent on an existing one (like TDF). Nor could a manufacturer reliably predict what effect a delay would have on patent protection for a family of medicines, because too many imponderables influence how and when patents issue on variations, combinations, and methods of treatment. (Contra RB46.) This case illustrates the point. As it turned out, some TAF and TDF-containing medicines are protected today by patents expiring in 2033—well after the 2017 horizon that Plaintiffs feature. (See U.S. Patent Nos. 10,857,102 & 10,039,718.)

Plaintiffs' argument is also refuted by the drug-development incentives Gilead explained. (OB53-54.) Because a patent term is based principally on its application date, manufacturers are incentivized to market new medicines as soon as possible to maximize the patent period. This is particularly so where the new medicine is "better" than an existing one, as no rational company would forgo years of immediate, materially increased profits for the highly uncertain prospect of later patent expiration. Again, this case illustrates the point. Plaintiffs nowhere dispute that Gilead projected making more money by

releasing a better medicine sooner. (OB18-19, 54.) But Gilead could not pursue that more lucrative path because TAF had not proven to be better by 2004.

Regardless, patents are a constitutionally recognized reward of temporary exclusivity to manufacturers for undertaking the expense and uncertainty of drug development. (See Fed. Trade Comm'n, *To Promote Innovation: The Proper Balance of Competition and Patent Law and Policy* (Oct. 2003), https://tinyurl.com/yphfy6jr.) An unbounded tort duty is not the answer to Plaintiffs' mistaken belief that the patent system insufficiently protects consumers; their recourse is to Congress.

Burden on defendants and community at large. Plaintiffs have almost nothing to say about the common-sense point that condoning an unprecedented new duty will invite a deluge of lawsuits. (OB54-56.) It is irrelevant that "negligence law has always" required manufacturers to "act reasonably" (RB47), because, as Plaintiffs concede, no court has "previously applied" it to require a manufacturer to develop and market an alternative to a non-defective product. (RB20-21.)

Plaintiffs try to temper the deluge by arguing that Gilead "exaggerate[s]" the duty's scope. (RB46.) But even focusing just on the pharmaceutical context, Plaintiffs do not deny that every drug-development decision gives rise to a new class of potential plaintiffs who could challenge the path not taken (or not taken quickly enough). (OB55.) And again, contrary to Plaintiffs' suggestion, making reasonable decisions is no barrier to lawsuits alleging otherwise. (RB47.)

Beyond that, Plaintiffs' only response is that there is "little direct empirical evidence" that tort duties affect manufacturer behavior. (RB47.) The whole premise of tort law is that it *does* "induce behavioral changes." (*Kuciemba*, *supra*, 14 Cal.5th at 1026.) This Court should presume that age-old wisdom until and unless direct empirical evidence refutes it.

Moral blame. Here, again, Plaintiffs confuse duty and breach. They identify an extreme (and extremely implausible) hypothetical in which a drug manufacturer chooses to make billions in profits, knowing for certain that it will kill or injure thousands of people. (See RB42-43.) They argue that this outlier hypothetical justifies a duty in all cases. (*Ibid*.) Plaintiffs then (again) wave away the massive potential breadth of affected—and non-culpable—manufacturers, arguing that *those* manufacturers will be able to prove their innocence at trial. (RB42.) Plaintiffs' focus on the worst imaginable conduct distorts the policy analysis and ignores the duty's burden on manufacturers. Moreover, if a duty is to be recognized because of extreme cases, it should be limited to extreme cases—for example, by applying only to "willful misconduct." (*Calvillo-Silva v. Home Grocery* (1998) 19 Cal.4th 714, 728; see OB43.)

Plaintiffs defy bedrock law in contending that moral blame attaches where a manufacturer "fails to take 'reasonable ameliorative steps' to avert the known harms of its existing product." (RB41.) There is nothing morally blameworthy about selling a product that is *already* reasonably safe.

Plaintiffs also claim moral blame is warranted because they had "no alternative" to Gilead's TDF-based medicines and thus were "forced" to risk side effects (however remote, OB12). (RB41.) But there were other non-tenofovir medicines already on the market—and 11 more approved between Gilead's decision to discontinue TAF development and the year FDA first approved a TAF medicine. (NIH, *FDA Approval of HIV Medicines* (2024), https://tinyurl.com/5cbfpve4.)

Finally, Plaintiffs argue that decisions not to develop a drug are immoral when financially motivated. (RB41.) But a plaintiff will always be able to allege that motive: Money is inevitably part of the equation when drug development is so expensive—averaging $2.6 billion to take a new medicine to approval. (OB58.) And Plaintiffs fail to address that a manufacturer deciding not to pursue one medicine is typically investing that money in other medicines. Such hard decisions are just not morally culpable. (OB57-58.)

Insurance. Plaintiffs have little to say about this factor, faulting Gilead for not providing evidence of the duty's effect on insurance coverage. But Gilead could not feasibly do so, when "the negligence liability under consideration" (RB47) had never before been adopted.

Beyond that, Plaintiffs try to discount *Brown*'s teachings by pointing out that *Brown* involved strict liability for pharmaceuticals. But *Brown* did not so limit its insurance analysis: It recounted that pharmaceutical companies faced insurance crises "even though almost all jurisdictions follow the

negligence standard of comment k." (44 Cal.3d at 1065, italics added.)

D. At the very least, any duty to continue developing an alternative medicine should not arise this early in the drug-development cycle.

The narrowest path to resolve this case is to hold that there is no duty arising at such an early stage in the drug-development cycle. (OB60-64.) Plaintiffs do not dispute any of the facts on which Gilead based this argument—most notably, the high odds of a pharmaceutical candidate failing at Phase III. Nor do they dispute that it is generally not possible to know that a candidate is safer and equally effective based only on Phase I/II data—and, indeed, that it is illegal to make a claim of superiority without Phase III research (and more). (OB61.)

Instead, Plaintiffs argue that there must be a duty unless "a drug manufacturer can *never* know after a Phase II trial." (RB50.) But again, the duty analysis assesses the entire category of cases, not just what could conceivably happen in outlier situations. (*Cabral v. Ralph's Grocery Co.* (2011) 51 Cal.4th 764, 772.)

In any event, Plaintiffs fail to show that it is possible to have the requisite knowledge so early. Plaintiffs' only argument otherwise is that Gilead had that knowledge here because of Study 1101. (RB50-51.) But, as explained, the only way Plaintiffs can make that claim is by ignoring the study's actual conclusion ("similar" safety profiles); blatantly misrepresenting the results of a much later study as if they were from Study 1101; and

ignoring their own expert's undisputed testimony that Gilead did *not* have that knowledge in 2004. (*Ante* 11-13.)

E. The issues are preserved.

Plaintiffs half-heartedly suggest that this Court should not engage in a policy analysis because Gilead purportedly waived a *Rowland* argument "before the trial court." (RB33.) That is wrong; the issue is preserved because the Court of Appeal provided a lengthy *Rowland* analysis following extensive briefing by both parties. (*Schroeder v. Auto Driveaway Co.* (1974) 11 Cal.3d 908, 918 fn.7; see Op.39-53.) Gilead also raised *Rowland* in its Petition, without opposition, and it is encompassed within the second issue presented. (Pet.6, 28-38.)

Even more farfetched is Plaintiffs' passing footnote that it is "not clear" whether this Court can consider a more limited holding: that there is no duty relating to early drug-development decisions. (RB49 fn.11.) Of course it can. Gilead fully briefed it below and raised it again in its Petition. (Pet.38-39.) Contrary to Plaintiffs' suggestion, Gilead did not forfeit the issue by acknowledging that the Court need not reach it if it reverses on broader grounds. (*Ibid.*)

CONCLUSION

This Court should reverse.

October 3, 2024

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 8.520(c)(1) of the California Rules of Court, the foregoing is proportionally spaced and contains 8,398 words, according to the word processing program used to prepare it.

Dated: October 3, 2024

ORRICK, HERRINGTON & SUTCLIFFE LLP

/s/ E. Joshua Rosenkranz
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CERTIFICATE OF SERVICE

I am a citizen of the United States, over eighteen years old, and not a party to this action. My place of employment and business address is Orrick, Herrington & Sutcliffe LLP, 51 West 52nd Street, New York, NY 10019.

On the date set forth below, I served the following document(s) described as follows: **PETITIONER'S REPLY BRIEF ON THE MERITS**

>> on the parties to this proceeding as follows:

☒VIA E-SERVICE) I caused the above-referenced document(s) to be transmitted by electronic service to its intended recipient(s) indicated above via Court's Electronic Filing System operated by ImageSoft TrueFiling (TRUEFILING)

I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed on October 3, 2024 at New York, New York

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