S283862

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

GILEAD SCIENCES, INC.,
Petitioner,

v.

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

GILEAD TENOFOVIR CASES,
Real Parties in Interest.

AFTER A DECISION BY THE CALIFORNIA COURT OF APPEAL
FIRST APPELLATE DISTRICT, DIV. 4, CASE NO. A165558
SAN FRANCISCO COUNTY SUPERIOR COURT CASE NO. CJC-19-005043
HON. ANDREW Y.S. CHENG, TRIAL JUDGE

PLAINTIFFS' ANSWERING BRIEF ON THE MERITS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Other Authorities

Rules

Regulations

ISSUE PRESENTED

Does a drug manufacturer have a duty of reasonable care to users of a drug it is currently selling, which is not alleged to be defective, when making decisions about the commercialization of an allegedly safer, and at least equally effective, alternative drug?

INTRODUCTION

The answer to the issue presented is *yes*, a drug manufacturer owes a duty of care to users of a drug it is currently selling, which is not alleged to be defective, when making decisions about commercializing an allegedly safer and equally effective drug. This duty is rooted in Civil Code section 1714 and anchored in California precedent as aptly held by the Court of Appeal. (*Gilead Tenofovir Cases* (2024) 98 Cal.App.5th 911, 917.) Applied here, Defendant Gilead Sciences, Inc. (Gilead) owed a duty of care to the 24,000 HIV-infected Plaintiffs in this coordinated proceeding, all users of Gilead's tenofovir disoproxil fumarate (TDF) medication, when it decided to delay the commercialization of a more effective and less toxic alternative drug, tenofovir alafenamide fumarate (TAF), in a deliberate effort to maximize its profits and manipulate its market exclusivity.

Gilead's efforts to mischaracterize the record do not change the reality of its wrongdoing. By the early 2000s (the same time that Gilead started selling TDF), Gilead was aware of the "spectacular success" of TAF, which could achieve the same antiviral effect as TDF with only one-tenth the amount of tenofovir: reducing the amount of tenofovir being filtered by the kidneys by roughly ninety percent and decreasing the risks of renal, bone, and tooth injuries. With TAF having "clearly demonstrated proof of concept" (6App:1907), Gilead laid out a detailed schedule for getting TAF to market in 2006. (6App:1970-1982). Gilead's initial excitement about TAF, however, was quickly tempered by its realization that sales of TAF would "*cannibalize*" sales of TDF. (5App:1662-

1670,1712-1724;6App:1970-1982.) 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. (7App:2151-2154.) Although Gilead's delay in bringing TAF to market for *nearly a decade* exposed users of TDF to catastrophic injuries that were otherwise avoidable, its plan was a commercial success. Gilead made *billions* in additional profit from tenofovir-containing drugs sold after 2017. (6App:2003.) A jury must now decide whether this boardroom decision to intentionally delay the commercialization of TAF at the expense of thousands of HIV-infected patients using TDF was *unreasonable.*

Gilead distorts the issue presented as framed by this Court and makes hyperbolic arguments that distract from the "narrowness of the duty at issue." (*Gilead,* 98 Cal.App.5th at 944.)[1] It launches a rhetorical assault on the Court of Appeal's opinion, accusing the Court of "over[riding] a century of common law to impose on manufacturers a duty that no court anywhere in the country has ever suggested," imposing a "boundless" and "endless" duty that "threatens liability for just about any product-development decision," and "mak[ing] us all less safe." (Petitioner's Opening Brief "POB":8,10,28,42,54.) None of this is true.

In affirming the trial court's order denying summary adjudication of Plaintiffs' negligence claim, the Court of Appeal simply recognized that a drug manufacturer's duty to the users of a drug it is currently selling can "extend beyond the duty not to market a defective product" and the policy factors set forth in *Rowland v. Christian* (1968) 69 Cal.2d 108 do not justify "precluding negligence liability for prescription drugs without proof

[1] While"[t]he body of the petitioner's brief on the merits must begin by quoting … [a]ny order specifying the issues to be briefed[]" (Cal. Rules of Court, rule 8.520, subd. (b)(2)), Gilead ignores the issue specified by this Court and crafts its own "issues presented."

of a defect." (*Gilead,* 98 Cal.App.5th at 917.) "The circumstances under which a manufacturer might appropriately be held liable for injury caused by its products are simply too varied to be so constrained. Under section 1714, harm resulting from a manufacturer's failure to exercise reasonable care may be compensable, *even if* the product causing the harm does not meet the legal definition of 'defective.'" (*Id.* at 922.)

As detailed below, Gilead's position that there is a "universal" rule that a manufacturer can *never* be liable in negligence to a consumer for physical injury caused by its product *unless* the product is defective (POB:9–10,22–24,33) is wrong. California courts have repeatedly held that negligence, which focuses on the manufacturer's *conduct*, has a broader reach than strict products liability, which focuses only on the condition of the *product*. The term "defect" is a defining component of the doctrine of strict products liability, which *expands* liability of manufacturers for injuries caused by their products rather than *curtailing* their liability for negligent conduct. Gilead fails to cite a *single* California case holding that a manufacturer's duty of care to its consumers is categorically limited to producing a non-defective product. Nor can Gilead distinguish the cases affirming negligence liability absent proof of a defective product. For all its posturing, Gilead fails to prove its central premise.

Likewise flawed is Gilead's argument that the Court of Appeal "fashioned" a duty with "disastrous consequences." (POB:22–23.) According to Gilead, the Court imposed a duty on *all* manufacturers "to develop, *without delay*, a different product that is safer for some consumers." (POB:8, italics added.) But the Court did not "fashion" any duty, let alone the duty alleged by Gilead. It merely recognized, under the facts alleged in this case, that (1) a drug manufacturer has a general duty of care to the users of *its* drug and (2) Gilead failed to justify a categorical exception under *Rowland* for decisions relating to the commercialization of

a safer alternative drug. The duty recognized is *not* "to develop" a safer product (POB: 8), but rather concerns a drug *already* "developed" by the manufacturer. (*Gilead*, 98 Cal.App.5th at 937, fn. 3.) It is *not* a "'duty to innovate,'" but is "premised on Gilead's *possession*" of a less-toxic and equally effective drug that it "*with[held]*" from users of its current drug. (*Id*. at 921, italics added.) And the Court did not describe a duty to act "without delay" but rather to "act with reasonable care for the users of the existing drug[.]" (*Id*. at 944.) The Court took pains to emphasize that the standard of care is *reasonableness*, not perfection. (*Ibid*.)

When Gilead finally, and begrudgingly, addresses *Rowland* in its Brief, it uses the *Rowland* factors to try to poke holes in the duty recognized by the Court of Appeal rather than to justify an exception, defying the two-step analysis repeatedly reiterated by this Court. In any event, California's public policy does *not* support a categorical exception for the type of conduct alleged here. As Gilead conceded before the Court of Appeal, its exception would immunize a drug manufacturer from liability even if its negligent failure to commercialize a safer alternative drug caused *thousands* of deaths and was motivated *exclusively* by profit. Gilead has not come close to justifying this radical limitation.

Nor does Gilead fare any better with its purportedly "narrower" exception that would exempt a drug manufacturer from liability for failing to develop an alternative drug before Phase III trials have established its safety and effectiveness. Such an exception would render tort liability toothless because a drug manufacturer could immunize itself from negligence suits by simply delaying its Phase III trial, an event solely within its control, until it achieved its financial windfall (as Gilead did here). And as the Court of Appeal concluded, Gilead failed to create a sufficient record to support the conclusion that a drug manufacturer is

categorically unable to determine before a Phase III trial that an alternative to *its* existing, FDA-approved drug is safer and more effective.

The Court of Appeal was right: Gilead owed a general duty of care to users of its drug under Civil Code section 1714 and has not established a categorical exception to that duty under *Rowland*.

STATEMENT OF FACTS AND PROCEDURAL POSTURE

Gilead's factual summary is misleading *and* superfluous. As the Court of Appeal noted, Gilead did not contest "plaintiffs' assertions about its knowledge and motivation … for the purposes of the summary judgment motion" and "did not seek summary judgment on the ground that undisputed evidence established that it lacked actual knowledge that TAF was safer and at least as effective as TDF." (*Gilead*, 98 Cal.App.5th at 921–922.) The Court thus "accept[ed] the allegations of the complaint in adjudicating Gilead's present arguments." (*Id*. at 922.)[2] As summarized by the Court (and supported by the evidence), those allegations are as follows:

> Plaintiffs allege that in 1991 Gilead obtained an exclusive license to develop tenofovir, a substance known to be "an incredibly potent antiretroviral," as a treatment for HIV/AIDS. [3App:1078.] Tenofovir could not be used as a medication in its pure form, however, because it is not effective when administered orally and produces "rapid and severe decline in kidney function" when injected directly into the body. [3App:1079–1167;8App:2558–2562.] To create a usable medication from tenofovir, Gilead was required to develop an alternative form of the chemical, known generally

[2] Where, as here, "a motion for summary judgment is used to test whether the complaint states a cause of action, the court will apply the rule applicable to demurrers and accept the allegations of the complaint as true." (*American Airlines, Inc. v. County of San Mateo* (1996) 12 Cal.4th 1110, 1118.) Even if Gilead disputed the actionable conduct below, this Court would "liberally construe the evidence in support of the party opposing summary judgment and resolve doubts concerning the evidence in favor of that party." (*Yanowitz v. L'Oreal USA, Inc.* (2005) 36 Cal.4th 1028, 1037.)

as a "prodrug," that would be safe and effective when administered orally. [3App:1168–1169.]

Gilead eventually created TDF, a prodrug form of tenofovir, and focused its development efforts on that compound. TDF was approved by the FDA for sale as a treatment for HIV/AIDS in 2001. It was recognized at the time, however, that use of TDF carried the potential for harmful side effects. [3App:1079–1167;8App:2558–2562.]

At some point during its work, Gilead developed a second prodrug form of tenofovir, TAF, that also showed promise in the treatment of HIV/AIDS. [5App:1678,1712–1715.] Plaintiffs allege that TAF is more stable in the body than TDF, a property that permits TAF to be administered at a lower dose than TDF. [5App:1662–1670,1716–1724; 6App:1911.] The use of a smaller dose allegedly makes TAF more effective as a treatment while reducing adverse side effects. [5App:1662–1670,1716–1724.]

Plaintiffs allege that even before Gilead obtained regulatory approval to market TDF in 2001, the company "knew [TAF] to be more efficacious and less toxic to kidneys and bones than TDF." [5App:1712-1715.] In 2002, Gilead undertook Phase I/II testing of TAF. [6App:1851–1877.] According to the complaint, apparently quoting a Gilead document, this testing was done with the "explicit goal of '... deliver[ing] a more potent version of tenofovir that can be taken in lower doses, resulting in better antiviral activity and fewer side effects.'" [5App:1662–1711.] In 2004, however, Gilead discontinued development of TAF. [7App:2151-2154.] At the time, Gilead allegedly explained its decision by stating publicly that the differences between TDF and TAF were insufficient to justify further investment in TAF's development. [7App:2321.]

Plaintiffs allege, on the contrary, that Gilead's decision to discontinue work on TAF was actually driven by a conscious business strategy to maximize the financial value of TDF. [6App:1970–1982.] If TAF were developed immediately as a treatment, plaintiffs allege, its superiority to TDF would have resulted in its replacement of TDF as an HIV/AIDS treatment. [6App:1970–1982.] By deferring development of

> TAF, in contrast, Gilead was able to maximize its sales of TDF, while using the later release of TAF to extend the patent coverage of tenofovir-related medications. [6App:1970–1982; 2083–2085;7App:2151–2154.] As plaintiffs allege, this strategy "would effectively monetize both drugs." [6App:1970–1982; 2083–2085; 7App:2151-2154.]
>
> Following its pause in the development of TAF in 2004, and continuing through 2011, Gilead obtained FDA approval to sell a series of HIV/AIDS medications that featured TDF in combination with antiviral drugs produced by other manufacturers. Gilead eventually resumed work on TAF and received FDA approval to sell TAF as a treatment for HIV/AIDS in 2015. [8App:2579, 2628.] In 2011, Gilead's President allegedly told investors that TAF would be a "kinder, gentler" version of TDF. [7App:2393.] …
>
> The factual basis for plaintiffs' claim, as alleged in the complaint and confirmed by their supplemental briefing, is that (1) Gilead voluntarily invented TAF as part of the same research effort that led to the development of TDF; (2) prior to pausing work on TAF, Gilead had developed TAF sufficiently to evaluate its performance in a controlled trial, referred to as a Phase I/II trial; (3) by the time it paused work in 2004, Gilead knew that TAF would treat HIV/AIDS as effectively as TDF, yet would allow patients to avoid the bone and kidney side effects associated with TDF; and (4) Gilead made the decision to defer further commercialization of TAF for the purpose of extending the duration of its patent protection for tenofovir-related treatments, thereby increasing its financial return, rather than because of any concerns for TAF's successful commercialization.

(*Gilead*, 98 Cal.App.5th at 918–919.)

Gilead moved for summary adjudication of Plaintiffs' negligence claim on the ground that "state tort law does not recognize" a "free-standing negligence claim, separate from a design defect claim." (1App:111.) The trial court rejected the argument: "Gilead does not seek to disprove any essential elements of a negligence claim. Rather, Gilead argues that Plaintiffs' negligence claim is not legally cognizable as a

general matter. … In actuality, *Gilead's argument is contrary to California law:* Plaintiffs may proceed on a theory of negligence and are not required to proceed on a product liability theory." (10App:3246-3247.) And the court emphasized that Gilead did not "dispute the existence of its duty of care" and did not "undertake[] an analysis of the *Rowland* factors to establish that it did not owe the alleged duty of care under Civil Code section 1714." (*Id*.)[3]

Shortly before trial, Gilead filed a writ petition challenging the trial court's ruling. It disavowed the *Rowland* framework, staking its claim on the premise that "products-liability law" bars any liability "for alleged injuries caused by non-defective medications." (Writ:9,21,43.) And it only provided a *Rowland* analysis after the Court of Appeal requested supplemental briefing. (*Gilead*, 98 Cal.App.5th at 936.)

The Court of Appeal affirmed the denial of summary adjudication of Plaintiffs' negligence claim. After recognizing that Gilead owed a duty of reasonable care to Plaintiffs pursuant to section 1714, the Court held that nothing argued by Gilead warranted a categorical exception to the duty owed under *Rowland*. (*Id*. at 917, 934.) The Court concluded that a broader exception to a drug manufacturer's duty of care "precluding negligence liability for prescription drugs without proof of a defect" was "unwarranted" and a narrower exception limiting a drug manufacturer's liability to "decisions … made after obtaining the results of Phase III clinical trials of the alternative drug" was "unsupported on the present record[.]" (*Id*. at 917.)

[3]Gilead did not argue in its motion for summary judgment that it "had no *duty* to develop and market TAF earlier." (POB:19.)

ARGUMENT

I.

THE APPROPRIATE FRAMEWORK FOR THE ANALYSIS OF LIABILITY

"California law establishes the general duty of each person to exercise, in his or her activities, reasonable care for the safety of others. (Civ. Code, § 1714, subd. (a).)" (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 770.) Section 1714 provides in relevant part: "Everyone is responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person." (Civ. Code, § 1714(a); see also *Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1016 ["The 'general rule' of duty in California is established by statute"].) The "*basic policy of this State* set forth by the Legislature in section 1714" is that liability is imposed for injury occasioned to another by want of ordinary care or skill. (*Rowland,* 69 Cal.2d at 118–119.) "[I]n the *absence of* statutory provision declaring an exception to the fundamental principle enunciated by section 1714 … no such exception should be made unless *clearly* supported by public policy." (*Id*. at 112, italics added.)

Despite a substantial body of case law on the two-step analysis of duty, where the court first considers whether a duty exists under section 1714 or some other source, and second, looks to the *Rowland* factors to determine whether a categorical exception should be made for a certain category of conduct or defendants, Gilead argues that the court here erred in *creating* a "new duty" for product manufacturers. (POB:41; see also Pet. Review:8,14,17 [arguing that the court imposed a "radical" "new duty"].) And it accuses the Court of "appl[ying] the wrong legal framework" in its duty analysis. (POB:38.) Gilead asserts that under *Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456, the burden is on Plaintiffs to justify creation of the "new duty" alleged here. (POB:41-42.)

This misrepresents *Parsons* and ignores settled California law. *Parsons* began its analysis by recognizing the duty owed by the defendant and *then* considered whether the *Rowland* factors warranted an exception. (*Id*. at 472–475.) And this Court has repeatedly clarified in the decades since *Parsons* that section 1714's default rule of duty is the "*starting point* for [its] duty analysis." (*Kuciemba*, 14 Cal.5th at 1018; see also *Cabral*, 51 Cal.4th at 783 ["The question is not whether a *new duty* should be created, but whether an *exception* to Civil Code section 1714's duty of exercising ordinary care in one's activities … should be created."].)

Gilead gets the proper framework backwards: Under section 1714, this Court presumes the defendant owed the plaintiff a duty of care and then considers whether "'carving out an entire category of cases from that general duty rule is justified by clear considerations of policy.'" (*Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1145.) Manufacturers owe users of their products a duty of reasonable care and California law does not categorically limit this duty to simply producing a non-defective product. (Argument II, *infra*.) And while Gilead has repeatedly refused to "resort" to a *Rowland* analysis (Reply.Return:20), nothing now argued by Gilead justifies an exception to the duty owed here. (Argument III, *infra*.)

II.

A DRUG MANUFACTURER'S DUTY TO USERS OF A DRUG IT IS CURRENTLY SELLING IS *NOT* CONSTRAINED BY PROOF OF DEFECT

Gilead's appeal rests on its contention that a manufacturer cannot be held liable in negligence for injury caused by its product without proof of a defect. "Defect" is a legal term of art that limits the circumstances under which strict products liability applies. While a "defect" in the product is a predicate to any claim for strict products liability, it is *not* a limitation on a claim for ordinary negligence against a manufacturer.

A. Under Section 1714, A Drug Manufacturer Has A General Duty Of Care To Users Of A Drug It Is Currently Selling.

Section 1714 "establishes the *default rule* that each person has a duty 'to exercise, in his or her activities, reasonable care for the safety of others.'" (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 214, italics added.) "'[W]henever one person is by circumstances placed in such a position with regard to another ... that if he did not use ordinary care and skill in his own conduct ... he would cause danger of injury to the person or property of the other, a duty arises to use ordinary care and skill to avoid such danger.'" (*Rowland,* 69 Cal.2d at 118-119.) The default rule of duty applies "when it is the defendant who has '"created a risk"' of harm to the plaintiff, including when '"the defendant is responsible for making the plaintiff's position worse."'" (*USA Taekwondo*, 11 Cal.5th at 214.) "The proper question … is … whether the defendant's "'entire conduct created a risk of harm'" to the plaintiff." (*Kuciemba*, 14 Cal.5th at 1017, quoting *USA Taekwondo*, at 215, fn. 6.)

Gilead did not argue below, and does not now argue, that it owed *no duty* to Plaintiffs. (*Gilead,* 98 Cal.App.5th at 919-920; 1App:132; 10App:3246-3247.) Rather, Gilead's position is that "[b]ecause Plaintiffs

do not assert that the TDF medicines are *defective*, their negligence claim cannot survive summary judgment." (POB:33, italics added.)

Gilead's acknowledgement of its duty is unsurprising: There is no question that the duty to take ordinary care in one's activities under section 1714 applies to a manufacturer of prescription drugs and is owed to the users of such drugs. (See *Bettencourt v. Hennessy Indus., Inc.* (2012) 205 Cal.App.4th 1103, 1117-1119 ["Under established California law, a manufacturer … owes a duty of care to foreseeable users of its product."].)

As framed by the allegations and supported by the evidence, Gilead sold Plaintiffs a drug with harmful side effects (TDF) and delayed the development of a "safer, more effective" alternative drug (TAF). (1App:45, 47–48.) As the Court of Appeal aptly concluded, Gilead "created the risk of harm to plaintiffs by selling TDF, a drug with harmful side effects[.]" (*Gilead*, 98 Cal.App.5th at 935.) And Gilead made Plaintiffs' "position worse" (*USA Taekwondo*, 11 Cal.5th at 214) by pausing—for nearly a decade—the development of an alternative drug without the same adverse effects. (1App:46.) As Gilead held the "exclusive rights to develop, manufacture, distribute and sell … tenofovir," its conduct deprived Plaintiffs of an essential choice in their battle with HIV/AIDS and needlessly "exposed [them] to a more toxic form of the drug[.]" (1App:45–46.) Because Gilead's "entire conduct created a risk of harm" (*Kuciemba*, 14 Cal.5th at 1017), section 1714's default rule of duty applies.

Gilead contends that the Court of Appeal erred in its analysis of section 1714. (POB:39.) First, it accuses the Court of assuming that section 1714 imposes a "free-floating duty of care" even though it "does not modify or supplement common law duties; it *subsumes* them." (*Ibid.*, italics added.) According to Gilead, section 1714 *only* requires compliance

with the "traditional duties that products-liability law imposes on manufacturers." (*Ibid.*)[4]

As discussed below, Gilead is mistaken: California has *never* conditioned a manufacturer's liability in negligence for harm caused by its product on proof that the product was defective. But even if Gilead were right, section 1714 "states a civil law and not a common law principle." (*Hoffmann v. Young* (2022) 13 Cal.5th 1257, 1266, quoting *Rowland*, 69 Cal.2d at 112.) Thus, in *Rowland*, this Court relied on section 1714 to replace the common-law concept of landowner liability based on an entrant's status with an application of liability based on ordinary principles of negligence. (*Rowland*, 69 Cal.2d at 115–119; see also *Sprecher v. Adamson Companies* (1981) 30 Cal.3d 358, 363 [rejecting common law rule of absolute immunity that was inconsistent with policy embodied in section 1714].) *Rowland* squarely contradicts Gilead's claim that section 1714 merely "subsumes" a defendant's common law duties. And Gilead's narrow interpretation of Section 1714 is impossible to square with this Court's cases grounding novel applications of the duty to use ordinary care on the policy outlined in the statute. (See, e.g., *Kesner,* 1 Cal.5th at 1142–1143 [Section 1714 "establishes a general duty to exercise ordinary care in one's activities [including] the use of asbestos in one's business"].)

Second, Gilead proclaims that it is "absurd to suggest that the duty the Court of Appeal recognized has existed since 1872 and no one thought to invoke it." (POB:39.) But this is the *rare* case in which a plaintiff has evidence that a drug manufacturer had a safer and more effective drug but chose not to proceed with that drug for profit. And more fundamentally, it

[4] Gilead fails to define "products-liability law," but appears to be referring to the duties recognized in the *strict* products liability context. It then equates "traditional products liability law" with "common law" without accounting for the distinctive principles recognized in negligence actions.

is *irrelevant* that section 1714 has not been previously applied in this setting. (See, e.g., *Kuciemba*, 14 Cal.5th at 1020–1021 [concluding that section 1714 imposes a general duty of care on employers to prevent the spread of COVID-19 to employees and their household members].) Section 1714 was not enacted to "insulate the matters therein expressed from further judicial development" and was intended to permit "continuing judicial evolution." (*Li v. Yellow Cab Co.* (1975) 13 Cal.3d 804, 814.)

Third, Gilead asserts that Plaintiffs' challenge to its failure to commercialize TAF sooner "violates" section 1714's distinction between "misfeasance and nonfeasance." (POB:40, citing *USA Taekwondo*, 11 Cal.5th at 214.) But *USA Taekwondo* referred to this distinction "in support of the general rule that a party has no duty to prevent harm by a *third person*," rather than to suggest "that a party's failure to act *cannot constitute* a breach of the duty of reasonable care." (*Gilead*, 98 Cal.App.5th at 935, italics added.) As the *USA Taekwondo* Court itself emphasized, the distinction between "misfeasance" and "nonfeasance" is "imprecise and prone to misinterpretation." (*USA Taekwondo*, 11 Cal.5th at 215, fn. 6.) "'The proper question is not whether an actor's failure to exercise reasonable care entails the commission or omission of a specific act.' … Rather, it is 'whether the actor's entire conduct created a risk of harm.'" (*Ibid.*) Here, Gilead's "entire conduct"—marketing a drug with harmful side effects and delaying the commercialization of a safer, equally effective alternative in its possession—created a risk of harm to Plaintiffs that gave rise to a general duty of care.

Under this Court's settled framework, a drug manufacturer—like Gilead—owes a general duty of care under section 1714 to users of a drug it is currently selling *unless* an exception is declared by statute or "'clearly supported by public policy.'" (*USA Taekwondo*, 11 Cal.5th at 217.)

B. There is No "Proof of Defect" Requirement for Negligence Claims Against Drug Manufacturers.

According to Gilead, a manufacturer can *never* be liable in negligence for harm its product causes without proof of a defect. (POB:9.) Yet Gilead fails to cite a *single* California case holding that a manufacturer's duty of care to its consumers is categorically limited to not producing a defective product. Further, Gilead ignores the many California cases rejecting the notion that a finding of "no product defect" necessarily precludes a finding of negligence by a product manufacturer. (See, e.g., *Mexicali Rose v. Superior Court* (1992) 1 Cal.4th 617, 633 [manufacturer of foodstuffs may be liable for negligently causing harm to a consumer even though the food product was not defective under strict products liability law]; *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 58, 64–68 [drug manufacturer liable in negligence for overpromoting drug despite trial court granting nonsuit on strict liability claim]; *Hasson v. Ford Motor Co.* (1977) 19 Cal.3d 530, 530–531, 542 ["failure to find a 'defect' … would not necessarily preclude all liability" for a product manufacturer]; *T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, 177, fn. 4 [strict products liability and negligence are "separate and distinct bases for liability"]; *Hernandez v. Badger Construction Equipment Co.* (1994) 28 Cal.App.4th 1791, 1826–1827 [a finding that a product "had no design defect [does] not preclude a finding [the defendant] was nonetheless negligent," especially where the plaintiff presents "evidence on negligence quite apart from [a] design issue"]; *Lunghi v. Clark Equipment Co.* (1984) 153 Cal.App.3d 485, 494 [despite jury's finding of no defect in the product's design, trial court erred in refusing to instruct jury on negligence where there was evidence of negligence outside design of product itself]; *Scott v. C.R. Bard, Inc.* (2014) 231 Cal.App.4th 763, 777–778 [despite finding of no defect, verdict as to negligence on multiple non-defect

theories affirmed on appeal]; see also *Ileto v. Glock Inc.* (9th Cir. 2003) 349 F.3d 1191, 1201 [no bar to a non-defect negligence claim against product manufacturer].)

As explained by the Court of Appeal, Gilead misapprehends the fundamental distinction between strict products liability and negligence causes of action. (*Gilead*, 98 Cal.App.5th at 923–924, 931.)

The doctrine of strict products liability was adopted to "insure that the costs of injuries resulting from defective products are borne by the manufacturers that put such products on the market rather than by the injured persons who are powerless to protect themselves." (*Greenman v. Yuba Power Products, Inc.* (1963) 59 Cal.2d 57, 63.) "'A manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being.'" (*Cronin v. J.B.E. Olson Corp.* (1972) 8 Cal.3d 121, 130.) The doctrine of strict liability "was intended to simplify a consumer plaintiff's evidentiary burden, as well as to serve the public policy function of placing the financial burdens associated with defective products on manufacturers, who are liable regardless of any fault in their conduct." (*Gilead*, 98 Cal.App.5th at 923.)

Strict products liability, unlike negligence, focuses on the nature of the product rather than the manufacturer's conduct with respect to the product. (*Barker v. Lull Eng'g Co.* (1978) 20 Cal.3d 413, 434.) To prevent strict liability from becoming absolute liability, the predicate for any claim for strict products liability is a showing of a "defect" in the product. (*Cronin,* 8 Cal.3d at 133–134.) As explained by the Court of Appeal, the requirement to prove a product defect is "necessary to constrain the reach of strict liability," *whereas* for negligence claims, "the requirement of a duty of care imposes its own limits on the potential scope of liability, governed by an array of policy considerations as they bear on a particular

context." (*Gilead,* 98 Cal.App.5th at 924.) Thus, "[t]he adoption of strict liability in *Greenman* did not purport to displace negligence as a cause of action." (*Ibid*.) [5]

While a defect in the product is a predicate to any claim for strict products liability, the same is not true for all negligence claims against a manufacturer. (See, e.g., *T.H.,* 4 Cal.5th at 163, 175–177 & fn. 4; *Conte v. Wyeth, Inc*. (2008) 168 Cal.App.4th 89, 108.) Requirements of strict liability do not *restrict* theories of negligence against drug manufacturers.[6]

This Court's decision in *Mexicali Rose* is instructive. The plaintiff was injured after he swallowed a chicken bone contained in an enchilada while dining at defendants' restaurant. (*Mexicali Rose*, 1 Cal.4th at 620.) Plaintiff alleged that defendants were "liable in negligence for their failure to exercise reasonable care in the preparation of the food" *and* "strictly liable because the food item was 'defective' under the theory of Restatement Second of Torts section 402A, comment i, imposing strict liability when food is 'dangerous beyond that which would be contemplated by the ordinary consumer who purchases it[.]'" (*Ibid.*) This Court

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[5] Citing the Court of Appeal's analysis, the Court in *Williams v. J-M Mfg. Co., Inc.* (2024) 102 Cal.App.5th 250, 262–63, review filed (June 27, 2024), rejected the notion that a limitation on an employer's duty of care to prevent secondary exposure to asbestos carried on the bodies and clothing of on-site workers should likewise apply to strict liability claims against suppliers or sellers of asbestos products. The Court emphasized that not only are the elements of strict liability and negligence different, the "policy considerations" are not "identical" and thus limitations in one context do not transmute to the other. (*Id*. at 263.)

[6] As this Court recently explained, a "manufacturer's failure to warn … results in a breach of its general duty of care to the patient under negligence principles *or* a breach of its obligation to market a product free from defects under strict liability principles." (*Himes v. Somatics, LLC* (2024) 16 Cal.5th 209, 224, italics added.) The Court's language recognizes that the term "defect," which is integral to strict liability law, should not be casually imported into the negligence context.

concluded that the plaintiff failed to state a cause of action in strict liability because the food was not "defective" under the reasonable expectation test. (*Id*. at 631.)

This conclusion did not, however, "negate a defendant's duty to exercise reasonable care in the preparation and service of the food." (*Ibid*.; *see also* 632 [noting that allowing a cause of action for negligence "corresponds to modern developments in tort law," including "our modern emphasis on Civil Code section 1714."].) The Court thus expressly authorized an "injured patron [to] sue [a manufacturer] under a negligence theory" even though the manufactured product was not defective under strict liability law. (*Id*. at 633.)[7]

As the Court of Appeal here explained, *Mexicali Rose* "effectively resolves [this] claim … [by holding] that a plaintiff may recover under the doctrine of negligence for harm caused by a product otherwise subject to the doctrine of strict liability, notwithstanding the plaintiff's inability to prove a product defect." (*Gilead*, 98 Cal.App.5th at 926.) While "the concept of a 'defect' is one of the defining components of the doctrine of strict products liability, it should not in every case constitute the outer boundary of a manufacturer's liability for its conduct[.]" (*Id*. at 922, 926). "In our view, neither logic nor jurisprudential history compels the conclusion that the two concepts must be coextensive in every case in which a plaintiff is injured by a product." (*Id*. at 924.)

This Court's decision in *T.H.* confirms the principle that under California law: '"Negligence and strict products liability are separate and

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[7] Gilead feebly suggests that *Mexicali Rose* is distinguishable because "there *was* a defect … a bone that should not have been in [the] chicken enchilada." (POB:31.) But this Court was emphatic: The food product at issue could not "be determined to be … defective" under the test applicable in strict liability law. (*Mexicali Rose,* 1 Cal.4th at 633.)

distinct bases for liability that do not automatically collapse into each other because the plaintiff might allege both when a product warning contributes to her injury.'" (*T.H.*, 4 Cal.5th at 177, fn. 4; see also *Kuciemba*, 14 Cal.5th at 1019 [Section 1714's "default duty to use due care in its operations to avoid foreseeable injuries" is not limited to "business-specific activities" (i.e., manufacturing a product)].)

At issue in *T.H.* was whether a brand-name drug manufacturer, Novartis, could be liable for negligent failure to warn where the plaintiff was injured by a generic bioequivalent drug made by a *different* manufacturer. (*T.H.*, 4 Cal.5th at 154.) Novartis argued that the requirements of a traditional product liability claim (i.e., that the plaintiff had been injured by the product manufactured by the defendant) governed the negligence claim and because Novartis did not manufacturer the drug that caused the injury, there could be no duty owed to the plaintiffs. (*Id.* at 175–177 & fn. 4.) Rejecting the argument, this Court explained that "California law does not conflate negligent misrepresentation and strict liability." (*Id*. at 177.) The Court noted its "longstanding recognition that 'California law recognizes the differences between negligence and strict liability causes of action.'" (*Id.* at 163, 175-177 & fn. 4; see also *Conte*, 168 Cal.App.4th at 101-102 [holding, under similar facts, that "Wyeth's reliance on numerous strict products liability cases for the rule that a plaintiff in a products liability case must prove the defendant made or sold the allegedly defective product that causes injury, *sheds no light* on the issue presented" concerning the viability of a claim for negligence and explaining that "[w]e are not marking out new territory" by finding that the defendant owed a duty to the plaintiff "even though the defendant would not be liable in strict products liability because it did not manufacture or sell the product."].)

In sum, Gilead owed the HIV-infected patients that ingested its drug a duty to act reasonably in its decisions about the commercialization of a safer alternative, *regardless* of whether the existing drug was itself defective. (See *Gilead,* 98 Cal.App.5th at 925.) Just as in *Conte*, the duty owed is not novel but is "rooted in common sense and California common law." (*Conte,* 168 Cal.App.4th at 100–101 ["We perceive no logical or legal inconsistency between allowing the suit for negligence and disallowing the suit for strict products liability."].)

C. Gilead Fails to Justify Its Absolutist "No Defect No Duty" Position.

According to Gilead, the Court of Appeal "abandon[ed] the *age-old* and *universal* common-law rule requiring proof of a defect." (POB:22, italics added.) But this so-called "rule" is neither "age-old" nor "universal." As for its vintage, Gilead asserts that until the 1930s, consumers could not bring third party claims against manufacturers for injuries caused by their products unless they could prove that the "conduct resulted in *something wrong* with a product—a defect." (POB:26.) But this is imprecise: The general rule at common law was that a manufacturer "is not liable for injuries *sustained by reason of defects* in articles unless there is a contractual relationship between him and the one injured." (*Dahms v. General Elevator Co.* (1932) 214 Cal. 733, 738, italics added.) In other words, unless an exception applied, a plaintiff could only bring a claim for damages against a manufacturer *based on an allegedly defective product* if *privity of contract* existed. This common law rule did not bar a manufacturer's liability to a consumer for conduct *independent* of producing a defective product.

As for the universality of its rule, Gilead cites *Prentis v. Yale Mfg. Co.* (Mich. 1984) 365 N.W.2d 176, 181–182 for the expansive proposition that the "plaintiff must, *in every case*, in *every* jurisdiction, show that the

product was defective." (POB:25.) But as a federal district court recently explained in rejecting Gilead's claim that "it cannot be held liable for negligence if it is not liable under a strict-liability theory," *Prentis* is "not persuasive because it cites *no* out-of-state authority." (*Holley v. Gilead Sciences, Inc.* (N.D. Cal. Sep. 28, 2023) No. 18-cv-06972-JST, 2023 WL 6390598, *6, italics added.)[8] And there are *multiple* decisions from other jurisdictions recognizing negligence liability for injury caused by a product that is not defective under strict products liability law. (*Toner v. Lederle Lab'ys* (9th Cir. 1987) 828 F.2d 510, 513 [negligence and strict liability law "require[ ] the jury to examine the case from two different points of view," such that "it is reasonable" to read jury verdicts finding negligence but not strict liability "as saying that" defendant's failure to develop allegedly safer product was "unreasonable conduct" even though product's danger "was not greater than an ordinary consumer would reasonably expect"]; *Phillips v. Cricket Lighters* (Pa. 2003) 841 A.2d 1000, 1010 [design of cigarette lighter used by child to start fire did not give rise to strict liability because lighter was not unsafe for its intended users, adults, whereas negligent design claim was sufficient because children were foreseeable users]; *Fredericks v. General Motors Corp.* (Mich.App.1973) 211 N.W.2d 44, 46 ["[A] chattel need not be proved defective before recovery is permitted under the doctrine of negligent entrustment."].)

Gilead next insists that this Court has "repeatedly assured manufacturers that satisfying" their duties to sell a product "without defects

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[8] Setting aside that *Prentis* was a case involving liability for "defective design" only, and that Michigan—unlike California—has a statute that legislatively subsumes all causes of action into one requiring the showing of a "defect," the decision of another state concerning its negligence law is unpersuasive when interpreting section 1714 of California's Civil Code. (See *T.H.,* 4 Cal.5th at 162, 175–8 [rejecting argument that duty should not exist based on out-of-state authority].)

in design, manufacture, or labeling" "protects them from liability." (POB:23–24.) But this Court has made no such assurance, and as noted above, has reached the *opposite* conclusion on multiple occasions. (See, e.g., *Mexicali Rose,* 1 Cal.4th at 633; *Stevens,* 9 Cal.3d at 58, 64–68 [where drug manufacturer complied with FDA's warning directives but otherwise promoted drug in a manner that "appeared to minimize [its] dangers," trial court granted motion for nonsuit on strict liability claim but permitted negligence claim for "overpromotion of the drug" to go to the jury; this Court affirmed establishing that drug manufacturer may be liable for negligent post-sale conduct *regardless* of whether drug is defective under strict liability law]; *T.H.,* 4 Cal.5th at 177, fn. 4.)[9] Proof of a defective product under strict liability law is *not* the sine qua non for a negligence claim alleging physical injury caused by a manufacturer's product.

Gilead also relies on cherrypicked language from decisions of this Court, stripping them of all context. (Cf. *People v. Gray* (2023) 15 Cal.5th 152, 169, fn. 5 ["[C]ases are not authority for propositions not considered."].) It points to the statement in *Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 568, fn. 5 that manufacturers "are liable in tort *only* when 'defects' in their products cause injury." (POB:24.) Gilead conveniently omits the full sentence: "*[W]e have consistently held that*

[9] As noted earlier, numerous courts of appeal have also permitted recovery for claims of negligence in the absence of a defect. Gilead tries to distinguish *Hernandez* and *Lunghi* by arguing that those cases "implicate[d]" what later became characterized as a product "defect." (POB:32.) But as explained by the Court of Appeal: "Neither case … held that the products had become 'defective' as that term is used in strict products liability law, nor characterized such a finding as a prerequisite to imposing a duty to warn or to retrofit under principles of negligence." (*Gilead*, 98 Cal.App.5th at 927.) Whether the doctrine of strict liability ultimately embraced these alleged theories as "defects" is "legally irrelevant to a finding of negligence liability." (*Id*.)

manufacturers are not insurers of their products; they are liable in tort only when 'defects' in their products cause injury." (*Soule*, 8 Cal.4th at 568, fn. 5, italics added.) In context, the *Soule* court's "point was simply that strict liability is not unlimited" in response to the plaintiff's objection to "any limitation on use of the consumer expectations test." (*Gilead*, 98 Cal.App.5th at 934.) Given that the plaintiff in *Soule* did not even assert a negligence theory of liability, *Soule* plainly does not limit a manufacturer's negligence liability.

Next, Gilead emphasizes this Court's "pronounce[ment]" in *Merrill* that "to recover from a manufacturer, a plaintiff *must* prove that a defect caused injury." (POB:24, citing *Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 469, 479.) Gilead, again, ignores the context of this Court's decision. In *Merrill*, the plaintiffs brought a negligence action against a gun manufacturer following a mass shooting. After explaining that "we '*begin always with the command of ... section 1714,*" the Court focused on *a legislatively created exception* to the duty owed. (*Id*. at 477-478, citing former Civ. Code, § 1714.4 ["In a products liability action, no firearm or ammunition shall be deemed defective in design on the basis that the benefits of the product do not outweigh the risk of injury posed by its potential to cause serious injury, damage, or death when discharged."].) The Court considered the theories of negligence alleged and concluded that the claim was, "in essence," based on the contention that the manufacturer "defectively designed the weapons" used. (*Merrill*, 26 Cal.4th at 470.) In light of the plain language of the statute and the Legislature's intention to proscribe "'design defect claims,'" the allegations fell within the statutory exception. (*Id*. at 480–481.) The analysis was entirely cabined to the *statutory exception* at issue.

As recognized by the Court of Appeal here, *Merrill* made no findings regarding the equivalency of a strict liability theory and negligent

design defect theory in any context beyond the now repealed statutory exception. (*Gilead*, 98 Cal.App.5th at 929.) Unlike in *Merrill,* where the Legislature specifically intended to create an exclusive remedy in the firearms context, tort law principles of negligence do not generally restrict theories against other product manufacturers.

D. Gilead's Policy Justifications Are Entirely Unpersuasive.

Perhaps recognizing that there is no precedent supporting its "no defect no duty" rule, Gilead spends much of its brief detailing the purported policy justifications for such a rule. These arguments are misplaced because they belong in a *Rowland* analysis of whether an exception to the duty is justified. And they are also meritless.

Gilead claims that it is unworkable for a manufacturer to have any duty beyond producing a non-defective product because there is "no meaningful standard for assessing [such] conduct." (POB:10,45.) But the meaningful standard is reasonableness. "In most cases, *courts have fixed no standard of care for tort liability more precise than that of a reasonably prudent person* under like circumstances." (*Ramirez v. Plough, Inc.* (1993) 6 Cal.4th 539, 546-47, italics added].)

Gilead then asserts that juries are simply incapable of determining the reasonableness of "complex" decisions made by pharmaceutical companies. Nonsense. Juries are often charged with reviewing corporate decisions to determine liability. As Gilead acknowledges, jurors are already entrusted with making complex risk/utility determinations in products liability cases. (See, e.g., *Hasson,* 32 Cal.3d at 397–398 [plaintiffs' strict liability and negligence claims required jury to consider, "in excruciating detail," the design of alternative brake systems, "the scientific properties of brake fluid," and measures the defendant could or should have taken to "alleviate the danger of brake failure."].) In a variety of contexts, juries review complex evidence bearing on whether a

defendant's conduct was unreasonable and fell below the standard of care without issue. While the "amount of due care" varies based on the circumstances, "the standard of conduct itself remains constant, i.e., *due care commensurate with the risk posed by the conduct* taking into consideration all relevant circumstances." (*Regents of Univ. of California v. Superior Ct.* (2018) 29 Cal.App.5th 890, 907, fn. 16.)

Gilead also tries to support its "no defect no duty" position by arguing that the "defect requirement" "achieves the key goal of negligence law: to strike a balance between safety and access." (POB:29.) Gilead goes as far as to assert that the "defect requirement" "*fully protects consumer safety.*" (*Id*.) The irony of Gilead's position is stark. For nearly a decade, Gilead, which held an exclusive license to develop tenofovir, deprived consumers suffering from HIV/AIDS of the choice of a safer, more effective, alternative drug, causing skeletal and kidney damage to the 24,000 plaintiffs. Requiring proof of a defect does not "fully protect[] consumer safety" in cases like this.

Gilead's faith in the "defect requirement" is especially misguided in the pharmaceutical context. State law design defect claims against pharmaceutical companies are usually preempted. (*Gilead*, 98 Cal.App.5th at 922, fn. 6, citing Bernstein, *(Almost) No Bad Drugs: Near-Total Products Liability Immunity for Pharmaceuticals Explained* (2020) 77 Wash. & Lee L.Rev. 3, 32–37.) And California has barred strict liability design defect claims against prescription drug manufacturers. (*Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1061.) Yet as this Court noted in *Brown*, manufacturers can still be liable for defective drugs "under general principles of negligence." (*Id*. at 1069, fn. 12.) Negligence is thus one of the only avenues remaining for plaintiffs to challenge unreasonable conduct of drug manufacturers that causes them harm.

III.

GILEAD HAS FAILED TO JUSTIFY A CATEGORICAL EXCEPTION TO A DRUG MANUFACTURER'S GENERAL DUTY OF CARE TO USERS OF A DRUG IT IS CURRENTLY SELLING UNDER THE *ROWLAND* FACTORS

Gilead did not argue before the trial court or in its Writ Petition that the *Rowland* factors warranted a categorical exception to its duty of care. (See *Gilead,* 98 Cal.App.5th at 935 ["Gilead's failure to offer a *Rowland* analysis in the trial court—to say nothing of its failure to do so in this court before we requested supplemental briefing—constitutes sufficient reason for us to decline to reach the issue."].) Although the Court of Appeal "exercise[d]" its "discretion to address the *Rowland* factors" to "the extent the record permit[ted]" the court "to do so" (*id*. at 936), this Court need not. (See *Doe v. Lawndale Elementary Sch. Dist.* (2021) 72 Cal.App.5th 113, 130-131 [a defendant who fails to argue no duty was owed because a categorical exception is warranted under *Rowland* fails to meet its moving burden on summary judgment]; *Morris v. De La Torre* (2005) 36 Cal.4th 260, 277 [defendant failed to justify exception to duty of care because facts relevant to *Rowland* factors were disputed].) Indeed, Gilead waived the argument that its categorical exceptions should be recognized by this Court as neither were identified in Gilead's statement of issues nor developed with argument in its Petition for Review. (See Cal. Rules of Court, rule 8.516(a)(1) & (b)(1).)

Perhaps because of its repeated insistence that *Rowland* does not apply, Gilead's attempt at a *Rowland* analysis before this Court falls woefully short of justifying a categorical exception. (POB:48–59.) Gilead advances a moving target of possible exceptions ranging from a blanket immunity for *all* manufacturers unless the product is defective (POB:45,53–55), to immunity for *all* manufacturers for decisions about commercialization of an alternative product (POB:45–49,51–58), to a

"narrow" exception for pharmaceutical manufacturers before Phase III trials have been conducted on the allegedly safer alternative drug. (POB:48,50,56,66,62-64). Without clarity as to what categorical exception it is seeking, Gilead's *Rowland* analysis falls apart.

And to the extent this Court engages in a *Rowland* analysis, public policy in no way supports shielding drug manufacturers from liability for their *unreasonable* conduct in delaying commercialization of a less toxic and equally effective drug that prevents harm to the manufacturer's patients suffering known and avoidable side effects.

A. The *Rowland* Factors Do Not Warrant A Categorical Exception To The Duty Of Care Owed By Drug Manufacturers To Users Of A Drug It Is Currently Selling For Decisions About The Commercialization Of A Safer, And At Least Equally Effective, Alternative Drug.

"The *Rowland* factors fall into two categories. Three factors—foreseeability, certainty, and the connection between the plaintiff and the defendant—address the foreseeability of the relevant injury, while the other four—moral blame, preventing future harm, burden, and availability of insurance—take into account public policy concerns that might support excluding certain kinds of plaintiffs or injuries from relief." (*Kesner*, 1 Cal.5th at 1145.) "Because a judicial decision on the issue of duty entails *line-drawing* based on policy considerations, 'the *Rowland* factors are evaluated at a relatively broad level of factual generality,'" where "'*carving out an entire category of cases* from that general duty rule [must be] justified by *clear* considerations of policy.'" (*Id*., italics added, citing *Cabral,* 51 Cal.4th at 772.)

"'By making exceptions to Civil Code section 1714's general duty of ordinary care only when foreseeability and policy considerations justify a categorical no-duty rule, we preserve the crucial distinction between a

determination that the defendant owed the plaintiff no duty of ordinary care, which is for the *court* to make, and a determination that the defendant did not breach the duty of ordinary care, which in a jury trial is for the *jury* to make.'" (*Cabral*, 51 Cal.4th at 772; see also *Kesner*, 1 Cal.5th at 1144 ["'No-duty rules are appropriate only when a court can promulgate relatively clear, categorical, bright-line rules of law applicable to a general class of cases.'"].)

1. Foreseeability and Related Factors.

Foreseeability. "The most important factor to consider in determining whether to create an exception to the general duty to exercise ordinary care articulated by [Civil Code] section 1714 is whether the injury in question was foreseeable." (*Kesner*, 1 Cal.5th at 1145.) Foreseeability in this context "'"is not to be measured by what is more probable than not, but includes whatever is likely enough in the setting of modern life that a reasonably thoughtful [person] would take account of it in guiding practical conduct." ... [I]t is settled that what is required to be foreseeable is the general character of the event or harm—e.g., being struck by a car while standing in a phone booth—not its precise nature or manner of occurrence.'" (*Id.*, citing *Bigbee v. Pac. Tel. & Tel. Co.* (1983) 34 Cal.3d 49, 57–58.) It is certainly foreseeable to a drug manufacturer such as Gilead that the delay in the commercialization of a safer and at least equally effective alternative drug will expose users of the drug it is currently selling to otherwise avoidable injury.

In *T.H.*, this Court recognized that a drug manufacturer "could reasonably have foreseen" that its failure to use reasonable care in warning of known or reasonably knowable adverse effects of a brand-name drug could mislead physicians about the safety of the generic bioequivalent. (*T.H.,* 4 Cal.5th at 166.) As explained in *T.H.*, pharmaceutical manufacturers are in the *best position* to understand the potential adverse

effects of their products during the development and approval process. They have the *greatest access to and control* over data involving their drugs and the communication of risks to their patients. (*Id*. at 168.)

In the pharmaceutical context, the unique patent protections afforded drug manufacturers and the exclusivity these manufacturers have over certain chemical compounds accentuate the foreseeability of harm caused by a manufacturer's decision to withhold a safer alternative from consumers relying on the manufacturer for treatment of their illness. It is highly foreseeable that a pharmaceutical company's unreasonable decision to stall the release of a drug with fewer devastating side effects than its current drug *would cause unnecessary harm* to the vulnerable individuals taking the first drug. It is also entirely foreseeable, given a drug manufacturer's exclusivity over a compound (as Gilead held here over tenofovir), that the failure to exercise reasonable care in making decisions about the commercialization of an alternative drug would leave users with *no choice* but to suffer the side effects of the current drug.

While Gilead speculates about potential uncertainties that may face *any* product manufacturer, it ignores the context of the issue here, which involves a *pharmaceutical* manufacturer. (POB:48-49.)

The record illustrates the foreseeable risk of injury to a drug's users from a manufacturer's refusal to commercialize a safer alternative. When Gilead deliberately delayed TAF's development to extend its market exclusivity, it *knew* that TAF would significantly reduce or eliminate TDF's renal and bone toxicity risks. (5App:1662–1670,1716–1724). The foreseeability of the injury suffered could not be clearer.

To the extent Gilead criticizes the Court of Appeal's decision to evaluate the *Rowland* factors against the allegations that Gilead *knew* that TAF was a safer and at least equally effective alternative drug to TDF (POB:42-43), Gilead ignores the procedural backdrop of this case. Gilead

never contested the allegations or evidence that it knew TAF was safer than TDF and only argued in a post-argument supplemental brief in the Court of Appeal that a categorical exception under *Rowland* was warranted. And it emphasized that "plaintiffs' allegations of knowledge and motivation [are not] material to the legal issues its motion raised." (*Gilead*, 98 Cal.App.5th at 922, fns. 4–5.) The Court of Appeal simply indulged Gilead's belated and arguably forfeited *Rowland* argument against the allegations and disputed facts framing the issue of duty.[10]

In any event, whether a manufacturer knew or should have known it had developed a safer and at least equally effective alternative drug at the time it made allegedly unreasonable decisions about its commercialization, the harm to users deprived of the allegedly superior drug is generally foreseeable. Gilead concedes that "manufacturers often have the knowledge necessary to develop and commercialize alternatives to their existing products that would *avoid harms* to some consumers." (POB:36;47 [manufacturers "*routinely* have [this] knowledge."].)

In *Kuciemba*, where this Court considered whether the duty owed by an employer to prevent the spread of COVID-19 to an employees' household member under section 1714 should be limited under the *Rowland* factors, the Court explained that although information about the

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[10] Indeed, Gilead's argument concerning the difficulties of limiting the duty to commercialize an alternative drug to those manufacturers who "knew" the alternative drug was safer and just as effective *does not* support a categorical exception *but* cautions against it. (POB:47,51.) A judicially created "no duty" rule is appropriate *only* where the court "'can promulgate relatively clear, categorical, bright-line rules of law applicable to a general class of cases.'" (*Kesner*, 1 Cal.5th at 1143-1144.) Gilead does not ask this Court to carve out an exception to the duty of care here for *only* those manufacturers with constructive notice of the safety and efficacy of an alternate drug but instead seeks to carve out the duty altogether. Such a broad exception is unwarranted.

spread of Covid-19 was imprecise during the early months of the pandemic, it was nevertheless *reasonably foreseeable* that an employer's failure to take adequate protections against the spread of the virus could result in transmission to employees' households. (*Kuciemba,* 14 Cal.5th at 1024; see also *Kesner,* 1 Cal.5th at 1145–46 [it "'requires no leap of imagination'" to presume that "[a] reasonably thoughtful person making industrial use of asbestos" would consider "the possibility" that "asbestos fibers could become attached to an employee's clothing or person, travel to that employee's home, and thereby reach other persons who lived in the home."].)

The foreseeability of injury strongly weighs in favor of the duty and against recognizing a categorical exception to a drug manufacturer's general duty of care.

The degree of certainty that the plaintiff suffered injury. As noted by the Court of Appeal, "[b]ecause we assume the existing drug creates identifiable and characteristic physical injury, the fact of injury is certain." (*Gilead,* 98 Cal.App.5th at 939.)

The closeness of the connection between the defendant's conduct and the injury suffered. Gilead cannot meaningfully dispute the *close connection* between the alleged negligence here in delaying access to a safer and as effective drug and the otherwise avoidable injuries to users of the manufacturer's current drug. By failing to exercise reasonable care in decisions about the commercialization of a less toxic and equally effective drug, users of the current drug will *continue to suffer* harmful and otherwise avoidable side effects.

Gilead argues that "[g]enerally, a decision to stop developing an alternative product is remote from injuries caused by an existing, non-defective product." (AOB 48.) This is not helpful. By framing its analysis of a carve out as to *all* product manufacturers rather than drug

manufacturers, Gilead ignores the context of the issue as framed by this Court. Gilead then offers a "string of contingencies" that are either irrelevant or insignificant to the specific duty at issue. (POB:48-49.) For example, Gilead asks what would happen if a manufacturer does not market the product because a "need emerge[s] that is far more important." (*Id*.) But that is a reason to conclude that a *particular* manufacturer was not *negligent,* not a reason to find a categorically insufficient connection between a manufacturer's failure to develop an alternative product and the harm suffered. (See *Regents*, 4 Cal.5th at 634 ["The reasonableness of [the] actions … is a question of breach."].) Likewise, if an existing product is "superseded by another (and therefore becomes incapable of injuring anyone)" or if a different manufacturer "invent[s]" a product "obviat[ing] the need for another alternative" (POB:49), there will be no negligence since the failure to make reasonable decisions about the commercialization of the alternative drug would not have caused any harm. None of Gilead's general product hypotheticals support the categorical exception it is seeking.

Even when Gilead addresses the context of a pharmaceutical manufacturer, it minimizes the connection between the conduct and the injury by arguing that FDA approval is "unpredictable." (POB:49-50.) But, again, Gilead ignores that the duty is framed with the premise that the decision about commercialization concerns a safer and equally effective alternative drug to the one that the manufacturer is *currently selling*. The duty here concerns a manufacturer that has *already* secured FDA approval of a drug and is developing an alternative candidate that is less toxic and at least as effective as the existing drug. As the Court of Appeal recognized, "[t]hat makes FDA approval far less uncertain that might otherwise be the case … Nothing in the record presented to us establishes that drug companies are never able, at any point, to assess the likelihood of FDA

approval of a particular medicine beyond what can be gleaned from general industry averages." (*Gilead*, 98 Cal.App.5th at 939–940.)

Rowland's foreseeability factors weigh against recognizing the sweeping categorical exception advanced by Gilead.

2. Considerations of Public Policy.

The final four factors of the *Rowland* test are referred to as the "public policy factors." (*Cabral,* 51 Cal.4th at 781.) "The overall policy of preventing future harm is ordinarily served, in tort law, by imposing the costs of negligent conduct upon those responsible. The policy question is whether that consideration is *outweighed*, for a category of negligent conduct, by laws or mores indicating approval of the conduct or by the undesirable consequences of allowing potential liability." (*Ibid*.) Nothing argued by Gilead demonstrates that this is such an "exceptional case" where public policy warrants a categorical exception to the duty owed. (*T.H.*, 4 Cal.5th at 168.)

The moral blame attached to the defendant's conduct. This Court has "said that if there were reasonable ameliorative steps the defendant could have taken, there can be moral blame 'attached to the defendants' failure to take steps to avert the foreseeable harm.'" (*Vasilenko v. Grace Family Church* (2017) 3 Cal.5th 1077, 1091.) "[M]oral blame is typically found when the defendant *reaps a financial benefit* from the risks it has created." (*Kuciemba*, 14 Cal.5th at 1026.) And the "[r]elative *inequality between the parties* may also bear upon moral blame. 'We have previously assigned moral blame, and we have relied in part on that blame in finding a duty, in instances where the *plaintiffs are particularly powerless or unsophisticated compared to the defendants* or where the defendants exercised greater control over the risks at issue.'" (*Ibid*., italics added.)

Here, the moral blame factor weighs strongly against Gilead's proposed exception. (See *Gilead*, 98 Cal.App.5th at p. 942 ["[N]egligence

in a decision that deprives people of a safer drug and leaves them reliant on a more dangerous drug is morally blameworthy."].) Blame is warranted for a manufacturer that fails to take "reasonable ameliorative steps" to avert the known harms of its existing product. (*Vasilenko*, 3 Cal.5th at 1091.) Blame is warranted for a manufacturer that "reaps a financial benefit" from delaying the commercialization of an alternative product to maximize the patent protection of its existing product. (*Kuciemba*, 14 Cal.5th at 1026; see also *Gilead*, 98 Cal.App.5th at 941 ["[T]he exception Gilead seeks would allow them to extend the time patients are subjected to the risks associated with a more dangerous drug precisely because delaying the commercialization of a safer alternative would confer a financial benefit."].) And blame is especially warranted when a powerless patient population—like the HIV/AIDS sufferers in this case—have no alternative to the manufacturer's product and are forced to suffer serious side effects that could have been prevented by the continued development of safer drug. (*Gilead*, 98 Cal.App.5th at 941 ["Users of a particular medicine generally have no ability to avoid its harmful side effects. …And it is the manufacturer's decisions about commercialization of the safer alternative that are the primary determinants of whether patients will continue to be subject to those risks."].)

Gilead's responses fall flat.

First, it argues that manufacturers may "*know* that the alternatives are safer for some subset of consumers, but … choose not to devote finite resources to developing the safer alternative for a variety of legitimate, even compelling reasons," including using those resources to "develop a treatment for a currently untreated disease." (POB:57–58.) This misses the point: A manufacturer's *reasonable* decision not to develop a safer alternative is not negligent *or* morally blameworthy. Gilead offers no reason to *preclude* the possibility of negligence liability for an

unreasonable decision not to develop a safer alternative. (See *Gilead*, 98 Cal.App.5th at 942 [the court's "task is to evaluate the degree of moral blame that attaches to *negligence* in a drug manufacturer's decisions about commercializing a safer drug, *not to potential non-negligent reasons* for its actions."].)

Second, Gilead argues that "moral opprobrium is even less warranted when the manufacturer does not *know* an alternative is safer, but merely has information from which a detractor can assert that it should have known." (POB:57.) But Gilead's proposed exception confers sweeping immunity on manufacturers who *have* actual knowledge of the superior safety of an alternative product. And those manufacturers with constructive knowledge need not be categorically immunized from liability because they will have a strong argument before a jury that their conduct was not unreasonable.

Third, Gilead contends that "socially beneficial conduct," including the development of "lifesaving medicines," "should not expose actors to liability." (POB:57.) But the negligent conduct at issue here is not the *development* of lifesaving products but rather the *failure* to commercialize an existing product that would alleviate the harm caused by the manufacturer's existing product. There is no social utility to *this* conduct.

The moral inadequacy of Gilead's position was laid bare in the oral argument in the Court of Appeal. The Court posed the following hypothetical to Gilead's counsel:

> Let's make the facts a little bit more egregious and say, okay, so Gilead reduced – or released TDF, and then a couple of years later as it was developing TAF, they started to have this conversation about whether or not it would make sense to pause TAF's development for purely profit reasons.
>
> And as part of that discussion, executives asked for an estimate on, okay, well, if we did that, *how many people would actually be injured from TDF that would not be injured from TAF*. And

> so, they crunched the numbers, and they came back with a hard estimate, 25,000 people would be injured or killed -- 5,000 killed, 20,000 injured.
>
> And the company said, okay, let's pause it and we'll just accept that. And to make it even more egregious they could say, how much money will we make, and they crunched those numbers and they come back, and they say, well, even if we're stuck with liability for paying those claims, *we'll still make $5 billion more if we pause TAF*.
>
> Now, would you say that the law essentially still immunizes or doesn't recognize the duty at all? There's no cause of action for that sort of claim?

(OA:60:10-61:10.) Gilead's response: "Yes. So, *yes, there is no duty*." (OA:61:20-21.)

When the Court sought to clarify, asking: "So, under the hypo I gave you when *Gilead actually calculated precisely how many people would be injured by their product and they decide to pause it anyway*, and … potentially pay those claims just because they're going to earn more money. You're saying … the law doesn't reach that at all. You can't challenge it. They're immune to that kind of liability," Gilead's counsel responded: "So, *yes, that is correct*." (OA:62:10-19.) This position is morally unacceptable. In this case—and more generally—the moral blame factor strongly favors the existence of a duty.

The policy of preventing future harm. The policy of preventing future harm "is ordinarily served, in tort law, by imposing the costs of negligent conduct upon those responsible." (*Cabral*, 51 Cal.4th at 781–782.) "The policy question is whether that consideration is outweighed, for a category of negligent conduct, by laws or mores indicating approval of the conduct or by the undesirable consequences of allowing potential liability." (*Ibid*.) It is clear that holding drug manufacturers liable for their *unreasonable* conduct in delaying commercialization of a less toxic and equally effective drug prevents harm to those patients taking the original

drug with its known, devastating side effects. Indeed, the policy of preventing future harm has special relevance where, as here, the drug manufacturer is the only entity with the incentive and *control* to prevent a known harm to its consumers. (See *T.H.*, 4 Cal.5th at 168–180.)

Gilead's responses are illogical and internally contradictory. *First*, Gilead argues that the fear of liability would cripple innovation and result in manufacturers refusing to develop new drugs. (POB:10,51-52.) It relies on this Court's decision in *Brown* for the sweeping proposition that imposition of tort liability for the negligence alleged will "weaponize[] innovation" and thwart development of "lifesaving" drugs. (POB:8,30,37-38,52-53.) Nothing in *Brown* supports this assertion.

As detailed by the Court of Appeal, *Brown* rejected application of strict product liability design defect for injuries caused by prescription drugs because strict liability makes manufacturers liable for unforeseen and unforeseeable harm. (*Gilead,* 98 Cal.App.5th at 943.) "[T]he [*Brown*] court expressly declined to protect [drug manufacturers] from claims based in negligence, in which the harm must be foreseeable." (*Ibid*, citing *Brown,* 44 Cal.3d at 1069, fn. 12.) The Court of Appeal explained that "while drug manufacturers have continued to resist the imposition of liability in other contexts by asserting that it would chill innovation, courts after *Brown* have declined to accept those assertions as unsupported by an evidentiary showing," and Gilead's argument here is "similarly unsupported." (*Gilead*, 98 Cal.App.5th at 943.) Beyond this, the societal need for access to medications that may help alleviate such suffering that warranted an exception to *strict* products liability in *Brown* is the very policy justification that cautions against immunizing drug manufacturers from liability when they unreasonably deprive patients of life-saving drugs solely for profit.

Second, Gilead argues that "manufacturers will veto studies to avoid the risk of acquiring too much knowledge about the possibility of a safer

alternative." (POB:51.) Yet in the same breath, it claims that "because so many drug candidates fail in clinical studies, it is *standard practice* to collect data on back-up candidates while proceeding with a lead candidate[.]" (*Ibid*., italics added.) Gilead is asking this Court to believe that drug companies, in the "highly competitive" and immensely profitable pharmaceutical industry (POB:54), would refuse to collect "essential" data (POB:12) on back-up candidates to protect themselves from liability, even though this limits the likelihood of finding a candidate that could secure FDA approval. The argument makes no sense.

Third, Gilead contends that "once a business discovers a safer product, it will have to think twice about *ever* bringing it to market" because "[d]oing so automatically creates a new class of plaintiffs who can say that the alternative should have been released earlier." (POB:51.) To be clear: a plaintiff will only be able to *successfully* assert a claim against a manufacturer if they can prove that the delayed release of a product was *negligent*. And Gilead fails to recognize that manufacturers have *ample* incentive to release safer products into the marketplace even if doing so marginally increases their exposure to negligence liability, including winning market share and avoiding the reputational damage of harmful effects from their products. (See generally *T.H.*, 4 Cal.5th at 171.)

Finally, Gilead asserts that "this duty will improperly skew research priorities" by encouraging manufacturers to "prioritize addressing relatively minor side effects affecting small percentages of users" rather than "developing some new technological marvel" for a "historically neglected population for whom no treatment has yet been developed." (POB:52.) Gilead grossly exaggerates the extent to which pharmaceutical companies are channeling their resources toward neglected diseases, which were estimated in 2006 to "account for less than 1% of pharmaceutical research and development expenditures." (Sinha et. al, *Expansion of the Priority*

Review Voucher Program under the 21st Century Cares Act: Implications for Innovation and Public Health (2018) 44 Am. J.L. & Med. 329, 330.) And Gilead provides no reason to conclude that the mere possibility of tort liability for harm caused to a "small percentage[] of users" is sufficient to dissuade manufacturers in the "highly competitive" pharmaceutical industry from pursuing the next "technological marvel." (POB:52-53.) To the extent companies are "incentivized to avoid liability" as argued by Gilead (*id*.), it is precisely because companies are *incentivized to maximize profits*. Gilead has not come close to proving that the duty in this case would lead to "less innovation, fewer alternative products, and abandonment of products consumers need the most." (POB:52.)

Given the near blanket immunity pharmaceutical manufacturers enjoy through preemption, state tort actions for ordinary negligence may serve as the only deterrent to drug companies from choosing to put profits over patient safety. Indeed, the duty of care serves an important policy function given that the current patent system incentivizes drug manufacturers to extend their monopolies for as long as possible, with deleterious effects on innovation and competition. (See, e.g., *Bernstein, supra*, at 71–74; Gurgula, *Strategic Patenting by Pharmaceutical Companies—Should Competition Law Intervene?*, IIC Int Rev Ind Prop Copyr Law 2020; 51(9): 1062–1085, https://doi.org/10.1007/s40319-020-00985-0 [as of Aug. 12, 2024].)

The extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach. According to Gilead, recognition of the duty will "inundate" drug manufacturers with "time-consuming, complex litigation." (POB:54.) But Gilead's "floodgates" arguments rests on its exaggerated portrayal of the reach of the duty in this case. The duty only applies to a drug manufacturer that has *already invented* a less toxic and equally effective alternative to the

drug it is *currently selling*. A drug manufacturer *already* owes a duty of care to the users of its drug. This duty does not "threaten[] liability for just about any product-development decision" but rather ensures, as negligence law has always done, that a manufacturer act reasonably when making decisions that increase the risk of harm to the consumers of its product.

Next, Gilead's assertion that tort litigation will wreak havoc on its benevolent purpose of bringing life-saving drugs to consumers is unsupported. In 2013, a study from the RAND Institute for Civil Justice evaluating the economic effects of product liability litigation on the pharmaceutical industry concluded: "In sum, there is little direct empirical evidence concerning the economic effects of product liability or the other forms of liability considered in this monograph. Most of the direct evidence available about product liability pertains to particular drugs, and almost all of that evidence pertains to events that occurred a decade or more ago. …. Policymakers should, then, *be wary of broad claims about economic effects of pharmaceutical liability*, including generalizations based on anecdotes or examples." (See Steven Garber, Rand Institute for Civil Justice, *Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals* (2013), p. 17, italics added.)

Holding a drug manufacturer accountable for its failure to act reasonably in making decisions about the commercialization of an already-invented alternative drug does *not* burden society but rather protects society. The pharmaceutical industry already enjoys multiple safe harbors from legal accountability for the harm it causes – no clear public policy exists to justify more.

The availability, cost, and prevalence of insurance for the risk involved. Gilead has provided *no* evidence about the ability of pharmaceutical companies to obtain insurance coverage for the negligence liability under consideration. Instead, it relies on the statement in *Brown*

that the "possibility that the cost of insurance and of defending against lawsuits will diminish the availability and increase the price of pharmaceuticals is far from theoretical." (*Brown*, 44 Cal.3d at 1064.) But *Brown* concerned an entirely different issue: *strict liability* for defectively designed drugs. Nothing in *Brown* suggests that recognition of the narrow duty here would spike insurance premiums and increase the price of pharmaceuticals.

***

In sum, the *Rowland* factors do not justify a categorical exclusion from the duty owed by drug manufacturers under the circumstances here. Gilead's exaggerated and unsupported argument that the pharmaceutical industry will be unable to save lives if manufacturers are held accountable for their negligent conduct is mistaken. No reason exists to create an exemption to a drug manufacturer's duty to act reasonably in making decisions about the commercialization of an allegedly safer and equally effective drug to the one currently being sold by the manufacturer that exposes thousands of users to devastating side-effects. And as cases like this are rare, there is no reason to think there would be a tidal wave of litigation or any effect on a drug manufacturer's powerful profit incentives to innovate. (Cf. *Loeffler v. Target Corp.* (2014) 58 Cal. 4th 1081, 1142 dis. opn., Liu, J. ["Before today's decision, no authority foreclosed suits like this one, yet there is no indication that such suits are common."].)

B. Gilead Has Failed To Justify Its Purportedly Narrower Exception Under *Rowland*.

According to Gilead, "[t]he narrowest way to resolve this appeal is to rule that there is no duty for the class of cases that arise this early in the drug-development cycle." (POB:60.) To justify this alternative exception, Gilead offers a skewed analysis based on purportedly "undisputed or indisputable" facts. (POB:60-64.) None of this is sufficient to justify a categorical limitation to the duty owed here.[11]

Gilead's narrower exception posits that "any duty to continue developing a purportedly safer alternative cannot attach *this early* in the drug development process." (POB:34, italics added.) It fails to specify exactly *when* a duty can attach but asserts that a "drug manufacturer *cannot generally know* that a candidate is safer than, and as effective as, an existing approved drug before Phase III studies and head-to-head clinical comparisons." (POB:60, italics added.) It relies on purported industry averages showing that "[s]even out of eight drug candidates (88%) that start clinical trials fail" and "70-75% of drug candidates that start Phase III trials fail," as well as the regulatory statement that Phase III trials gather the additional information about effectiveness and safety that is needed to evaluate the "overall benefit-risk relationship of the drug." (POB:61.)

Gilead is essentially concocting a limitation that immunizes it from liability for failing to conduct a Phase III trial of TAF after Phase I/Phase II study data demonstrated that it had fewer side effects than TDF. (See 21 C.F.R § 312.21(b) [noting that Phase II trials are "conducted to evaluate the effectiveness of the drug for a particular indication or indications in patients with the disease or condition under study and to determine the common

[11] It is not clear that this issue is properly before the Court: In its Petition for Review, Gilead argued that that "this Court need not decide" whether the narrow exception applies here. (Pet. Review:38-39.)

short-term side effects and risks associated with the drug."].) But it does not come close to justifying a *categorical* limitation of a drug manufacturer's duty of care to develop an alternative to its harm-causing drug before Phase III trials are conducted.

The notion that a drug manufacturer can *never* know after a Phase II trial that an alternative drug is safer and at least equally effective than an FDA-approved drug produced by the same manufacturer is belied by the record in this case. By 1996, Gilead knew that TDF has disproportionately low absorption into target cells and thus requires 300 milligrams of tenofovir to be effective, leading to high concentrations of tenofovir going directly to the kidneys and causing injury. (3App:1079–1167; 5App:1662–1663; 8App:2558–2562.) By 2000, Gilead recognized that TAF's "level of potency coupled with a minimum resistance profile could make [TAF] the most effective and widely used HIV therapeutic on the market, regardless of compound class." (5App:1678.) Gilead then completed a head-to-head comparison of TAF and TDF in human beings in 2002 (the Phase I/Phase II trial), which showed that 50 mg. of TAF delivered a higher tenofovir concentration in HIV infected cells than 300 mg. of TDF. (6App:1851–1877.) In Gilead's words, the head-to-head comparison of TDF and TAF in humans "clearly demonstrated proof of concept" that TAF produces increased concentrations of tenofovir at significantly lower doses than TDF. (6App:1907.) The findings from the human clinical study supported preclinical data showing TAF was "a more stable prodrug of tenofovir" than TDF. (6App:1911.) And it showed that compared with those receiving TDF, patients on TAF "experienced significantly smaller changes in estimated creatinine clearance, renal tubular proteinuria, and bone mineral

density." (9App:2835–2841.) Gilead thus had *ample* evidence to evaluate the safety and effectiveness of TAF before Phase III trials.[12]

Gilead has given this Court no reason to conclude that a manufacturer is *categorically* incapable of knowing (for purposes of negligence liability) that an alternative candidate is safer and at least equally effective than the FDA-approved drug it is selling to consumers. Even if it is true that a drug manufacturer cannot be *certain* about the superiority of an alternative drug until Phase III trials are completed, that does not mean that a drug manufacturer can *never* have sufficient information to be found liable for negligently failing to develop an alternative drug. Gilead is welcome to argue at trial that it did not *breach* any duty to Plaintiffs because it had insufficient information about the safety profile of TAF to make it foreseeable that a failure to develop that drug would harm patients of TDF. But it offers no basis to categorically exclude a manufacturer's liability, beyond relying on general industry FDA-approval averages that do not address the likelihood of a manufacturer receiving approval of an alternative to its *already-produced* drug that is demonstrably superior following Phase II trials.

Gilead's cursory *Rowland* analysis does not disturb this conclusion. As for foreseeability, Gilead claims that "[i]f a manufacturer generally cannot know that a drug candidate is safer and equally effective without additional side effects, then it is far less foreseeable that the candidate would prevent patient injuries, and the link between the manufacturer's decision to discontinue an investigation and the injury is even more attenuated." (POB:62-63.) But Gilead has failed to provide any *evidence*

[12] Tellingly, Gilead's Executive Vice President of Research and Development could not recall a *single* example of a Gilead prodrug that looked "promising in preclinical or early clinical studies" but ultimately did not "pan out by the time it reache[d] Phase III[.]" (2App:460–461.)

that a manufacturer of a drug that is already approved by the FDA "generally cannot know" that its alternative candidate is safer and equally effective following a Phase II trial. As the Court of Appeal explained, "no factual record has been developed in the trial court" that would enable the making of "any meaningful generalizations about what can be reasonably known after Phase II trials as compared to Phase III trials." (*Gilead*, 98 Cal.App.5th at 946.) And on the flipside, it is foreseeable to a manufacturer that failing to develop an alternative drug that is safer and at least equally effective in Phase II trials than the related drug it is currently selling to consumers could cause harm to those consumers. The foreseeability factors weigh against Gilead's exception.

Public policy concerns also do not favor recognizing Gilead's exception. Gilead claims that the "earlier in the development trajectory that the duty attaches, the more severe the costs to society (in lost drug candidates and innovation) and the burden on manufacturers and the community." (POB:63.) But it does not explain why *this* duty would undermine innovation given that it applies to drugs that have already been invented. Instead of frustrating innovation, this duty would *incentivize* drug manufacturers to continue the "development and marketing of beneficial new drugs" that reduce the "pain and suffering" caused by existing drugs. (*Brown*, 44 Cal.3d at 1063.) As for moral blame, a drug manufacturer *controls* whether a drug with promising Phase II results is submitted for Phase III trials, and the users of the existing drug are powerless to influence that decision. This Court should not permit a manufacturer to evade liability for negligently failing to commercialize a safer and at least equally effective alternative drug by refusing to submit the drug for Phase III trials.

Gilead's narrower exception should also be rejected.

III.

CONCLUSION

For the foregoing reasons, the Court of Appeal's Opinion should be affirmed.

Dated: August 14, 2024

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This brief contains 13,934 words per a computer generated word count.

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I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 234 East Colorado Boulevard, Suite 975, Pasadena, CA 91101.

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s/ Kelsey Wong
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SERVICE LIST

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(S283862 | A165558 | CJC-19-005043)

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AIDS Healthcare Foundation

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/s/Kelsey Wong

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