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CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT

DIVISION FOUR

GILEAD TENOFOVIR CASES.	
GILEAD LIFE SCIENCES, INC., Petitioner, v. THE SUPERIOR COURT OF THE CITY AND COUNTY OF SAN FRANCISCO, Respondent; PLAINTIFFS IN JCCP NO. 5043, Real Parties in Interest.	A165558 (San Francisco City & County Super. Ct. No. CJC-19-005043, JCCP No. 5043)

Defendant Gilead Life Sciences, Inc. (Gilead), a pharmaceutical manufacturer, developed and sold one of the first medications to treat HIV/AIDS. That drug, tenofovir disoproxil fumarate (TDF), was approved for sale by the Food and Drug Administration (FDA) in 2001. Although TDF was effective in suppressing the effects of HIV, its use carried a risk of skeletal and kidney damage. The 24,000 plaintiffs in this coordinated

proceeding allege that they suffered these or other adverse effects from their use of TDF.

While Gilead was developing TDF, it discovered a similar, but chemically distinct, potential drug, tenofovir alafenamide fumarate (TAF). Plaintiffs allege that Gilead's early testing indicated TAF could be as effective as TDF at treating HIV/AIDS, while carrying a lower risk of adverse effects. According to plaintiffs, however, Gilead elected to defer development of TAF because it was concerned that the immediate development of TAF would reduce its financial return from TDF. Years later, Gilead resumed the development of TAF and obtained FDA approval for its sale in 2015.

Although plaintiffs are seeking compensation for injuries caused by their use of TDF, they do not assert any claim seeking to prove that TDF is defective. Instead, they characterize their claim as one for ordinary negligence, contending that Gilead's decision to defer development of TAF to maximize its profits breached its duty of reasonable care to users of TDF. They also assert a claim for fraudulent concealment, reasoning that Gilead had a duty to disclose information about TAF to users of TDF.

Gilead filed a motion for summary judgment or summary adjudication. With respect to plaintiffs' claim for negligence, Gilead argued that a plaintiff seeking to recover for harm caused by a manufactured product must prove that the product was defective. Given plaintiffs' decision not to prove a defect, Gilead contended, they cannot recover for harm caused by their use of TDF. With respect to fraudulent concealment, Gilead argued

that it had no duty to disclose facts relating to TAF when it had not been approved as an alternative to TDF for the treatment of HIV/AIDS. The trial court denied the motion in its entirety. Gilead then filed a writ petition in this court. Because of the potentially dispositive nature of these issues for this large coordinated proceeding, we issued an order to show cause. After oral argument, we requested supplemental briefing on certain issues raised by plaintiffs' negligence claim, including whether, if the law does not require proof of a defect, the factors set forth in *Rowland v. Christian* (1968) 69 Cal.2d 108 (*Rowland*) nonetheless warrant an exception to the duty of care in this context.

We now grant the petition for writ of mandate in part and deny it in part. We affirm the trial court's denial of Gilead's motion insofar as it sought summary adjudication of plaintiffs' negligence claim. First, we conclude that the legal duty of a manufacturer to exercise reasonable care can, in appropriate circumstances, extend beyond the duty not to market a defective product. Second, in light of that conclusion, we then explain why *Rowland* supplies the appropriate framework for evaluating plaintiffs' negligence claim. Third, applying *Rowland*, we consider two proposed exceptions to the duty of care. The first exception mirrors Gilead's original argument by precluding negligence liability for prescription drugs without proof of a defect. The second exception is narrower in that it would allow plaintiffs to assert a claim for negligence without proof of a defect, but only as to decisions the drug manufacturer made after

obtaining the results of Phase III clinical trials of the alternative drug. We find that the broader proposed exception is unwarranted, and that the narrower exception is unsupported on the present record, although we do not preclude the possibility that Gilead could establish it on a more developed record.

Finally, we reverse the trial court's decision insofar as it denied Gilead's motion for summary adjudication of plaintiffs' claim for fraudulent concealment. We conclude that Gilead's duty to plaintiffs did not extend to the disclosure of information about TAF.

BACKGROUND

I. Plaintiffs' Allegations

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. 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. To create a usable medication from tenofovir, Gilead was required to develop an alternative form of the chemical, known generally as a "prodrug," that would be safe and effective when administered orally.

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.

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. 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. The use of a smaller dose allegedly makes TAF more effective as a treatment while reducing adverse side effects.

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." In 2002, Gilead undertook Phase I/II testing of TAF. 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.' " In 2004, however, Gilead discontinued development of TAF. 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.

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. 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. 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. As plaintiffs allege, this strategy "would effectively monetize both drugs."

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. In 2011, Gilead's President allegedly told investors that TAF would be a "kinder, gentler" version of TDF.[1]

The complaint asserted claims for negligence, strict products liability, breach of express and implied warranties, and fraudulent concealment. Over the course of the litigation, however, plaintiffs significantly narrowed the scope of their claims. In two separate stipulations, plaintiffs dismissed with prejudice their causes of action for strict liability and breach of warranty, as well as any claims "that solely provide support for failure to warn liability." By the time of the summary judgment motion, plaintiffs' only remaining claims were for negligence and fraudulent concealment.

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[1] According to the statement of undisputed material facts Gilead submitted in connection with the summary judgment motion, Gilead resumed work on TAF in 2011 and conducted a Phase III study to compare TDF- and TAF-based medications in 2013. That study, Gilead's motion conceded, provided "substantial evidence that TAF had less impact than TDF on renal function [and] bone metabolism."

II. Gilead's Summary Judgment Motion

Although the allegations on which plaintiffs' negligence cause of action is based did not change over the course of the litigation, the framing of their claim evolved. By the time Gilead filed its summary judgment motion, plaintiffs' contention was that Gilead's 2004 decision to postpone development of TAF, despite its knowledge that TAF presented a safer alternative to TDF, breached its duty of reasonable care to users of its TDF medications. Plaintiffs aver that they will not attempt to demonstrate that TDF's design was defective, nor that TDF should be withdrawn from the market. Rather, what matters is that "Plaintiffs and their physicians were deprived of the *choice* between TDF or TAF by Gilead's actions."

Gilead did not, for purposes of the summary judgment motion, dispute plaintiffs' primary allegations of actionable conduct. Rather, its motion was premised solely on evidence of the FDA's approval of a series of medications featuring TDF. Based on this approval, Gilead argued that plaintiffs' claim for negligence (1) is preempted by federal law and (2) fails to state a claim under state tort law. The latter argument was premised on Gilead's contention that a product seller is liable only for harm caused by products proven to be defective. Because plaintiffs do not seek to prove that TDF-containing medications are defective, Gilead argued, plaintiffs cannot hold the company liable for harm caused by TDF. Acknowledging plaintiffs' current claim that Gilead had a duty of reasonable care to commercialize a TAF-based medication once it knew of TAF's superiority to TDF,

Gilead argued that "there is no such thing as a claim to redress alleged injuries caused by a defendant's product without 'prov[ing] that a defect caused [the] injury'—i.e., without proving a design defect."

Plaintiffs' claim for fraudulent concealment alleged that Gilead actively concealed that TAF was a safer means for delivering tenofovir into the body; that the toxicity of tenofovir was not unavoidable; and that Gilead's true motive for shelving TAF development was financial. With respect to this claim, Gilead argued that (1) it was preempted by federal law; (2) Gilead had no duty to disclose to plaintiffs information "about an *unapproved* drug that they were *not* taking"; and (3) plaintiffs could not demonstrate that information about TAF's safety, provided prior to TAF's approval by the FDA, would have been material to their doctors' decisions to prescribe TDF. As noted, the summary judgment motion was denied, and these writ proceedings followed.[2]

DISCUSSION

I. Negligence

Civil Code section 1714 (section 1714), which states the statutory rule of negligence, provides that "[e]veryone is responsible . . . for an injury occasioned to another by his or her

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[2] In connection with its writ petition and again in connection with a subsequent motion to stay proceedings, Gilead filed separate motions for judicial notice. Although we granted the relief sought by Gilead in both instances, we did not expressly rule on its motions for judicial notice in doing so. Because both motions for judicial notice were rendered moot by our grant of the relief Gilead was seeking, we now deny the motions.

want of ordinary care or skill in the management of his or her property or person." (Civ. Code, § 1714, subd. (a).) The familiar elements of a negligence cause of action are duty, breach, causation, and damages. (*Achay v. Huntington Beach Union High School Dist.* (2022) 80 Cal.App.5th 528, 535.) "In California, the 'general rule' is that people owe a duty of care to avoid causing harm to others and that they are thus usually liable for injuries their negligence inflicts." (*Southern California Gas Leak Cases* (2019) 7 Cal.5th 391, 308; see *Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 214 (*USA Taekwondo*) [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' "].) "Whether a duty exists is a question of law to be resolved by the court." (*USA Taekwondo*, at p. 213.)

Drawing on the language of section 1714, plaintiffs characterize Gilead's duty as simply the duty "to exercise reasonable care not to cause foreseeable injury to the users of its products." But it is generally more appropriate to consider the claimed duty in its factual context. (See, e.g., *Verdugo v. Target Corp.* (2014) 59 Cal.4th 312, 336 [considering whether duty of reasonable care obligates department store to maintain an AED for use in a medical emergency]; *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89, 103 (*Conte*) [considering "whether a name-brand prescription drug manufacturer in disseminating product warnings owes a duty of care to patients who take a generic version of the drug pursuant to a prescription written in reliance on the name-brand maker's information"].) Doing so is

particularly important here because Gilead occasionally describes plaintiffs' proposed duty as imposing obligations—such as a "duty to innovate"—that plaintiffs expressly disavow. Plaintiffs do not claim that a manufacturer that obtains FDA approval to sell a prescription drug has a legal duty to invent a safer alternative drug, and by failing to do so may be held liable to users of the existing drug for injuries caused by the disclosed side effects of its use.[3] On the contrary, their negligence claim is premised on Gilead's *possession* of such an alternative in TAF; they complain of Gilead's knowing and intentional *withholding* of such a treatment following its invention. While we agree with Gilead that a duty that placed manufacturers "under an endless obligation to pursue *ever-better* new products or improvements to existing products" would be unworkable and unwarranted, plaintiffs are not asking us to recognize such a duty.

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

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[3] We use the term "invent" here, rather than "develop," because the meaning of "develop" in the pharmaceutical context is ambiguous. Gilead refers to the entire process of drug creation, from invention through FDA approval, as drug development. Because plaintiffs' claim is focused only on the latter stages of this process, Gilead's general reference to a "duty to develop" obscures the precise nature of plaintiffs' claim.

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. Again, while Gilead's briefing disputes plaintiffs' assertions about its knowledge and motivation, it did not contest those assertions for the purposes of the summary judgment motion presently under review. We therefore accept the allegations of the complaint in adjudicating Gilead's present arguments.[4]

In context, then, the duty question we must address is whether a drug manufacturer, having invented what it knows is a safer, and at least equally effective, alternative to a prescription drug that it is currently selling and that is not shown to be defective, has a duty of reasonable care to users of the current drug when making decisions about the commercialization of the alternative drug.[5]

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[4] Although Gilead cites some evidence in the appellate record to support its rebuttal of plaintiffs' factual allegations, that evidence was submitted in connection with proceedings in the litigation that occurred prior to the summary judgment motion. Plaintiffs contend that Gilead's evidence is contradicted by evidence similarly submitted by plaintiffs.

[5] At a few points in the complaint, plaintiffs allege that Gilead knew "or should have known" that TAF was safer than TDF. In general, however, plaintiffs' complaint, summary judgment papers, and briefs in this court, assert without

A. Negligence Without Proof of Defect

Gilead's original argument against plaintiffs' negligence claim in its writ petition was based on plaintiffs' decision to abandon any attempt to prove that TDF is defective. (Plaintiffs state that their decision is not a concession that TDF is *not* defective, but rather arises from a concern that any claim requiring proof that TDF is defective would be subject to federal preemption.[6]) Gilead argued that, in the products liability context, a manufacturer satisfies its duty of reasonable care by making a product that is not defective. Therefore, according to Gilead, a manufacturer cannot be held liable in negligence for harm its product causes if the plaintiff's showing does not include proof that the injury was caused by a defect.

The concept of a "defect" is one of the defining components of the doctrine of strict products liability, which provides that the manufacturer of a product is liable "if a defect in . . . its product

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qualification that Gilead *knew* TAF was safer than TDF. Moreover, actual knowledge appears to be necessary to the motivation plaintiffs attribute to Gilead's decision—Gilead's alleged concern that TAF would "cannibalize" sales of TDF and its belief that TAF's later release would allow Gilead to maximize its financial return by extending the duration of its patent protection for tenofovir-related treatments. We therefore analyze plaintiffs' claim as premised on actual knowledge, although we take no position on whether plaintiffs should be permitted to include a constructive knowledge theory on remand, should they seek to do so.

[6] Plaintiffs contend that the doctrine has developed in such a way as to severely limit the availability of design defect claims. (See, e.g., Bernstein, *(Almost) No Bad Drugs: Near-Total Products Liability Immunity for Pharmaceuticals Explained* (2020) 77 Wash. & Lee L.Rev. 3, 32–37 (Bernstein).)

causes injury while the product is being used in a reasonably foreseeable way." (*Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 560 (*Soule*).)[7] Prior to California's adoption of the doctrine in *Greenman v. Yuba Power Products, Inc.* (1963) 59 Cal.2d 57 (*Greenman*), negligence was the primary tort theory under which persons could recover for injuries caused by a manufactured product. (E.g., *Escola v. Coca Cola Bottling Co.* (1944) 24 Cal.2d 453, 457.) Because strict liability "focusses not on the conduct of the manufacturer but on the product itself" (*Brown, supra*, 44 Cal.3d at p. 1056), it 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. (See *Cronin v. J.B.E. Olson Corp.*

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[7] Product defects fall into three categories: manufacturing defects, design defects, and defects of warning. A manufacturing defect occurs from "a flaw in the manufacturing process, resulting in a product that differs from the manufacturer's intended result." (*Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1057 (*Brown*).) A design defect can be found (1) "if the plaintiff demonstrates that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner" (*Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 429 (*Barker*)) or (2) "if the jury finds that the risk of danger inherent in the challenged design outweighs the benefits of such design." (*Id.* at p. 430; see generally *Kim v. Toyota Motor Corp.* (2018) 6 Cal.5th 21, 30.) A failure-to-warn defect results if the manufacturer "did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution." (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1112 (*Carlin*).)

(1972) 8 Cal.3d 121, 133 (*Cronin*) ["the very purpose of our pioneering efforts in this field was to relieve the plaintiff from problems of proof inherent in pursuing negligence [citation] and warranty [citation] remedies, and thereby 'to insure that the costs of injuries resulting from defective products are borne by the manufacturers' "].)

The purpose of requiring proof of a defect is to prevent strict liability from expanding into absolute liability, in which manufacturers would effectively be made insurers for the safety of their products. (See, e.g., *Cronin, supra*, 8 Cal.3d at pp. 133–134; *Soule, supra*, 8 Cal.4th at p. 568, fn. 5; *Daly v. General Motors Corp.* (1978) 20 Cal.3d 725, 733; see also *Jiminez v. Sears, Roebuck & Co.* (1971) 4 Cal.3d 379, 383 (*Jiminez*) [noting that "the manufacturer's strict liability depends upon what is meant by defect"].) Early commentators, including *Greenman*'s author, Justice Traynor, remarked on the difficulty of defining what constitutes a "defect." (See Traynor, *The Ways and Meanings of Defective Products and Strict Liability* (1965) 32 Tenn. L.Rev. 363, 366–367; Wade, *On the Nature of Strict Tort Liability for Products* (1973) 44 Miss. L.J. 825, 832 ["It is not without reason that some people, in writing about it, speak of the requirement of being 'legally defective,' including the quotation marks"]; see also *Barker, supra*, 20 Cal.3d at p. 427 ["the term defect as utilized in the strict liability context is neither self-defining nor susceptible to a single definition applicable in all contexts"].) But while the "formidable task" (*id.* at p. 418) of defining the term "defect" may have been necessary to constrain the reach of strict liability, in

negligence 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. (See, e.g., *Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1143 (*Kesner*) [" ' "Courts . . . invoke[] the concept of duty to limit generally 'the otherwise potentially infinite liability which would follow from every negligent act. . . .' " ' "] (quoting *Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370, 397); *Rowland, supra*, 69 Cal.2d at pp. 112–113.) 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.

The adoption of strict liability in *Greenman* did not purport to displace negligence as a cause of action. It was soon settled that a plaintiff seeking compensation for harm caused by a product can plead and prove a claim for negligence as well as strict liability. (E.g., *Jiminez, supra*, 4 Cal.3d at p. 387 ["No valid reason appears to require a plaintiff to elect whether to proceed on the theory of strict liability in tort or on the theory of negligence"]; *T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, 177, fn. 4 (*T.H.*) [affirming that strict liability and negligence furnish distinct bases for liability].) After *Greenman*, plaintiffs harmed by products can focus on the product and prove a defect, or they can focus on the manufacturer's conduct and prove a breach of the duty of care—or both. In theory, there is no reason why a plaintiff who suffers harm as a proximate result of a manufacturer's breach of the duty of reasonable care should be

denied relief merely because the product that was the direct cause of harm did not satisfy the legal definition of "defective."

That said, Gilead's argument that proof of a defect is a necessary element of a negligence claim for injury from a product is not new to the law. The same argument was made, although not resolved, early in the development of strict liability law in *Hasson v. Ford Motor Co.* (1977) 19 Cal.3d 530 (*Hasson*). The plaintiff there was injured when the brakes failed on his four-year-old car. (*Id.* at p. 536.) The jury concluded that the car was not defective at the time it was sold, but it found the manufacturer liable in negligence. (*Id.* at p. 539.) The manufacturer argued that the jury's verdict was fatally inconsistent because "strict liability based upon a 'defect' of design or manufacture encompasses all of the conceptual bases which would give rise to a traditional common law liability for negligence of a manufacturer. In effect, the newer law subsumes the old. Accordingly, . . . a special finding that there was no 'defect' obviates any finding of 'negligence.' " (*Id.* at p. 540.) Unfortunately for our present purposes, the Supreme Court declined to "examine in detail the abstract legal relationship between the terms 'defect' and 'negligence' " and did not render a ruling on the manufacturer's argument. (*Ibid.*)[8] Since *Hasson*,

[8] *Hasson* did conclude that the jury's finding of no defect at the time the car was manufactured did not preclude a finding of negligence liability, but it did so by construing the negligence claim in a way that did not involve design. The court reasoned that, in light of the instructions given, the jury could have concluded "that the braking system and the fluid were, at the

no California case appears to have expressly considered the issue before us.[9] Nonetheless, a variety of cases demonstrate, contrary to Gilead's argument, that a manufacturer's duty of reasonable care can extend more broadly than the duty to make a non-defective product, thereby permitting recovery even when there is no showing that the injury resulted from a product defect.

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outset, sound and fit for their intended purpose," giving rise to the finding of no defect, "but that Ford was nonetheless liable for its failure during the ensuing four years to warn of conditions which might develop in use." (*Hasson, supra*, 19 Cal.3d at p. 543.) The court pointed out that, while the instructions *permitted* the jury to construe Ford's failure to warn as a product defect, they did not *require* it to do so, and thus the failure to warn could have been the predicate for the jury's negligence finding without also leading to a finding of defect. (*Ibid.*)

[9] In *Toner v. Lederle Laboratories* (9th Cir. 1987) 828 F.2d 510, 513 (*Toner*), the Ninth Circuit held, based on the Idaho Supreme Court's answers to certified questions (see *Toner v. Lederle Laboratories* (1987) 112 Idaho 328, 330), that under Idaho law the jury's verdict absolving the vaccine manufacturer under strict liability was not fatally inconsistent with its verdict finding it liable in negligence. The court concluded that the jury could have found that the vaccine that harmed the plaintiff was not defective, while also finding the manufacturer negligent for failing to develop an alternative, safer vaccine of which it was aware. (*Toner*, 828 F.2d at p. 513; but see, e.g., *Burton v. E.I. du Pont de Nemours and Co., Inc.* (7th Cir. 2021) 994 F.3d 791, 817–819 [concluding that, under Wisconsin law, a negligence claim requires proof of a defect].) In a federal case arising out of the same facts at issue here, the court recently "reject[ed] Gilead's argument to the extent it asserts it cannot be held liable for negligence if it is not liable under a strict-liability theory," but the question there was whether certain states require a plaintiff asserting a negligence claim to prove that the product was "unreasonably dangerous." (*Holley v. Gilead Sciences, Inc.* (N.D.Cal. Sept. 28, 2023, No. 18-cv-06972-JST) 2023 U.S. Dist.Lexis 176115, at *61–*62.)

The most prominent such case is *Mexicali Rose v. Superior Court* (1992) 1 Cal.4th 617 (*Mexicali Rose*), which considered whether restaurants can be held liable for injury caused by a naturally occurring substance in their food—there, a chicken bone in a chicken enchilada. (*Id.* at p. 620.) In its analysis, the Supreme Court first summarized the prevailing rule: "If the injury-producing substance is natural to the preparation of the food served, it can be said that it was reasonably expected by its very nature and the food cannot be determined to be unfit for human consumption or defective." (*Id.* at p. 630.) "Thus," the court concluded, "a plaintiff in such a case has no cause of action in implied warranty or strict liability." (*Id.* at pp. 630–631.)

The inability to prove a defect, however, was not fatal to a plaintiff's recovery for injury caused by a naturally occurring substance. Plaintiffs may still, the court held, assert a claim for negligence and prove that the presence of the substance resulted from the restaurant's failure to exercise ordinary care in preparation of the non-defective dish. As the court confirmed, "[t]he expectations of the consumer do not, however, negate a defendant's duty to exercise reasonable care in the preparation and service of the food. Therefore, if the presence of the natural substance is due to a defendant's failure to exercise due care in the preparation of the food, an injured plaintiff may state a cause of action in negligence." (*Mexicali Rose, supra*, 1 Cal.4th at p. 631.)

Mexicali Rose expressly rejected the argument that a restaurant's liability should be limited to food classified as

defective under the law of strict liability, thereby barring any claim for recovery "when a substance natural to the preparation of the food product has caused injury." (*Mexicali Rose, supra*, 1 Cal.4th at p. 632.) The court reasoned that allowing a cause of action for negligence "corresponds to modern developments in tort law," including "our modern emphasis on Civil Code section 1714." (*Ibid*.) "[W]e believe it is a question for the trier of fact to determine whether the presence of the injury-producing substance was caused by the failure of the defendants to exercise reasonable care in the preparation of the food, and whether the breach of the duty to exercise such care caused the consumer's injury." (*Id*. at p. 633.)

Although *Mexicali Rose* did not expressly consider the issue raised by Gilead—the need to prove a defect to recover for harm caused by a product—its holding effectively resolves the claim. *Mexicali Rose* holds 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. And although the decision arose in the atypical context of restaurant "products," it does not suggest that its ruling is limited to that context, and Gilead, when asked to address the decision at oral argument, provided no justification for restricting the decision to food products. Importantly, *Mexicali Rose* illustrates the continued utility of the negligence cause of action in products liability actions. Although the legal concept of a "defect" is extraordinarily useful, it should not in every case constitute the

outer boundary of a manufacturer's liability for its conduct. 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."

The Courts of Appeal have also permitted recovery under claims of negligence in the absence of a defect. (See, e.g., *Lunghi v. Clark Equipment Co.* (1984) 153 Cal.App.3d 485 (*Lunghi*); *Hernandez v. Badger Construction Equipment Co.* (1994) 28 Cal.App.4th 1791 (*Hernandez*).) The plaintiff's decedent in *Lunghi* was killed by a machine manufactured several years earlier. The jury entered judgment for the defendant, finding no defect in the product's design. (*Lunghi*, at p. 489.) The Court of Appeal reversed, concluding the trial court had erred in refusing to instruct on negligence. (*Id.* at p. 491.) As the court explained, "[e]ven if, properly instructed, the jury had found that none of the mechanical design features in issue . . . constituted a defect, it could still have found that [the defendant's] knowledge of the injuries caused by these features imposed a duty to warn of the danger, and/or a duty to conduct an adequate retrofit campaign. A finding that [defendant] had not met the standard of reasonable care with regard to either of these duties would have had some support in the evidence, and would have been consistent with a finding that the product's design was not defective." (*Id.* at p. 494, italics omitted.) To similar effect is

Hernandez, which also involved an injury from heavy equipment manufactured several years prior. Although the jury found against the plaintiff on the issue of design defect (*Hernandez*, at p. 1802), the court affirmed a verdict of negligence on the theory that the manufacturer, once it began offering as standard equipment a safety device that would have prevented the plaintiff's injury, could be found liable under a duty to take reasonable steps to prevent injury to users of earlier models lacking the device. (*Id*. at p. 1828.)

Gilead argues that *Hernandez* and *Lunghi* are inapposite because, in its view, they stand only for the proposition that a product can be free of defects at the time it is manufactured and sold, but can "become defective," for example as a result of technological developments or new information or understanding. Neither case, however, 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. Whether or not the products could have been characterized as "defective" at the time of the plaintiffs' injuries, the plaintiffs did not have to prove that they were, and the characterization is legally irrelevant to a finding of negligence liability.

In short, although the utility of a cause of action for negligence in products liability actions has been greatly reduced by the doctrine of strict liability, it has not been eliminated. In those circumstances in which a manufacturer's duty of reasonable care properly extends beyond the duty not to market a

defective product, a claim for negligence continues to provide a remedy.

We are not persuaded by Gilead's arguments to the contrary. Gilead relies on isolated language from a variety of decisions that characterize products liability law as premised on the existence of a defect. Because the doctrine of strict liability provides the rule of law for the vast majority of products liability cases, this is an understandable generalization. As the Supreme Court has had frequent reason to observe, however, " ' " 'cases are not authority for propositions not considered.' " ' " (*Geiser v. Kuhns* (2022) 13 Cal.5th 1238, 1252.) The mere fact that a decision contains language that can be construed to suggest that a defect is a sine qua non for recovery against a manufacturer does not make the decision authority for that proposition unless the issue has been considered and the conclusion embraced. (*Id.* at p. 1252 [the cited case "is not controlling because that issue was not presented in [the case]"].)

Merrill v. Navegar, Inc.

Gilead places primary reliance on *Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465 (*Merrill*), which considered the connection between claims of negligent and defective design in construing former Civil Code section 1714.4. That statute, repealed in 2002 (Stats. 2002, ch. 906, § 2), prohibited recovery against gun manufacturers on a classic risk/benefit theory of design defect.[10]

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[10] Former Civil Code section 1714.4, subdivision (a), read: "In a products liability action, no firearm or ammunition shall be deemed defective in design on the basis that the benefits of the

(*Merrill*, at p. 470.) The plaintiffs attempted to avoid the bar of former section 1714.4 by alleging that semi-automatic assault pistols were *negligently* designed "because, given their particular characteristics, the benefits of making them available to the general public—which were nonexistent—did not outweigh the risk they might inflict serious injury or death when discharged." (*Ibid.*)

In rejecting the attempt, the court recognized that a plaintiff in a products liability action can recover under theories of both strict liability and negligence. (*Id.* at p. 478.) In a products liability action based on negligence *in the design of a product*, however, "the test of negligent design 'involves a balancing of the likelihood of harm to be expected from a machine with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm.' " (*Id.* at p. 479.) "Thus," the court observed, " 'most of the evidentiary matters' relevant to applying the risk/benefit test in strict liability cases 'are similar to the issues typically presented in a negligent design case.' " (*Id.* at p. 480.) Although the plaintiffs argued "that they seek to hold [the defendant] liable for 'negligent conduct, not for making a defective product,' " the court found the distinction immaterial because "in asserting that the [assault pistol] had a 'negligent design' and that [the defendant] 'negligently designed' it, plaintiffs have in fact alleged that the

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product do not outweigh the risk of injury posed by its potential to cause serious injury, damage, or death when discharged." (*Merrill, supra*, 26 Cal.4th at p. 478.)

[assault pistol] is, in the words of [former] section 1714.4, subdivision (a), 'defective in design.' " (*Ibid.*) The court rejected the plaintiffs' effort to recast the claim as one for "negligent distribution to the public," because it was already implicit in negligence and strict liability theories of products liability that the manufacturer was in the business of distributing goods to the public. (*Id.* at p. 481.) Therefore, the court concluded, the plaintiffs' allegation that the defendant made the assault pistol available to the general public "adds nothing to the standard products liability action." (*Ibid.*)

As this summary suggests, *Merrill* did not consider whether *every* negligence claim against a manufacturer must include proof of a defect. Rather, it concluded that, regardless of how the plaintiffs labeled it, the gravamen of their purported negligence claim was that the assault pistol "was defective in design because the risks of making it available to the general public outweighed the benefits of that conduct, and that defendants knew or should have known this fact." (*Merrill, supra*, 26 Cal.4th at p. 481.) This is not a holding that every negligence claim to recover for injuries from a product (unless based on failure to warn or manufacturing defects) is necessarily one for negligent design, measured by one of *Barker*'s two tests for design defects.

In arguing for a broader interpretation of *Merrill*, Gilead relies on the decision's introductory summary of the law of products liability: "As Professors Prosser and Keeton explain, 'Products liability is the name currently given to the area of the

law involving the liability of those who supply goods or products for the use of others to purchasers, users, and bystanders for losses of various kinds resulting from so-called defects in those products.' [Citation.] As relevant here, a plaintiff may seek recovery in a 'products liability case' either 'on the theory of strict liability in tort or on the theory of negligence.' [Citations.] The rules of products liability 'focus responsibility for defects, whether negligently or nonnegligently caused, on the manufacturer of the completed product.' [Citation.] Thus, *under either a negligence or a strict liability theory of products liability, to recover from a manufacturer, a plaintiff must prove that a defect caused injury*. [Citations.] Under a negligence theory, a plaintiff must also prove 'an additional element, namely, that the defect in the product was due to negligence of the defendant.' " (*Merrill, supra*, 26 Cal.4th at pp. 478–479, italics added.) Read in isolation, the italicized language from *Merrill* certainly supports, if not flatly confirms, Gilead's legal theory.

We decline to find *Merrill* controlling on this issue for three reasons. First, as explained above, the requirement of a defect in every products liability case was not an issue actually considered in *Merrill*. Rather, the court addressed only whether the legal test for negligent design overlapped with the test for defective design in such a way that the plaintiffs could not evade a ban on recovery under a theory of design defect by alleging negligent design.

Second, the authority cited by *Merrill* in its summary of the law did not consider this issue, either. The primary authority

was an early law review article on products liability law by Professor William Prosser, which was published only three years after California adopted strict products liability in *Greenman*—well before the doctrine's legal framework was well defined. (Prosser, *Strict Liability to the Consumer* (1966) 18 Hastings L.J. 9.) The cited portion of the article did not purport to opine on the requirements of a negligence claim in products liability actions; the point was that the evidence supporting a claim of defect under strict liability "does not appear to differ in any significant respect from the proof of negligence." (*Id*. at p. 50.) The California cases cited by *Merrill* as authority, *Jiminez, supra*, 4 Cal.3d 379, and *Cronin, supra*, 8 Cal.3d 121, are similarly beside the point. *Cronin* considered whether a plaintiff alleging defective design must demonstrate that the alleged defect made the product "unreasonably dangerous" and ultimately rejected this element. (*Id*. at pp. 132–134.) *Jiminez* held that a trial court erred in refusing to instruct the jury on negligence and res ipsa loquitur in a products liability case. (*Jiminez, supra*, 4 Cal.3d at pp. 384–387.) Neither decision holds that a plaintiff alleging negligence in a products liability action must in every case prove a product defect; although *Jiminez* adopted, without discussion, defendant's assertion that proof of a defect was required, it explained that "under the facts of the case before us instructions on negligence would serve the plaintiff better than instructions on defect in several respects," suggesting the jury

might have found the manufacturer liable in negligence without finding the product defective. (*Id.* at pp. 383–384.)[11]

Third, accepting *Merrill* as controlling authority on this point would require a conclusion that the decision was intended to overrule, sub silentio, the various cases discussed above that permit a negligence claim to proceed in the absence of proof of a product defect. There is simply no indication that *Merrill* intended such a change.

Although Gilead does not expressly distinguish the argument, it also contends that, even if *Merrill* does not establish that proof of a defect is required in every case, the court's analysis demonstrates that plaintiffs here are likewise asserting a claim for negligent design, and only repudiate the label in an effort "to avoid their concession that the TDF medications are not defective." As an initial matter, plaintiffs' decision to forgo a claim that TDF is defective is not a concession that TDF is not defective. (Cf. *Toner, supra*, 828 F.2d at p. 513 ["We decline to treat Toner's litigation decision not to pursue the warning theory

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[11] The plaintiff was injured by a ladder that broke while he was using it on the cement floor of his garage. He had tried to use it only once previously to prune a tree but stopped because the ground was too muddy. (*Jiminez, supra*, 4 Cal.3d at p. 381.) There was some evidence that the ladder may have broken because its previous use on soft soil caused the load on its legs to be unevenly distributed. (*Id.* at p. 382.) The court opined that a jury instructed on negligence might have found the manufacturer liable for failing to warn that the ladder should not be used on soft ground, but if instructed only on strict products liability, could have concluded that the ladder was not defective because it was safe for use on hard ground, even if use on soft ground would be considered a normal use of the product. (*Id.* at p. 385.)

as if it were a stipulation that Toner had adequate warning"].) And in any event, we find plaintiffs' claim to be significantly different from the negligence claim in *Merrill*. Plaintiffs do not contend that Gilead was negligent because it made TDF available for sale, or because the risks of TDF outweighed its benefits. Rather, they contend that Gilead breached its duty of reasonable care by postponing, solely to maximize profit, its effort to commercialize TAF as a treatment for HIV/AIDS while continuing to market a medication with serious side effects that it knew TAF would have enabled patients to avoid.

Unlike in *Merrill*, we cannot say that these allegations "add[] nothing to the standard products liability action." (*Merrill, supra*, 26 Cal.4th at p. 481.) Gilead's alleged financially motivated deferral of the development of TAF for seven years, despite its recognition of TAF's superiority, is discrete conduct independent of the design and marketing of TDF. For this reason, plaintiffs' cause of action, unlike a typical negligent design case, will focus on "the reasonableness of the manufacturer's conduct," rather than "the condition of the product itself." (*Barker, supra*, 20 Cal.3d at p. 434.)

Brown v. Superior Court

Gilead also relies on *Brown, supra*, 44 Cal.3d 1049, which held that prescription drugs are exempt from strict liability claims of defective design pursuant to comment k to section 402A of the Restatement Second of Torts, pages 353–354. (*Brown*, at

p. 1061.)[12] The court did not exempt prescription drugs from such claims because it concluded that prescription drugs cannot be defectively designed. On the contrary, as the court recognized, the design of a prescription drug might be found defective under the risk/benefit test if, for example, the plaintiff demonstrates that a particular component of the drug rendered it unsafe and that removal of that component would not have affected the efficacy of the drug or if other, less harmful drugs were available to treat the same condition. (*Id*. at p. 1062.) Rather, the court's decision was grounded in public policy concerns. Subjecting prescription drug manufacturers to strict liability for design defects, the court worried, might discourage drug development or inflate the cost of otherwise affordable drugs. (*Id*. at p. 1063.)

Gilead points to the first two sentences of *Brown*'s footnote 12, which read as follows: "Our conclusion does not mean, of course, that drug manufacturers are free of all liability for defective drugs. They are subject to liability for manufacturing defects, as well as under general principles of negligence, and for failure to warn of known or reasonably knowable side effects." (*Id.* at p. 1069, fn. 12.) According to Gilead, the first sentence establishes that "a defect is a necessary precondition of any such suit."

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[12] Section 402A of the Restatement Second of Torts governs claims for strict products liability; comment k exempts from such claims "unavoidably unsafe products," which the comment defines as "products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." (Rest.2d Torts, § 402A, com. k, pp. 353–354; *Brown, supra*, 44 Cal.3d at p. 1058.)

As with *Merrill*, however, the court in *Brown* was not considering whether every claim against a manufacturer of prescription drugs must prove that the drug was defective. The "conclusion" to which the first sentence of footnote 12 refers is the court's holding that "a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution." (*Brown, supra*, 44 Cal.3d at p. 1069.) Since the existence of a defect is the sine qua non of strict products liability—and the plaintiffs alleged that the drug was defective (*id.* at p. 1055)—it is not surprising that the court referred to manufacturers of "defective drugs" when explaining that its holding about strict liability did not exempt them from liability on other grounds. Those words reflect the issue before the court. Because the court had no occasion to consider any claim that was not premised on a defect, in context the sentence cannot be read to mean that every viable claim against a prescription drug manufacturer requires proof that the drug was defective.

Gilead further contends that the reference to "general principles of negligence" in the second sentence of the footnote could only mean claims for negligent design defect, which here plaintiffs have abandoned. It is true that footnote 12 has been read to preserve claims for negligent design defect in light of the court's rejection of strict liability design defect claims. (See, e.g., *Garrett v. Howmedica Osteonics Corp.* (2013) 214 Cal.App.4th

173, 182; *Artiglio v. Superior Court* (1994) 22 Cal.App.4th 1388, 1393.) But even if the court had in mind claims of negligent design defect, again the context of the footnote prevents us from construing it to say that no other negligence claims are cognizable. Nothing in the case presented that question.

Gilead also suggests that *Brown*'s reasoning may call into question some aspects even of negligent design defect claims insofar as the court's policy concerns about evaluating the merits of a drug's design are relevant whether the claim is based in strict liability or negligence.[13] It is unnecessary for us to explore this issue in depth given plaintiffs' disavowal of a design defect claim, and we again note that we do not view the negligence claim here as a disguised claim that TDF, at the time of its distribution to plaintiffs, was negligently designed. Not only does the claim require the trier of fact to consider conduct independent of TDF's design—Gilead's alleged recognition of TAF's superiority and its reasons for pausing development—but even as to TDF's design, the claim does not depend on an evaluation of the risks

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[13] Gilead echoes an argument expressed by some commentators that there is a tension between *Brown*'s preservation of claims for negligent design defect and its rejection (*Brown, supra*, 44 Cal.3d at pp. 1066–1068) of the case-by-case approach to the application of comment k adopted in *Kearl v. Lederle Laboratories* (1985) 172 Cal.App.3d 812. (See Conk, *Is There A Design Defect in the Restatement (Third) of Torts: Products Liability?* (2000) 109 Yale L.J. 1087, 1125–1126; O'Neill, Jr., *Unavoidably Unsafe Products and the Design Defect Theory: An Analysis of Applying Comment K to Strict Liability and Negligence Claims* (1989) 15 Wm. Mitchell L.Rev. 1049, 1061–1062 & fn. 90.)

and benefits of TDF as an HIV/AIDS medication, as would be necessary in a claim for negligent design. Although the characteristics of TDF as a medication are central to plaintiffs' claim, these characteristics will not be evaluated in the abstract to determine, on balance, whether TDF should have been marketed at all. The risks and benefits of TDF *relative to each other* are irrelevant to plaintiffs' claim, which does not call into question Gilead's decision to market TDF. On the contrary, plaintiffs' claim is entirely consistent with a conclusion that the benefits of TDF use for hundreds of thousands of HIV/AIDS sufferers have vastly exceeded the harm from its side effects. Rather, the critical question for plaintiffs' purposes is simply whether Gilead's years-long delay in bringing TAF to market, despite knowing its equivalent efficacy and superior safety to TDF, breached a duty of reasonable care to users of TDF if the reason was solely to maximize Gilead's profits. Such a claim is meaningfully different from the abstract consideration of risks and benefits central to a claim of negligent design.

Other Cases

Although a lengthy discussion is not required, the other cases Gilead cites similarly do not stand for the proposition that any negligence claim in the products liability context requires proof of a defect. Gilead points to the Supreme Court's statement in *Soule, supra*, 8 Cal.4th at page 568, footnote 5, that manufacturers "are liable in tort only when 'defects' in their products cause injury." But the court was not considering any question about negligence liability or its scope; the question

before it was whether a jury should be instructed on *Barker*'s "consumer expectations" test for product defect in every case, or whether in some cases only the risk/benefit test is appropriate. (*Soule*, at p. 568.) The statement quoted by Gilead came in a footnote responding to an argument that "any limitation on use of the consumer expectations test contravenes *Greenman*'s purpose to aid hapless consumers," and the court's point was simply that strict liability is not unlimited. (*Id.* at p. 568, fn. 5.)

Likewise, Gilead's reliance on *Milwaukee Electric Tool Corp. v. Superior Court* (1993) 15 Cal.App.4th 547 ignores its context. In suggestive introductory language quoted by Gilead, *Milwaukee Tool* states, "we conclude Milwaukee owes a general duty to produce defect-free products, which translates into a duty similar to that in negligence law not to depart from the appropriate standards of care in manufacturing its product." (*Id.* at p. 551.) The issue actually considered in *Milwaukee Tool*, however, was the application of a then-recent Supreme Court decision concerning the defenses of assumption of the risk and comparative fault. (*Id.* at pp. 550, 559–564.) Although the court discussed the relationship between strict liability and negligence (*id.* at pp. 555–559), the discussion occurred entirely in this context. *Milwaukee Tool* did not consider whether a claim for negligence could be asserted in the absence of a product defect.

Accordingly, we conclude that plaintiffs' negligence claim is not foreclosed by their decision to forgo any attempt to prove that TDF is defective.[14]

B. New Duty Versus Exception to Existing Duty

We pause here to consider the parties' dispute about the proper legal framework for analyzing plaintiffs' negligence claim, since it is relevant to how we proceed in light of our conclusion in the preceding subsection. According to Gilead, the question is whether plaintiffs can establish a "new" duty—one that would impose further obligations on manufacturers that have produced a non-defective prescription drug. According to plaintiffs, the duty they are invoking is simply the one imposed on all persons by section 1714, so the question is whether Gilead can establish that an exception to that duty is warranted under the *Rowland* factors. Both in the trial court, and originally in these writ proceedings, Gilead's view of the proper question led it to disavow any invocation of *Rowland*, citing the Supreme Court's explanation that "[t]he multifactor test set forth in *Rowland* was not designed as a freestanding means of establishing duty, but instead as a means for deciding whether to limit a duty derived from other sources." (*USA Taekwondo, supra*, 11 Cal.5th at p. 217.)

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[14] Although plaintiffs now disavow any intent to prove negligent design, we agree with Gilead that the trial court's ruling was in error to the extent it suggested plaintiffs can pursue a claim for negligent design without proving the equivalent of a design defect. Plaintiffs do not argue otherwise on appeal.

Gilead's position has some logical appeal if one accepts the premise that, in the products liability context, the duty section 1714 imposes on a manufacturer is simply to ensure that any product it offers for sale is not defective. In that case, plaintiffs would have to identify a proper basis for the imposition of a greater duty.[15] Because we have disagreed with the premise, however, we are unpersuaded that the burden lies with plaintiffs to establish the existence of a duty beyond that imposed by section 1714.

In arguing that plaintiffs should be required to establish the existence of a new duty, Gilead relies on cases that concern the existence of a duty to protect against harm from third parties. (E.g., *USA Taekwondo, supra*, 11 Cal.5th at p. 215; *Golick v. State of California* (2022) 82 Cal.App.5th 1127, 1140.) In that context, there must be a "special relationship" between the plaintiff and the defendant to give rise to a duty; the duty cannot be created through application of the *Rowland* factors. (*USA Taekwondo*, at pp. 216–222.) But the reason for requiring a special relationship is that "the law imposes a general duty of care on a defendant only when it is the defendant who has

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[15] Plaintiffs argue that Gilead can be held liable under a "negligent undertaking" theory. (See *Artiglio v. Corning Inc.* (1998) 18 Cal.4th 604, 612–614.) Gilead responds, first, that this theory is waived both because it was not pled in the complaint and because plaintiffs failed to raise it in response to Gilead's summary judgment motion, and second, that it fails on the merits in any event. We do not address these arguments given our conclusion that Gilead has not established its entitlement to summary adjudication under an "ordinary negligence" theory pursuant to section 1714.

‘ “created a risk” ’ of harm to the plaintiff, including when ‘ “the defendant is responsible for making the plaintiff’s position worse.” ’ ” (*Id.* at p. 214.) Here, Gilead itself created the risk of harm to plaintiffs by selling TDF, a drug with harmful side effects, making inapposite the cases on which Gilead relies.[16]

Gilead also argues that its conduct, which it characterizes as the failure to bring a product to market, constitutes nonfeasance, rather than misfeasance, and quotes *USA Taekwondo*’s observation that the law is “ ‘reluctan[t] to impose liability’ ” for nonfeasance. (*USA Taekwondo, supra*, 11 Cal.5th at p. 214.) The court’s observation, however, was made in support of the general rule that a party has no duty to prevent harm by a third person, and was not a ruling that a party’s failure to act cannot constitute a breach of the duty of reasonable care. As the court clarified in a footnote, “[a]lthough our precedents have sometimes referred to the distinction between ‘misfeasance’ and ‘nonfeasance,’ we now understand this terminology to be imprecise and prone to misinterpretation. ‘The proper question is not whether an actor’s failure to exercise reasonable care entails the commission or omission of a specific act.’ [Citation.] Rather, it is ‘whether the actor’s entire conduct created a risk of harm.’ ” (*Id.* at p. 214, fn. 6.) We are satisfied that, in this case, that question can be answered affirmatively, and accordingly that Gilead must establish that an exception to

[16] The fact that Gilead was the manufacturer of both drugs is also an essential element of its alleged motivation for delaying the commercialization of TAF and breaching its duty of care.

the imposition of a duty of care is warranted under the *Rowland* factors.

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. However, in its response to our request, Gilead urged us to decide the applicability of a *Rowland* exception if we concluded that it furnished the proper framework for analyzing the claimed duty. Given the posture in which the case has come to us—on writ review of the denial of Gilead's summary judgment motion—we believe that, to avoid to the extent possible the need for piecemeal adjudication and to provide guidance for the parties and the trial court, it is appropriate to exercise our discretion to address the *Rowland* factors to the extent the record permits us to do so.

C. Application of the *Rowland* Factors

In *Rowland*, the California Supreme Court "identified several considerations that, when balanced together, may justify a departure from the fundamental principle embodied in Civil Code section 1714." (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 771 (*Cabral*).) The *Rowland* analysis "is conducted 'at a relatively broad level of factual generality.' [Citation.] We analyze the *Rowland* factors to determine 'not whether they support an exception to the general duty of reasonable care on the facts of the particular case before us, but whether carving out an entire category of cases from that general duty rule is justified by clear considerations of

policy.' " (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1021 (*Kuciemba*).) "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. . . . While the court deciding duty assesses the foreseeability of injury from 'the category of negligent conduct at issue,' if the defendant did owe the plaintiff a duty of ordinary care the jury 'may consider the likelihood or foreseeability of injury in determining whether, in fact, the particular defendant's conduct was negligent in the first place.' " (*Cabral*, at p. 773.)

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, supra*, 1 Cal.5th at p. 1145). Issues related to foreseeability are assessed on the basis of information available at the time of the alleged negligence, while " 'our duty analysis is forward-looking' in regard to policy issues surrounding burdens that would be placed on defendants." (*Kuciemba, supra*, 14 Cal.5th at p. 1022.)

1. Gilead's Proposed Expansive Exception

In requesting a *Rowland* exception to the duty of section 1714, Gilead proposes two alternatives. The first, the more expansive exception, would hold that when an FDA-approved prescription drug is accompanied by an adequate warning of its side effects, and is not shown to be defective in design or manufacture, the manufacturer does not owe users of the current drug a duty of reasonable care in its decisions about commercializing any alternative drug the manufacturer might invent. We emphasize that it is a necessary premise of this analysis that the same manufacturer has developed *both* drugs. As discussed above, the manufacturer's duty with respect to any alternative drug arises only because its sale of the first drug has created the risk of harm. (See *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 342 (*O'Neil*) ["a product manufacturer may not be held liable . . . for harm caused by another manufacturer's product unless the defendant's own product contributed substantially to the harm, or the defendant participated substantially in creating a harmful combined use of the products"].)

Because plaintiffs assert that Gilead knew TAF was safer than TDF, we also conduct the *Rowland* analysis under the assumption that the drug manufacturer knows that the alternative drug is safer than (and at least as effective as) the current drug. As noted earlier, we offer no opinion about whether plaintiffs should be permitted to argue constructive knowledge on remand, assuming they were to seek to do so, but we think a

different *Rowland* analysis would be required for a claim based on constructive knowledge. Among other things, a constructive knowledge standard would be more susceptible to hindsight bias by the jury, and would therefore present more challenging policy issues than in a case in which no duty arises in the absence of proof that the manufacturer knew it had developed a safer and at least equally effective alternative.

i. Foreseeability factors

The first three *Rowland* factors are commonly referred to as the foreseeability factors: "the foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, and the closeness of the connection between the defendant's conduct and the injury suffered." (*Rowland, supra*, 69 Cal.2d at p. 113.) Again, we evaluate these factors on the basis of information available at the time of the alleged negligence. (*Kuciemba, supra*, 14 Cal.5th at p. 1022.) In considering foreseeability, we focus not on particularities of the defendant's conduct and the plaintiff's injury, but on "whether the category of negligent conduct at issue is sufficiently likely to result in the kind of harm experienced that liability may appropriately be imposed . . . ." (*Cabral, supra*, 51 Cal.4th at p. 772.)

Foreseeability of injury. Of the seven *Rowland* factors, the foreseeability of harm to a plaintiff from the defendant's conduct is "[t]he most important factor to consider in determining whether to create an exception to the general duty to exercise ordinary care articulated by section 1714." (*Kesner, supra*, 1 Cal.5th at p. 1145.)

In any case involving a drug with a proper warning of side effects, it is a given that injury from side effects is foreseeable. We agree with Gilead, however, that in this context the relevant question is whether it is foreseeable that the new, safer, drug would enable users to avoid the injury. Gilead posits several considerations that it contends weigh against foreseeability, such as the degree to which the new drug avoids side effects, the relative efficacy of the new drug, and any additional side effects of the new drug. However, because Gilead's proposed expansive exception would impose no duty of care notwithstanding the manufacturer's knowledge that the new drug is at least equally effective and poses a lower risk of side effects, we think it is foreseeable that the manufacturer's delay in commercializing the new drug will cause some users to suffer injury they could have avoided had the new drug been available. Although the factors Gilead identifies affect the extent of harm that will be anticipated, and therefore will factor into any evaluation of the reasonableness of the manufacturer's conduct, they do not alter the conclusion that Gilead's proposed expansive exception will result in foreseeable injury. Speaking generally, as we must in applying *Rowland*, Gilead's proposed expansive exception, which would permit manufacturers to delay the release of a safer drug indefinitely, will make otherwise avoidable injury foreseeable.

Degree of certainty that the plaintiff suffered injury. "The second *Rowland* factor, the degree of certainty that the plaintiff suffered injury, 'has been noted primarily, if not exclusively, when the only claimed injury is an intangible harm such as

emotional distress.' " (*Kesner, supra*, 1 Cal.5th at p. 1148.) Because we assume the existing drug creates identifiable and characteristic physical injury, the fact of injury is certain.

Closeness of the connection between the defendant's conduct and the injury. This factor is "strongly related to the question of foreseeability itself." (*Cabral, supra*, 51 Cal.4th at p. 779.) The premise of our analysis is that some patients will suffer the warned-of side effects associated with the existing drug and the manufacturer knows that the alternative drug would allow some of those patients to avoid them. We therefore find the connection close even though, as Gilead points out in its foreseeability analysis, there are two additional steps in the causal chain that are necessary in order for patients to avoid the harm: first, the FDA must approve the alternative drug candidate, and second, the patient's doctor must decide to switch the patient to the new medication after it is approved. Of the two, we view the second consideration as less significant because once the FDA has approved an alternative that is safer and at least equally effective for the patient concerned, the manufacturer would reasonably expect doctors to prescribe the new medication in place of the old. (Cf. *T.H., supra*, 4 Cal.5th at p. 167 [close connection where defective label led doctor to prescribe the drug].)

As to the question of FDA approval, we do not doubt that there is often considerable uncertainty associated with it. While plaintiffs' claim here was brought after the FDA approved TAF, hindsight bias should not be permitted to affect the analysis.

Plaintiffs do not dispute the assertion by Gilead and its amici that, of medicines entering clinical trials, fewer than one out of eight will obtain FDA approval. However, because we are considering a categorical exception that would apply at any point in the development process to a drug candidate that the manufacturer knows to be as effective as, and safer than, an existing drug, these two common grounds for denial of FDA approval are likely to be adequately addressed. That makes FDA approval far less uncertain than might otherwise be the case.[17]

While the record does not tell us whether the example of TAF is typical, plaintiffs emphasize that TAF was another form of the known compound tenofovir; Gilead made its decision to pause development after TDF had already been approved by the FDA, and after Gilead had the results of its Phase I/II testing of TAF. Plaintiffs contend that Gilead knew FDA approval of TAF would not be difficult, and their allegation that Gilead was motivated by its concern that TAF would cannibalize sales of TDF and believed it could maximize profitability by extending the life of its tenofovir patents necessarily assumes as much. Nothing in the record presented to us establishes that drug

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[17] Some commentators have argued that any design defect claim that requires a court to predict whether the FDA would approve what a plaintiff proposes as a "reasonable alternative design" of the allegedly defective drug is unworkable given the uncertainty involved. (See, e.g., Twerski, *The Demise of Drug Design Litigation: Death by Federal Preemption* (2018) 68 Am. U. L.Rev. 281, 295.) We do not see the same uncertainty, at least as a categorical matter, in a situation in which the manufacturer has developed an alternative drug that it knows to be safer than its original 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. Drug manufacturers' decisions about whether to continue to pursue commercialization of a drug are presumably informed in part by their assessment of the likelihood of FDA approval; Gilead does not argue to the contrary. We are not persuaded that the need for FDA approval necessarily renders the harm unforeseeable or severs what would otherwise be a close connection between the manufacturer's decisions and the patients' harm.

Finally, citing *O'Neil, supra*, 53 Cal.4th at p. 365, Gilead argues that we should not find a close connection because the alleged negligent conduct is not the manufacturer's sale of the injurious product, i.e., the existing drug. But *O'Neil* concerned the circumstances under which a manufacturer could be held liable for injuries caused by products it did not manufacture, sell, or supply. That is not the situation we are considering here, and the fact that the alleged negligence is the decision to delay commercialization of the alternative drug rather than the sale of the existing, more dangerous drug does not make the connection between the negligent conduct and the injury remote where the manufacturer has control over the timing of the availability of the safer drug. (See *T.H., supra*, 4 Cal.5th at p. 168 [distinguishing *O'Neil* based on brand-name drug manufacturer's control over the content of the label].)

Accordingly, the foreseeability factors weigh against Gilead's proposed expansive *Rowland* exception to the duty of reasonable care.

ii. Public policy factors

"[F]oreseeability alone is not sufficient to create an independent tort duty. ' " . . . [The] existence [of a duty] depends upon the foreseeability of the risk and a weighing of policy considerations for and against imposition of liability." ' " (*Erlich v. Menezes* (1999) 21 Cal.4th 543, 552.) "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." (*Cabral, supra*, 51 Cal.4th at p. 781; see *Merrill, supra*, 26 Cal.4th at p. 502 [foreseeability may be overcome "where the social utility of the activity concerned is so great, and avoidance of the injuries so burdensome to society, as to outweigh the compensatory and cost-internalization values of negligence liability"].)

The final four factors of the *Rowland* test are referred to as the "public policy factors" (*Cabral, supra*, 51 Cal.4th at p. 781): "the moral blame attached to the defendant's conduct, the policy of preventing future harm, 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, and the

availability, cost, and prevalence of insurance for the risk involved." (*Rowland, supra*, 69 Cal.2d at p. 113.)

Moral blame. Developing and selling a life-saving drug, even one with potentially severe side-effects, is morally praiseworthy. But that is not the conduct at issue; Gilead seeks an exception that would allow, in a sense, the opposite conduct: a manufacturer's decision not to market, or to delay marketing, a drug it invented that would avoid the harm caused by an existing drug that the manufacturer continues to sell. "We have 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 (*Vasilenko*).)

Moral blame is typically found when the defendant benefits financially from its conduct. (*Kuciemba, supra*, 15 Cal.5th at p. 1025; *Kesner, supra*, 1 Cal.5th at p. 1151.) In general, drug manufacturers reasonably expect to profit from the medicines they sell, and the 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.

In addition, "[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.' " (*Kuciemba, supra*, 15 Cal.5th at p. 1026.) Users of a particular medicine generally have no ability to avoid its harmful side effects. (*Brown, supra*, 44 Cal.3d at p. 1063.) 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. (Compare *Vasilenko, supra*, 3 Cal.5th at p. 1091 [finding little moral blame because "landowners have limited ability to reduce the danger and generally exercise no greater control over the danger than the invitees who cross" public streets] with *Kesner, supra*, 1 Cal.5th at p. 1151 [finding moral blame because "commercial users of asbestos benefitted financially from their use of asbestos and had greater information and control over the hazard than employees' households"].)

We can agree with Gilead that a manufacturer's decision to delay the commercialization of a safer drug may be made for morally neutral, or even worthy, reasons. But while we do not assume in considering the requested exception that any claimed violation of duty will involve the precise conduct that plaintiffs attribute to Gilead in this case, our 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. (See, e.g., *Kesner, supra*, 1 Cal.5th at p. 1151 ["negligence in their use of asbestos is morally blameworthy"]; *Regents of University of*

California v. Superior Court (2018) 4 Cal.5th 607, 631 ["Some measure of *moral blame* does attach to a university's negligent failure to prevent violence against its students"].) Gilead argues that we are concerned here only with drugs that are not shown to be defective and so should be considered "reasonably safe." But even putting aside what plaintiffs contend are increasingly insurmountable legal barriers to the assertion of design defect claims notwithstanding their substantive merit, a life-saving drug may be considered reasonably safe, in the sense that its risks are outweighed by its benefits, even when its side effects are grievously injurious. That such side effects are an acceptable trade-off when life is at stake does not mean that the manufacturer's decision to continue to subject patients to those injuries unnecessarily by delaying or withholding a safer alternative is morally unobjectionable.

In sum, although moral blame "can be difficult to assess in the absence of a factual record" (*Kesner, supra*, 1 Cal.5th at p. 1151), we conclude based on the considerations above that negligence in a decision that deprives people of a safer drug and leaves them reliant on a more dangerous drug is morally blameworthy.

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, supra*, 51 Cal.4th at p. 781.) For the purpose of the *Rowland* analysis, "[t]he 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." (*Id.* at pp. 781–782.) This factor thus "examines both the positive and the negative societal consequences of recognizing a tort duty." (*Kuciemba, supra*, 15 Cal.5th at p. 1026.)

Plaintiffs argue that recognizing a duty would result in speedier delivery of improved medications, whereas Gilead contends that the fear of liability or litigation would disincentivize manufacturers from undertaking the development of improved drugs in the first place, or would perversely skew their development priorities once they have produced some data suggesting that a drug candidate is safer.

Gilead purports to find support for its argument in *Brown*, because the court rejected strict liability out of a concern that it would make pharmaceutical manufacturers reluctant to undertake research projects to develop new drugs or to distribute others that are available to be marketed. (*Brown, supra*, 44 Cal.3d at p. 1063.) But as the court pointed out in its analysis, that possibility arises in significant part because strict liability makes manufacturers liable for unforeseen and unforeseeable harm. (See *id.* at pp. 1063–1064; see also *Carlin, supra*, 13 Cal.4th at p. 1117 [*Brown*'s policy-based rejection of strict liability for design defects was premised on the fact that it would "potentially subject drug manufacturers to liability for flaws in their products that they have not, and could not have, discovered"].) As we have discussed, the court expressly declined to protect them from claims based in negligence, in which the

harm must be foreseeable. (*Brown*, at p. 1069, fn. 12.)[18] Moreover, 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. (See, e.g., *Carlin, supra*, 13 Cal.4th at p. 1117; *T.H., supra*, 4 Cal.5th at p. 173; *Conte, supra*, 168 Cal.App.4th at p. 106.) It is similarly unsupported here.

Gilead elsewhere argues that the imposition of the duty plaintiffs propose is unnecessary, contending that "[i]f a drug manufacturer has a treatment that is much better or safer than what is already on the market, it has an economic imperative to bring it to market as soon as possible." Plaintiffs disagree, arguing that the patent system incentivizes drug manufacturers to try to extend their monopolies for as long as possible, with deleterious effects on innovation and competition. (See, e.g., Bernstein, *supra*, at pp. 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 Jan. 4, 2024].)

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[18] Plaintiffs also note that *Brown*'s categorical exemption for strict liability design defect claims is the minority view among courts that have adopted comment k (see *Moss v. Wyeth Inc.* (D. Conn. 2012) 872 F.Supp.2d 162, 167–168), and assert that fear of potential liability in other jurisdictions has not damaged the pharmaceutical industry. The significance of that point, however, may be diminished by what plaintiffs elsewhere describe as the substantial elimination of design defect claims by federal preemption.

Plaintiffs' argument supports a conclusion that the duty of care serves an important policy function, but even if we credit Gilead's suggestion that the duty aligns with economic imperatives that drug manufacturers already face, it would tend to undermine the hypothesis that imposition of the duty would radically alter their incentives to improve existing drugs or develop new ones. And again, we are considering here a duty that arises only with the manufacturer's knowledge that the alternative drug candidate it has invented is safer and would allow harm to be avoided. (See *T.H., supra*, 4 Cal.5th at p. 185 [policy of preventing future harm is furthered when the duty is placed on the entity with the power to act].) Moreover, although below we conclude that Gilead has not supported its proposed narrower exception on the existing record, the potential availability of a narrower exception militates against a conclusion that the broader one is necessary to avoid the undesirable social consequences that Gilead posits.

Finally, we emphasize that the duty of reasonable care does not require the pursuit of commercialization at all costs. Even if we assume that there will be some circumstances in which the duty causes a manufacturer to pursue a potentially safer product longer than it otherwise would have, resulting in some failed or wasted efforts, that loss must be weighed against the benefit to the community from successful efforts, which will result in safer products.

In short, we are not persuaded that Gilead has established that there are "undesirable consequences of allowing potential liability" (*Cabral, supra*, 51 Cal.4th at p. 782) that should

override the ordinary rule "imposing the costs of negligent conduct upon those responsible" in these circumstances (*id*. at p. 781).

The burden to the defendant and consequences to the community. Because the "consequences to the community" portion of this factor overlaps with our discussion of the policy of preventing future harm (cf. *T.H., supra*, 4 Cal.5th at pp. 168–173), we focus here on what Gilead contends will be an additional burden; namely, a flood of lawsuits because patients will contend that every improved medicine released by a manufacturer should have been made available sooner.

We think Gilead overstates the threat given the narrowness of the duty at issue. It does not apply generally to "improved" products, but only to products that the manufacturer knows will avoid significant side effects of a manufacturer's existing product. Gilead does not establish that this situation arises so frequently as to result in a flood of litigation. On the contrary, if this situation were common, the claim likely would have arisen long ago. Nor, contrary to Gilead's argument, will the duty upend products liability by creating a "perfect product" law. As we have noted, the duty does not require manufacturers to perfect their drugs, but simply to act with reasonable care for the users of the existing drug when the manufacturer has developed an alternative that it knows is safer and at least equally efficacious. Manufacturers already engage in this type of innovation in the ordinary course of their business, and most

plaintiffs would likely face a difficult road in establishing a breach of the duty of reasonable care.

Availability and cost of insurance. Gilead contends that recognition of a duty "would massively expand manufacturers' existing exposure to liability," which in turn would increase the cost of insurance "if it were available at all" and thereby raise the price of prescription medicines. But for the reasons discussed above, we are not persuaded that the expansion of liability is anywhere near as "massive" as Gilead suggests, and as plaintiffs note, there is nothing in the record regarding the cost and availability of insurance. We find that the parties have not supplied enough information "to settle the question of insurance one way or the other." (*Vasilenko, supra*, 3 Cal.5th at p. 1091.)

Again, the most important factor to be evaluated in applying *Rowland* is the prevention of foreseeable harm. In the narrow circumstances in which it applies, plaintiffs' duty would prevent manufacturers from delaying the development of safer treatments, thereby avoiding foreseeable harm to a potentially large class of persons. Although the duty may impose some burdens on pharmaceutical manufacturers, we are not persuaded that they would be so great as to overcome the benefit of safer products. The expansive exception proposed by Gilead is therefore not appropriate.

2. Gilead's Narrower Exception

Although Gilead does not offer two separate *Rowland* analyses, at various points in its supplemental briefing it suggests, as a fallback position, a narrower exception tied to

manufacturers' Phase III clinical trials, which are the final stage in the process required to obtain approval of a new drug. Following the submission of preclinical trial data to the FDA, the manufacturer conducts clinical trials in three phases. (21 C.F.R. §§ 312.23(a)(8), 312.21(a)–(c) (2022).) "Phase I clinical trials are conducted on healthy volunteers to determine the maximum tolerated dose, adverse events, and pharmacokinetics of a product. Phase II studies are conducted on a statistically relevant number of patients having a specific disease to determine initial efficacy in humans for that disease, and to identify possible adverse effects and safety risks. Phase III studies consist of wide-scale studies on patients with the disease for which the drug is intended and evaluate the overall risks and benefits of the drug." (*Deveny v. Entropin, Inc.* (2006) 139 Cal.App.4th 408, 413, fn. 2.) Phase I trials "are generally conducted on a small number of healthy volunteer subjects," whereas Phase II trials "usually involve several hundred people" and Phase III trials consist of "several hundred to several thousand" subjects. (*Schiff v. Prados* (2001) 92 Cal.App.4th 692, 696, fn. 2.)

Gilead's narrower exception would hold that when an FDA-approved prescription drug is accompanied by an adequate warning of adverse side effects, and is not shown to be defective in design or manufacture, the manufacturer does not owe users of the previously-approved drug a duty of reasonable care in its decisions about commercializing an alternative drug until Phase III trials have established its safety and effectiveness.

We conducted our analysis of the broader *Rowland* exception under the assumption that the duty of care arises when the manufacturer knows that the alternative drug candidate is safer than, and at least as effective as, the existing drug. But in many cases the parties will dispute, as they do in this case, whether the manufacturer actually knew that the alternative candidate was superior when the manufacturer made the decision or decisions at issue. Gilead's narrower exception essentially proposes, as a policy matter, that the amount of knowledge necessary to trigger the imposition of a duty of care cannot exist before the manufacturer has the results of Phase III trials of the alternative drug.[19]

i. Foreseeability factors

It is reasonable to expect a manufacturer to learn more about a drug candidate's safety and efficacy at each stage of the investigation process, so as a general matter, we see no reason to doubt that a manufacturer will be able to foresee with greater confidence that a new drug will avoid the harmful side effects associated with the existing drug, while providing the same therapeutic benefit, after Phase III than after Phase II.

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[19] Notwithstanding its Phase III proposal, Gilead actually contends that "[t]he earliest point at which it would be reasonably foreseeable that injury from an existing non-defective medicine could be prevented by a new product is when the FDA approves the drug and the drug's comparative safety has been proven in head-to-head to studies." According to Gilead, head-to-head studies are not necessary to obtain FDA approval, but are required to justify any claim comparing the safety or effectiveness of two drugs, and can be conducted during Phase III trials or after FDA approval.

Plaintiffs, however, argue that a manufacturer's knowledge prior to the conclusion of Phase III trials will vary, depending on how much is already known about the compound being studied and on what the Phase I and II results show.

While some generalizations are probably necessary to evaluate the appropriateness of any proposed *Rowland* exception, here no factual record has been developed in the trial court that would allow us to assess the parties' competing claims. In the absence of such a record, we cannot say whether it is possible to make any meaningful generalizations about what can reasonably be known after Phase II trials as compared to Phase III trials, and what those generalizations would be. And we do not know, for example, how often, or under what circumstances, a drug's apparent promise after Phase II is undermined by unexpected results in Phase III—or how often uncertain Phase II results are followed by confirmed successes in Phase III. Thus, on the existing record, Gilead has not established that it is not foreseeable before Phase III trials that the manufacturer's conduct would cause otherwise avoidable injury.

ii. Public policy factors

The policy rationale for Gilead's narrow exception is that allowing a jury to decide on a case-by-case basis whether the manufacturer had the requisite knowledge creates too much uncertainty, giving rise to unacceptable burdens on manufacturers, such as disincentivizing innovation and causing excessive and unwarranted litigation. The exception would create a safe harbor period in the drug development process in

which manufacturers may make decisions without fear that they may be second-guessed by a jury, and conversely, would let them know with certainty at what point their decisions could be scrutinized for failure to exercise reasonable care.

We do not rule out the possibility that such an exception could be warranted. "In conducting its [duty] analysis, the court may take into account factors that might escape the jury's attention in a particular case, such as the overall social impact of imposing a significant precautionary obligation on a class of actors. These cases are properly decided as duty or no-duty cases. When no such categorical considerations apply and reasonable minds could differ about the competing risks and burdens or the foreseeability of the risks in a specific case, however, courts should not use duty and no-duty determinations to substitute their evaluation for that of the factfinder." (*Cabral, supra*, 51 Cal.4th at p. 773, fn. 3 [quoting Rest.3d Torts, Liability for Physical and Emotional Harm, § 7, com. *i*, pp. 81–82].) As *Brown* indicates, "categorical considerations" may come into play in the prescription drug context, although nothing in that case suggests that manufacturers need greater protection than the decision itself supplies.

Still, we believe a decision to delay commercialization of a new drug, when it is made earlier in the development process, may be more complicated and challenging for a jury to evaluate, and more susceptible to hindsight bias, than one made after Phase III trials are completed. Phase III trials are likely to be substantially more difficult and expensive than those occurring

during Phases I and II, so the burden on pharmaceutical manufacturers is undoubtedly greater if those trials are undertaken out of a "precautionary obligation." On the other hand, plaintiffs counter that the proposed exception would render the remaining duty of care largely toothless because manufacturers often have sufficient information after Phase II and, like Gilead, could simply make the relevant decisions at that point in order to avoid liability.

Ultimately, however, the problem remains the lack of a factual record by which to assess whether it is appropriate to recognize a categorical exception for decisions made before the completion of Phase III trials. We recognize that the appropriateness of a *Rowland* exception can sometimes be identified early in a case, even on a motion addressed to the pleadings. (See, e.g., *Kuciemba, supra*, 14 Cal.5th at p. 1004; *Kesner, supra*, 1 Cal.5th at p. 1142.) In other cases, it is raised later, at summary judgment or even after a jury verdict. (E.g., *Vasilenko, supra*, 3 Cal.5th at pp. 1082–1083; *Cabral, supra*, 51 Cal.4th at p. 770.) While the *Rowland* analysis does not focus on the defendant's specific conduct, it may still present difficult factual questions that cannot be reliably resolved simply by weighing competing assertions in briefs by the parties and their amici. We conclude that Gilead has failed to establish that its narrow exception is warranted on the current record. However, our conclusion does not prevent Gilead from seeking the exception based on a record developed later in the trial court,

both before that court and, if necessary, on appeal from an adverse judgment.

II. Fraudulent Concealment

Plaintiffs' cause of action for fraudulent concealment alleges that Gilead was required to disclose that (1) TAF was a safer means for delivering tenofovir into the body, (2) the toxicity of tenofovir was not unavoidable, and (3) Gilead's true motive for shelving TAF development was financial. Gilead argues that it is entitled to summary adjudication of this claim because it was under no duty to disclose to plaintiffs facts relating to TAF, which was not available as an alternative to TDF for the treatment of HIV/AIDS. We agree.

" '[T]he elements of an action for fraud and deceit based on a concealment are: (1) the defendant must have concealed or suppressed a material fact, (2) the defendant must have been under a duty to disclose the fact to the plaintiff, (3) the defendant must have intentionally concealed or suppressed the fact with the intent to defraud the plaintiff, (4) the plaintiff must have been unaware of the fact and would not have acted as he did if he had known of the concealed or suppressed fact, and (5) as a result of the concealment or suppression of the fact, the plaintiff must have sustained damage.' " (*Roddenberry v. Roddenberry* (1996) 44 Cal.App.4th 634, 665–666.)

As explained in *Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, in the absence of a fiduciary relationship between the parties, the law " 'presuppose[s] the existence of some other relationship between the plaintiff and defendant in

which a duty to disclose can arise.' [Citation.] . . . [¶] Our Supreme Court has described the necessary relationship giving rise to a duty to disclose as a 'transaction' between the plaintiff and the defendant . . . . Such a transaction must necessarily arise from direct dealings between the plaintiff and the defendant; it cannot arise between the defendant and the public at large." (*Id.* at pp. 311–312.) Once the necessary relationship is found, a duty arises "to disclose facts material to the transaction." (*LiMandri v. Judkins* (1997) 52 Cal.App.4th 326, 337.) We have recently held, for example, that a vehicle manufacturer owes a duty to purchasers of its vehicles to disclose known defects. (*Dhital v. Nissan North America, Inc.* (2022) 84 Cal.App.5th 828, 844; see similarly, *Snow v. A. H. Robins Co.* (1985) 165 Cal.App.3d 120, 134–135 [manufacturer of intrauterine device had duty to disclose higher pregnancy rates from its use].)

Assuming that plaintiffs' use of Gilead's product, TDF, created the relationship necessary to invoke the law of concealment, we nonetheless conclude that such a duty did not extend to the disclosure of information about TAF. Gilead owed a duty to plaintiffs to disclose information material to the transaction that created the disclosure relationship—plaintiffs' use of TDF as a medicine. The facts material to this treatment decision concerned the efficacy, side effects, risks, and cost of TDF, which plaintiffs and their physicians could compare with similar information about other available medicines in deciding the best course of treatment. For the 14 years between the

commencement of Gilead's sales of TDF and the FDA's approval of TAF as an HIV/AIDS medication, TAF was not available to patients as a treatment. Information about a chemical compound that was not available as a treatment, and could not possibly become available as a treatment for many years as a result of the time-consuming FDA approval process, would not have been material to the treatment decision. Even the acknowledgment by Gilead that the toxicity of tenofovir was avoidable, as plaintiffs allege, would have been of no use to patients in deciding whether to take TDF, since their choice was between TDF and other available medications, not between TDF and its allegedly safer counterpart, TAF.

Plaintiffs argue that disclosure of information about TAF might have affected physicians' practices in prescribing TDF, but their reasoning is impermissibly speculative. Plaintiffs argue, in effect, that the disclosure of information suggesting that TAF was a superior alternative to TDF might have biased physicians against the use of TDF. This bias, they theorize, would have caused physicians to decrease their use of TDF, even though the disclosure would have in no way changed the value of TDF relative to other available treatments.[20] It is not clear, however,

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[20] For example, plaintiffs cite evidence suggesting some Gilead employees were concerned that disclosure of information about TAF would change medical perceptions of the risk profile of TDF. Such a change in perception, however, would not have been based on the relative value of TDF and other available medications. Rather, it would have been the result of bias against TDF generated by physicians' knowledge that Gilead could, if it chose, have produced a safer drug.

that information about TAF should be considered material to the treatment decision merely because it might have changed that decision for irrational reasons. Plaintiffs' contention is, in any event, entirely speculative and does not make information about TAF material to the decision to use TDF.

Plaintiffs also cite their allegation that Gilead stopped work on TAF because Gilead believed that a TAF-containing medication would "cannibalize" its sales of TDF. Even if true, that motivation did not create a duty to disclose information about TAF. TAF could cannibalize TDF sales only if TAF existed as an alternative treatment. So long as Gilead chose to avoid cannibalization by keeping TAF from the market, information about TAF's efficacy and risks relative to TDF had no bearing on physicians' or patients' treatment decisions.

DISPOSITION

Gilead's petition for a writ of mandate is denied in part and granted in part. Let a peremptory writ of mandate issue directing the superior court to vacate its order denying Gilead's motion for summary judgment, dated June 13, 2022, and enter a new and different order denying summary adjudication of Count I of plaintiffs' Master Long Form Complaint for Damages and granting summary adjudication of Count V of that document. The stay imposed in our order of September 9, 2022, shall remain in effect until issuance of the remittitur. Plaintiffs shall recover their costs on appeal.

GOLDMAN, J.

WE CONCUR: