Case No. A165558

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

GILEAD SCIENCES, INC.,
Petitioner,
v.
SUPERIOR COURT OF THE CITY AND COUNTY OF SAN FRANCISCO,
Respondent,
and
GILEAD TENOFOVIR CASES,
Real Parties in Interest.

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

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INTRODUCTION[1]

Design defect. Plaintiffs' novel negligence theory is fraught with disastrous consequences. This Court cannot avoid rejecting it by inviting Plaintiffs to revive a separate claim so devoid of proof that Plaintiffs emphatically and repeatedly renounced it, including through oral argument: "[T]here is no[] defect in the design that renders TDF defective" (Tr.40:20-22); Plaintiffs "[a]bsolutely" do not assert a negligent-design-defect claim (Tr.29:10-13).

Sophisticated plaintiffs' counsel do not utter those words—and certainly not in favor of a theory never accepted by any court—if there were any way to make a negligent-design-defect claim.

That claim was dead on arrival and cannot be revived for three reasons that track the Court's questions. First, a safer feasible alternative design does not make a product defective—especially for prescription drugs, given that *Brown* rejected comparing existing drugs to potential alternatives as a gateway to liability. Regardless, TAF was not a safer or feasible alternative in 2004. TAF was a hundred million dollars and years of intensive study away from even being an option for consumers, and even today it is not a safer treatment option for all patients. Plaintiffs did not misapprehend the law in disavowing any

[1] We cite Gilead's Writ Petition and accompanying Memorandum as "Pet.", Plaintiffs' Return as "Ret.", Gilead's Reply to Plaintiffs' Return as "Reply", and amicus briefs as "_____ Br." according to the lead amicus.

design-defect claim; they made the sound judgment that they could never win it.

Second, Plaintiffs cannot overcome a record replete with *factual* concessions fatal to any design-defect claim. Plaintiffs have repeatedly agreed that TDF's benefits outweigh its risks and disclaimed any assertion that Gilead should stop selling TDF. Again, Plaintiffs did not make those concessions out of ignorance of the law; their experts refused to testify that TDF is defective.

Third, Plaintiffs cannot establish the requisite state of mind for a negligent-design-defect claim. Plaintiffs must prove Gilead's negligence—that Gilead knew or should have known TDF was defective when it decided, in 2004, to stop TAF development. But Gilead cannot possibly have *known* that TDF was defective in 2004 when, even through oral argument, Plaintiffs still could not say that TDF is defective—with 20 additional years of data and TAF long since approved and marketed alongside TDF.

Duty to continue development. This leaves the Court no choice but to grapple with—and reject—Plaintiffs' novel negligence theory: that Gilead had a duty to develop TAF earlier even though existing TDF medicines were (concededly) not defective. A manufacturer has no duty to develop a new product that improves upon an existing non-defective product. Such a duty would replace product-liability law with "product-perfection law," requiring a manufacturer to commit tremendous resources to develop a new product, just because there is reason to think it

might be safer. That, in turn, would upend the delicate balance tort law has struck over the course of decades.

That said, to resolve this appeal, this Court need not decide there can never be such a duty—just that no such duty could apply in this category of cases. There are three problems with Plaintiffs' proposed duty. First, a duty consisting of nothing but a command to act reasonably is too nebulous to inform manufacturers when the duty is triggered, and what obligations that duty entails. Absent clear guidance—expressed in categorical terms—manufacturers will have no idea how to comply and will be forced instead to guard against crushing potential liability by investigating fewer new products and improvements. Second, Plaintiffs pin their proposed duty to a moment—after a single, 14-day Phase I/II clinical trial—that is far too early in the drug-development trajectory. A drug manufacturer generally cannot know that a drug will ever be as effective or safer than an existing medicine for any subset of a patient population until much later in the development and regulatory process. Third, Plaintiffs adopt too lax a scienter standard, allowing crushing liability based on what a jury later believes, with hindsight, the drug manufacturer "should have known."

The no-duty outcome is the same whether the Court analyzes the question as rejecting a new duty or carving out an exception under *Rowland*. Gilead has consistently advanced policy arguments that map onto the *Rowland* factors and justify an exception. The exception should exclude from liability any

decision to stop development of a new product. But again, this Court is free to craft a narrower exception that resolves this case (where the challenged decision was made before Phase III clinical studies had even begun), leaving for another day the decision on how broad the exception is. Particularly at early phases of drug development, a manufacturer cannot conceivably know that a drug candidate is safe and effective—much less safer or more effective than an existing FDA-approved medicine. Thus, it is speculative that the candidate would avoid or lessen the side effects of the existing medicine. Failure to take action with respect to an unproven, experimental drug likewise has a highly attenuated connection to injuries arising from an existing, non-defective medicine. Little "moral blame" under *Rowland* can attach to the decision to stop developing a drug candidate, where manufacturers must choose among multiple potentially beneficial development paths with finite resources and limited data. And imposing liability for the failure to pursue a promising drug candidate would hobble innovation and diminish the number of essential medicines available—consequences that vastly outweigh any uncertain benefits of imposing additional liability. The extraordinary burden alone requires an exception here, whether in terms of guarding against incalculable liability, incurring astounding development expenses, or a deluge of litigation burdening courts.

Because Plaintiffs do not and cannot establish a negligent-design-defect claim, the Court must address whether a duty exists in the circumstances of this litigation. It is a highly

consequential question of law that will impact countless manufacturers. The Court should resolve the question and hold that Plaintiffs have no cognizable claim.

DRUG DEVELOPMENT PRIMER

The Court's questions about safer feasible alternatives and a new duty to bring a drug to market call for a brief primer on drug development.

Only one drug candidate in 5,000 to 10,000 ever secures FDA approval. (2022 PhRMA Br. 21-22.) It must first undergo a battery of preliminary experiments, called "preclinical tests." (21 C.F.R. § 312.23(a)(8).) Preclinical tests generally start by studying the candidate in test-tubes and petri dishes. If those tests are promising, researchers move on to live animals. None of these experiments prove either safety or effectiveness in human subjects; the most they can do is support a hypothesis about how a compound may work in humans.

After obtaining the required preclinical data, the manufacturer can proceed to clinical trials in humans, which are conducted in three phases:

> ***Phase I:*** Evaluates in humans a drug's short-term side effects, metabolism, and pharmacology, and, if possible, effectiveness. Typically 20-80 subjects.
>
> ***Phase II:*** Evaluates particular indicators of a drug's effectiveness in patients with the disease or condition, short-term side effects, and risks. Typically no more than several hundred subjects.
>
> ***Phase III:*** Amasses enough proof to establish safety and effectiveness for FDA approval, "the overall benefit-risk relationship of the drug," and an adequate basis for

> physician labeling. Typically hundreds to thousands of subjects.

(21 C.F.R. §§ 312.21(a)-(c).) Each clinical trial commands a huge commitment in financial and human resources and requires a company to engage resource-constrained institutional partners, including regulatory agencies and hospitals. (7App.2214-22, 2285.) And each depends on the arduous task of recruiting hundreds of volunteers who both satisfy the study criteria and are willing to take experimental drugs. (4App.1313-16; 5App.1623; 9App.2743.)

All this may not be enough, as "less than one out of eight medicines entering clinical trials[] ultimately obtains FDA approval." (2022 PhRMA Br. 21-22.) Drug candidates can (and most do) fail at any one of these three phases. (U.S. Food & Drug Administration, Step 3: Clinical Research (2018), <https://tinyurl.com/fda-iii>.) Of the candidates that make it all the way to Phase III, new drug approval is sought in only 25-30%—with even fewer obtaining approval. (*Ibid.*) FDA may demand further testing, including additional clinical studies. (6App.1814-18.) And even after this expensive, lengthy process, FDA still rejects applications if it concludes that the data do not supply sufficient evidence of safety or effectiveness. (21 C.F.R. § 314.125.)

As described more fully a below (*post* 43-44), FDA approval does not require a drug manufacturer to conduct large-scale, head-to-head studies comparing the drug candidate to a drug already on the market. But the manufacturer *must* do that to justify any claim comparing the safety or effectiveness of two

drugs. Those studies can be conducted during Phase III or after FDA approval.

When Gilead made the decision to stop TAF development in 2004, it had performed a single clinical study in humans. The 1101 Study was a Phase I study that dipped a toe into Phase II, involving 20 subjects taking TAF and 10 taking TDF for 14 days total.

ARGUMENT

I. A Safer Feasible Alternative Does Not Make A Product Defective And, Even If It Did, TAF Is No Such Alternative.

The Court first asks about the role of "a safer feasible alternative" in the design-defect analysis. Traditionally, a safer feasible alternative is just one of several factors that may be considered in the risk-benefit analysis. § I.A. *Brown* seems to prohibit consideration of that factor for prescription drugs. § I.B. But this Court need not resolve that question, because, as a matter of law, even under traditional principles, TAF was not a safer feasible alternative in 2004. § I.C.

A. A feasible alternative is, at most, only a factor in determining whether a product is defective.

At least outside the prescription-drug context, a safer feasible alternative is *a factor* that *can* be considered in determining whether a product is defective. It is legally wrong to say that a product may be found defective solely "on the ground that there is a safer alternative design" or that a safer alternative

design itself is "sufficient to establish that a drug [or any other product] is defective." (Contra Questions 1-2.)

Barker v. Lull Engineering Co. (1978) 20 Cal.3d 413, 431 articulates the traditional design-defect test: a "risk-benefit" analysis assessing whether, "on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design." (*Id.* at 432.) In other words, the test assesses whether the product poses an "'*excessive* preventable danger.'" (*Id.* at 430 [italics added].) *Barker* listed some of the traditional factors to consider:

- "the gravity of the danger posed by the challenged design,
- the likelihood that such danger would occur,
- the mechanical feasibility of a safer alternative design,
- the financial cost of an improved design, and
- the adverse consequences to the product and to the consumer that would result from an alternative design."

(*Id.* at 431 [bullets added].) Courts subsequently added others, including:

- the product's warnings (*Hansen v. Sunnyside Products, Inc.* (1997) 55 Cal.App.4th 1497, 1519),
- compliance with regulatory standards, such as approval by a regulatory agency (*O'Neill v. Novartis Consumer Health, Inc.* (2007) 147 Cal.App.4th 1388, 1393-96), and
- industry custom and practice, including comparisons to other products on the market (*Kim v. Toyota Motor Corp.* (2018) 6 Cal.5th 21, 34).

As Plaintiffs have conceded, the primary focus of the analysis is always on the risks and benefits of the product in question—here, TDF. (Tr.28:15-19; see Tr.40:11-16.) A court may

not give dispositive weight to feasible alternatives, any more than it can give dispositive weight to industry custom and practice.

As the Court of Appeal held in *Hansen*: "[T]he determination of design defect does not turn *solely* on the existence of a safer alternative design. Rather, the determination requires balancing various factors, which include feasible alternatives, but which also include other factors." (55 Cal.App.4th at 1512.) In *Hansen*, the trial court found that the accused cleaning solution was defective as a matter of law in part because the manufacturer had since switched to a different formula that was safer and cheaper, yet still effective. (*Id.* at 1504, 1509.) The Court of Appeal reversed. It determined that "evidence of the existence of a safer design is but one factor to be weighed in the balance." (*Id.* at 1520.) There were other factors that favored the defendant and would have to be considered in the overall risk-benefit mix, including the label warning of risks and the "minimal" likelihood that someone would be injured. (*Ibid.*) Accordingly, the safer alternative could "not compel a verdict in plaintiffs' favor." (*Ibid.*)

If a safer alternative alone could make a product defective, the no-defect requirement would be replaced by a requirement that each product be the "safest feasible product." That is not the test: "[The risk-benefit test] allows the evaluation of competing designs, but it does not require proof that the challenged design is the safest possible alternative. The manufacturer need only show that given the inherent complexities of design, the benefits

of its chosen design outweigh the dangers." (*Soule v. Gen. Motors Corp.* (1994) 8 Cal.4th 548, 571 fn.8.)

Consider some examples. Under a test where "safer feasible alternative" is dispositive, any car that lacked feasible safety features like lane assist or a 360-degree camera would automatically be defective because those features later became available. So too would any facemask that is not an N95, and any table saw that does not have an automatic stop. But that is not how design-defect claims work. The manufacturer's duty is to produce a product that is reasonably safe—not to produce the safest feasible product. (See Pet. 40; Reply 22-23.) Put another way, "the [design-defect] test is not 'preventable danger'"—as it would be if a safer feasible alternative was alone enough—"but 'excessive preventable danger,'" which considers the full risk-benefit analysis. (*Hansen*, *supra*, 55 Cal.App.4th at 1512 [quoting *Barker*, *supra*, 20 Cal.3d at 430].)

B. *Brown* casts doubt on any consideration of feasible alternatives in the prescription-drug context.

The foregoing analysis would apply here unless *Brown* changed the risk-benefit analysis for prescription drugs. Justice Goldman asked at oral argument whether considering feasible alternatives to conclude that a prescription drug is defective is inconsistent with *Brown*'s treatment of *Kearl v. Lederle Laboratories* (1985) 172 Cal.App.3d 812. (See Tr.65:21-66:12.)

Brown gives mixed signals on that score. On the one hand, in introducing the traditional risk-benefit test, *Brown* quoted all the factors *Barker* recited, including "'the mechanical feasibility

of a safer alternative design.'" (*Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1061.) But *Brown*'s logic casts doubt on the viability of that factor. That is presumably why Plaintiffs were so insistent in responding to Justice Goldman's question whether "safer alternative design" was a factor in considering whether TDF was defective: "No.… [W]hen you look at the test for design defect, you're looking at only the design of TDF. You're looking at did the risks outweigh the benefits." (Tr.28:3-20.)

There is much to support that reading of *Brown*. *Brown* rejected the *Kearl* test because it would squander all the benefits the Court was trying to achieve by rejecting strict liability. (*Brown*, *supra*, 44 Cal.3d at 1067-69.) That is instructive because the *Kearl* test was so similar to an analysis of whether an accused prescription drug has a safer feasible alternative: whether a safer "alternative product … would have *as effectively* accomplished the *full intended purpose* of the … product" because then the product would not be "unavoidably unsafe." (*Id.* at 1066-68.)

Two of *Brown*'s rationales for rejecting this test apply here. First, the Court said that the rule would "diminish[]" a "manufacturer's incentive to develop … a superior product," because "a trial court could decide, perhaps many years later, that in fact another product which was available on the market would have accomplished the same result." (*Id.* at 1068.) That is the very ruling Plaintiffs seek here—except TAF was years away from getting to market.

Second, the Court was concerned that the inquiry into safer alternatives will be skewed: "the question of the superiority of one drug over another would have to be decided not in the abstract but in reference to the plaintiff," who presents just the risk side of the equation. (*Ibid.*) That is also the problem here: A jury would be considering the balance Gilead (or any other drug manufacturer) struck only from the perspective of an outlier patient who suffered the side effect—not from the perspective of the millions of people who benefited from the course Gilead took.

This case illustrates the point. The proportion of the population that suffer kidney or bone issues from TDF is small. In June 2004 (around the time Gilead stopped TAF development), a two-and-a-half-year review found that 0.0023% of patients (2.3 in 100,000) reported bone disorders in a given year (7App.2355) and 0.114% of patients (11.4 in 10,000) reported kidney disorders (7App.2358-60). In other words, from the perspective of the millions of patients who needed TDF to save their lives, the absolute risk of kidney or bone injury was known to be extremely low; meanwhile, the risks were disclosed, and the prescribing doctor could evaluate individualized patient needs. Yet, for a plaintiff who suffers the side effects, the risk has materialized. A jury viewing the situation from the perspective of that outlier patient will likely give undue weight to that rare downside (risk) over TDF's broad upside (benefits)—including the benefits that arose from the manufacturer's alternate path.

This case presents a powerful example of those benefits as well: The path Gilead took instead of further pursuing TAF

benefited the vast population of patients. At that time, people living with HIV/AIDs had to take multiple pills in different doses on differing schedules, requiring them to set alarms for the middle of the night. Many people could not follow that strict and complex regimen, which could yield drug-resistance that made medicine useless. (2App.494; 6App.1968; 7App.2291.) The *entire population* of HIV/AIDS patients wrestled with this problem. It was a matter of life and death. That was why FDA urged Gilead and others to prioritize developing a once-a-day, single pill that contained the whole treatment regimen. (2022 PhRMA Br. 31-33.) Gilead naturally built that once-a-day pill around TDF, which, unlike TAF, had FDA approval and years of clinical and real-world data supporting its safety and efficacy. (See Reply 16-17.) Gilead succeeded in developing (three) TDF-based single-tablet regimens, one of which FDA lauded as a "'watershed in HIV treatment.'" (2022 PhRMA Br. 31.)

Ultimately, this Court need not decide whether feasible alternatives remain part of the risk-benefit analysis for prescription medicines after *Brown*. Even if they do, *Brown*'s treatment of *Kearl* reinforces that a feasible alternative cannot alone render a drug defective. If the public policy imperative to "save lives and reduce pain and suffering" justifies suspending one of the bedrock principles of products-liability law—strict liability (*Brown*, *supra*, 44 Cal.3d at 1063)—then it must at a minimum prohibit giving dispositive weight to safer feasible alternatives in the risk-benefit analysis.

C. TAF was not a safer feasible alternative.

There is a second reason this Court need not decide whether safer feasible alternatives are just a factor in the defect analysis or are barred by *Brown*: Under no view of the law was TAF—a completely new experimental drug—a safer feasible alternative to TDF in 2004.

Feasibility. Feasibility is based on "the existing state of the art" at the relevant time. (*Rosburg v. Minnesota Mining & Manufacturing Co.* (1986) 181 Cal.App.3d 726, 735.) To qualify, an alternative design must both satisfy "mechanical feasibility" and feasibility in terms of "the financial cost of [the] improved design." (*Brown*, *supra*, 44 Cal.3d at 1061 [quotation marks omitted].)

TAF failed both requirements in 2004. Plaintiffs said it best: when TDF medicines were first released in 2001 and 2004 (1App.201), "TAF was not a safer alternative" because TAF "was still in development; [i]t was still being looked at." (Tr.42:20-22.) Plaintiffs also conceded that Gilead did not have anything near the data sufficient to persuade FDA of TAF's safety and efficacy when it stopped TAF development in 2004. (10App.3106.) All it had was that one very small, and very short, Phase I/II clinical trial (*ante* 14), which found TDF and TAF to have similar safety profiles. (10App.3105.) Plaintiffs' whole theory is that Gilead should have "continued TAF development," including "conduct[ing] the additional studies needed" to establish that TAF was safe and effective. (10App.3106.)

With so much resource-intensive and highly uncertain clinical work left to be completed, "[c]ontinu[ing] TAF development" through Phase III trials, head-to-head comparative studies with TDF, and regulatory approval made TAF the antithesis of a "feasible" alternative. The *lowest* estimate in the record of the projected cost for conducting those additional studies, obtaining FDA approval, and getting TAF to market was $82 million. (7App.2313.) And recall that the approval rate of drugs entering clinical trials is less than one out of eight. (*Ante* 13.) When Gilead revived TAF development in 2010, it took five years of additional study for Gilead to acquire enough data on TAF's safety and efficacy, and its safety as compared to TDF, to obtain FDA approval. (10App.3108, 3114-15.) In fact, FDA did not approve the TAF-containing medicines until Gilead devised a different composition of TAF than the one that had been tested in the 1101 Study. (Compare 6App.1889-1890, with Genvoya® FDA-approved label at 30 (Jan. 7, 2022), <https://tinyurl.com/2p8wujbn>.) In no world is an $82 million, multi-year research plan, with a significant chance of failure a feasible alternative either mechanically or financially.

Safety. This Court asked: "To be considered a safer alternative design, must the alternative be equally effective while posing lower risk for all patients, or only for plaintiffs?" The answer is that it must be safer for the entire population for which the drug is designed.

Outside the prescription-drug context, the question rarely arises, because generally a safety feature makes the product

safer for everyone and no more dangerous for anyone. Think of lane assist on cars or power cutoffs for a table saw.

The question is more complicated with prescription drugs. Changing the design of a prescription drug generally requires modifying its chemical formula. Here, it would mean swapping out one active ingredient for another (TDF for TAF). How the human body reacts to a different compound is highly unpredictable and variable. That change may make the medicine less effective; it might also cause different—possibly more dangerous—side effects for everyone or for a subset of people. When prescription drugs are designed for a large population (e.g., all people living with HIV/AIDS), development decisions must be made across the entire population—not for numerous micro-populations. Thus, those design decisions must be judged across the broader population.

This complexity is reflected in the Restatement: "What may be harmful to one patient may be beneficial to another.… [A] prescription drug … that has usefulness to any class of patients is not defective in design even if it is harmful to other patients." (Rest.3d Torts: Prod. Liab., § 6, com. b.) Thus, a prescription drug is not defective unless "the foreseeable risks of the harm posed by the drug … are sufficiently great in relation to its foreseeable therapeutic benefits that reasonable health-care providers … would not prescribe the drug … for *any class* of patients." (*Id.* § 6(c) [italics added].) To be defective, the prescription drug must be unreasonably unsafe for everyone.

That stands to reason: The imperative *Brown* recognized was to get medicines to patients who need them. It would be wrong to deprive a group of patients of the lifesaving benefits of a medicine just because that medicine is dangerous for a statistically small percentage (*ante* 19). Instead, the law relies on drug manufacturers to warn about the risks, and on prescribing doctors to conduct individualized risk-benefit analysis for each patient.

The broader point about defects in prescription drugs has a corollary for alternative designs: "When evaluating the reasonableness of a design alternative, the *overall safety* of the product must be considered. It is not sufficient that the alternative design would have reduced or prevented the harm suffered by the plaintiff if it would also have introduced into the product *other dangers* of equal or greater magnitude." (*Id.* § 2, com. f [italics added].)

This case illustrates why it is important to consider the entire patient population in assessing whether a design is defective or in weighing a feasible alternative. TDF remains FDA-approved and safe for a large population of patients. The U.S. Department of Health and Human Services (HHS) continues to list the TDF medicines among its recommended regimens for HIV antiretroviral therapy, and the World Health Organization continues to refer to TDF as "essential" to HIV treatment. (See Pet. 16 [citations].) As their different labels document, TAF medicines, like TDF medicines, are also associated with kidney and bone risks. (See Genvoya® label, *supra*, at 6, 9-12.)

TAF also presents risks that TDF medicines do not. According to HHS Guidelines, "TDF is associated with lower lipid levels" than TAF, whereas greater weight gain has been observed with initiation of TAF than with TDF or with a switch from TDF to TAF. (3App.993-95; see Genvoya® label, *supra*, at 10, 11.) These relative benefits of TDF inform a doctor's prescribing decisions for a particular patient. And that partly explains why Plaintiffs have not insisted that TDF should be taken off the market: physicians continue to reasonably prescribe TDF, which continues to be the right choice for many people. (Tr.40:17-21.)

That answers this Court's question whether "plaintiffs' allegations regarding TAF relative to TDF meet th[e] requirement" of "being equally effective while posing lower risk for all patients." Bearing in mind that the question at this summary-judgment stage is not about allegations, but about proof (*Aguilar v. Atl. Richfield Co.* (2001) 25 Cal.4th 826, 844), the answer is no.

II. Plaintiffs Have Intentionally And Emphatically Abandoned Any Claim For Negligent Design Defect, Because They Cannot Prove It.

The first half of Question 2 asks: "are plaintiffs effectively asserting a claim for negligent design defect?" The answer is no. Plaintiffs have repeatedly and emphatically declared that they are not. § II.A. For good reason: The claim fails as a matter of law. § II.B. Accordingly, this Court should reject it, whether on forfeiture grounds or on the merits. § II.C.

A. Plaintiffs' disavowal of a design-defect claim was intentional, emphatic, and persistent.

A refresher on how we got here: Gilead's position has always been that Plaintiffs' claim for injuries purportedly caused by TDF is a design-defect claim—just one that fails for lack of evidence of a defect. (Reply 25-26.) That was why it was so consequential when Plaintiffs declared that they were no longer alleging that Gilead's TDF medicines are defective. That was the whole premise behind this writ: There is no such thing as a design-defect claim without a defect and, even if there were, Plaintiffs' proposed alternative duty fails.

Plaintiffs' abandonment of the negligent-design-defect claim was not implicit, tentative, or ill-considered. It was unequivocal. It was repeated. And it was a considered choice Plaintiffs made because they could not prove a defect under the law. A waiver does not get more absolute than this: "To be *absolutely clear*, Plaintiffs are not pursuing a claim for negligent design defect." (Ret. 27 [italics added].) They emphatically distinguished their claim from a negligent-design-defect claim: "[T]his is *not* Plaintiffs' claim." (Ret. 40.)

Plaintiffs matched their absolutism at oral argument. Justice Brown asked, "So you're not alleging essentially a negligence claim based on design defect at all?" "*Absolutely*," Plaintiffs responded. (Tr.29:10-13 [italics added].) They added: "[T]he plaintiff is not making a design defect claim." (Tr.39:21-22.)

Plaintiffs' absolutism can be traced through the course of this litigation. Plaintiffs alleged and tried to prove a design-defect

theory in discovery. They first renounced that theory in response to Gilead's statement of undisputed facts on summary judgment: "Plaintiffs do not allege that *TDF* is defective." (10App.3103.) Gilead's summary-judgment motion had demonstrated at length that Plaintiffs could not prove a design defect. (1App.134-38.) Plaintiffs responded not by arguing that TDF was defective or marshalling evidence to support a triable issue regarding defect, but by arguing that this "is not what Plaintiffs are claiming in this case." (10App.3030.) They argued it was "irrelevant" "that the benefits of *TDF* outweigh the risks of *TDF*" (10App.3103), because "[t]his case is about how Gilead … chose to delay TAF's development." (10App.3030.)

On appeal, Gilead challenged the trial court's refusal to dismiss the design-defect claim. (Pet. 53-56.) This Court then issued the order to show cause, directing that Plaintiffs' "return shall identify the specific theory or theories of negligence that [Plaintiffs] intend to pursue at trial." In response, Plaintiffs did not identify negligent design defect as a theory they intended to pursue, nor did they address Gilead's Petition about negligent design defect. Instead, they pressed their novel negligence theory and even raised—for the first time—an unprecedented and radical theory of negligent undertaking. (Ret. 43-46.) And they even declared: "That the design of the tenofovir products may not be legally 'defective' has nothing to do with these claims." (Ret. 8.)

B. Plaintiffs had to disavow their design-defect claim because there was (and is) no way to sustain it.

Plaintiffs are represented by highly sophisticated and experienced products-liability counsel—nearly 150 lawyers according to the service list and six law firms that signed their Return. Why would so many products-liability experts disavow a long-established design-defect theory so emphatically and persistently in favor of a novel theory that no court has ever adopted? The only plausible reason is that they knew they had no chance of surviving summary judgment on a design-defect theory.

Plaintiffs conceded the point in oral argument: TDF has "been beneficial" and "greatly helped patients with HIV and AIDS," such that even taking into account its "side effects" and TAF purportedly having "less side effects," TDF is not "defective in design." (Tr.40:10-16.) Plaintiffs added that "tellingly again, the fact that TDF is still on the market and some patients are still using it shows that it is not necessarily a design defect, that there is not a defect in the design that renders TDF defective." (Tr.40:17-21.)

Discovery made it impossible for Plaintiffs to sustain the design-defect claim they had originally pled, leaving them no choice but to make several factual concessions beyond the legal conclusion that TDF was not defective. First, Plaintiffs adduced no expert testimony that the TDF medicines are defective, including no testimony that TDF's risks outweigh its benefits. That forced Plaintiffs to concede that they "do not allege that the risks of TDF outweigh[] its benefits." (10App.3021, 3103.) If the

risks do not outweigh the benefits, Plaintiffs cannot assert a design-defect claim. (*Ante* 15-16.)

Second, none of Plaintiffs' experts would opine that FDA erred in approving the lifesaving TDF medicines, which was based on FDA's determination that TDF's benefits outweigh the risks for the intended population. (10App.3100-01; see 1App.202 [discussing 21 U.S.C. § 355(d)].) Hence, Plaintiffs would not argue that FDA erred in approving TDF. (10App.3100-01.) Having conceded that the FDA got the risk-benefit assessment right, Plaintiffs would be hard-pressed to argue that the risks actually outweigh the benefits.

Third, none of Plaintiffs' experts would opine that Gilead should stop selling TDF medicines. (10App.3101.) That led to Plaintiffs' concession that they "do not contend that Gilead should stop selling any of the TDF medications or … should have refrained from ever selling them." (10App.3101; accord 10App.3021.)

This last concession implicates the final part of Question 2: whether Plaintiffs can "maintain a cause of action for negligent design defect … if they do not contend that Gilead should withdraw TDF from the market?" The answer is no. Establishing negligent design defect necessarily means that it is unlawful to sell the TDF medicines. The concession that Gilead could continue to sell them is at war with any such claim. A manufacturer can "avoid liability" only by "changing its product" or "leaving the market." (*Brinkley v. Pfizer, Inc.* (8th Cir. 2014) 772 F.3d 1133, 1141 [Missouri law]; accord *Houston v. United*

States (7th Cir. 2016) 638 F.App'x 508, 513 [Illinois law]; *Kallio v. Ford Motor Co.* (Minn. 1987) 407 N.W.2d 92, 97 & fn.8.) "[T]he failure to make changes in a defective product or the failure to withdraw a dangerous product from the market" even supports a claim of punitive damages. (*Hilliard v. A.H. Robins Co.* (1983) 148 Cal.App.3d 374, 401-02.) Simply put, Plaintiffs cannot claim that the TDF medicines are defective while, at the same time, saying that Gilead may continue to sell them. At bottom, an assertion of design defect is an assertion that a product cannot lawfully be sold in its current form. So if Plaintiffs want to claim TDF medicines are defective, they have to argue that Gilead cannot sell them. That contradiction alone defeats any negligent-design-defect claim.

C. The design-defect theory should be rejected, whether on the merits or on waiver grounds.

Question 2 also asks whether a design-defect "claim [is] forfeited by [Plaintiffs'] prior disavowal if it was premised on a different understanding of the meaning of the term 'defective.'" Yes. The claim is forfeited both because that could not have been Plaintiffs' premise, and the forfeiture should not be ignored. But the Court is free to address the issue—and reject it on the merits—in the interest of resolving the claim before it.

1. We know Plaintiffs' disavowal was not "premised on a different understanding of … 'defective,'" because Plaintiffs explicitly rejected that premise in oral argument. Justice Goldman asked: "Would you agree that plaintiffs are asserting a design defect claim, *if* in fact what renders TDF defective is that

there is a *safer alternative design* that would achieve the same therapeutic benefit without the same risk?" (Tr.39:12-17 [italics added].) Plaintiffs left no wiggle room: "[T]he plaintiff is not making a design defect claim," based on that premise or any other. (Tr.39:21-22.)

Plaintiffs' many lawyers are experienced products-liability litigators, and the notion that they based their concessions on a misunderstanding of the term "defective" is implausible. They were aware of the traditional factors for design defect when they disavowed the claim. They argued on summary judgment that even though TAF was not yet developed in 2004 and would not be for years, "TAF would have been an alternative feasible design" which "is just one of a [sic] several factors … in determining the reasonableness of Gilead's … conduct" (10App.3031)—only to abandon this assertion on appeal. If counsel believed it would have benefited them to continue pursuing that theory on appeal, they would have.

The only plausible explanation for the disavowal of that theory is that Plaintiffs knew that TAF was not a safer feasible alternative in 2004 and that, even if it were, it would not make TDF defective. (*Ante* § I.) To argue otherwise, Plaintiffs would have to take one of two unpalatable positions. The first is a concession that they somehow forgot that, as they argued below, a feasible alternative is generally relevant to the design-defect analysis. The other is that they concluded *Brown* so definitively shut down any consideration of feasible alternatives for

prescription drugs that they felt they could not ethically argue otherwise.

2. Whichever position Plaintiffs take, the claim is forfeited. This was an "'intentional relinquishment or abandonment of a known right.'" (*Quigley v. Garden Valley Fire Protection Dist.* (2019) 7 Cal.5th 798, 805 fn.4.) The question, then, is whether this Court should excuse the forfeiture. Courts generally have discretion to excuse forfeitures. But Gilead has found no case in which an appellate court has excused a disavowal this emphatic and this repeated—much less where the party unambiguously refused an invitation at oral argument to withdraw the disavowal. (See Tr.39:3-21.)

At some point, excusing the intentional waiver is inconsistent with the role of a court. (See *Constitution Party of Kan. v. Kobach* (10th Cir. 2012) 695 F.3d 1140, 1144 ["If a party … expressly disavows[] a certain argument on appeal, we generally will not consider that argument in our review."].) "When a party disavows a particular theory of the case, it is not an appellate court's proper role to make the disavowed argument for him" (*Vaz Dos Reis v. Holder* (1st Cir. 2010) 606 F.3d 1, 4), nor to invite the party to reconsider its disavowal. It is "'an elemental matter of fairness'" that "'[t]he scope of issues upon review must be limited to those raised during argument'" (*People v. Williams* (1999) 20 Cal.4th 119, 136)—by the parties, not after argument at the Court's initiative.

That said, the point of this writ is to reach a definitive resolution of Plaintiffs' claims at summary judgment. This Court

should do whatever it feels it must to resolve the claims before it. But excusing Plaintiffs' forfeiture will not change the outcome of this appeal because Plaintiffs cannot prevail under a design-defect claim, particularly in light of their factual concessions.

III. Even If Plaintiffs Were Asserting Design Defect, They Could Not Possibly Prove Negligence.

Assuming Plaintiffs were permitted to assert a negligent-design-defect claim and establish that TDF is defective despite their disavowal and factual concessions, Question 3 asks, could Plaintiffs satisfy the mental state requirement for a *negligent*-design-defect claim: "[H]ave plaintiffs adequately alleged that Gilead's negligence consisted in more than a decision to continue marketing TDF rather than TAF" such that the claim would not be effectively "strict liability" premised on Gilead's "decision to market" a defective medicine? The answer is no. To make out a negligent-design-defect claim, Plaintiffs would need to prove that Gilead *knew or should have known* in 2004 that TDF was defective. And since even *Plaintiffs*—with the benefit of two decades of hindsight and years of discovery—still have not claimed that TDF is defective, it cannot be that Gilead *knew or should have known* TDF was defective in 2004.

To start, this Court is correct that under *Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, the negligent conduct in a negligent-design-defect claim cannot consist of a manufacturer's "decision to market a product with [one] particular design" as opposed to another. (Question 3.) In *Merrill*, the plaintiffs tried to "reformulat[e]" a design-defect claim as one for "negligent

distribution [of a product] to the general public." (26 Cal.4th at 481.) The Court rejected that ploy, reasoning that "implicit in both the negligence and strict liability theories of products liability is that the defendant manufacturer was 'engaged in the business of distributing goods to the public.'" (*Ibid.*) So the fact that a manufacturer might make a defectively designed product "available to the general public"—or fail to replace it with a safer, alternative design—"adds nothing to the standard products liability action." (*Ibid.*)

In *Merrill*, that ruling was important because a statute prohibited a plaintiff from bringing a standard products-liability claim. The ruling is relevant here because *Brown* supplies a similar constraint: Plaintiffs cannot sue Gilead on a standard *strict*-liability design-defect theory. (44 Cal.3d at 1065.) They must prove negligence, which depends on the "add[ed]" element of the manufacturer's knowledge. (*Merrill*, *supra*, 26 Cal.4th at 479, 485.) "Strict products liability differs from negligence in one key respect: it obviates the need for a plaintiff to show a manufacturer *knew or should have known* of the risk posed by the product." (*Id.* at 485 [italics added, and alteration omitted].) In other words, a negligent-design-defect claim cannot succeed unless the manufacturer either *knew or should have known* that its product (here, TDF) was unreasonably safe and sold it anyway. (*Ibid.*)

The Court asks whether Plaintiffs have "alleged" the element beyond design defect that would give rise to a negligent-design-defect claim. Again, what matters on summary judgment

is proof, not allegations. (*Ante* 25.) Still, the answer is no: Plaintiffs have neither alleged nor proven it—precisely because Plaintiffs have abandoned any claim that TDF is defective. Plaintiffs cannot plausibly prove that *Gilead* knew or should have known that TDF's risks outweighed its benefits in 2004, where, to date, Plaintiffs concede that the opposite is true. More to the point, and as discussed at length below (*post* 44-46), nothing in the record establishes that the hypothesized safety of TAF over TDF was backed by data so unambiguous and verified in human testing that Gilead could reasonably have known in 2004 that TDF was defective. Even if there were some reason to hypothesize that TAF might one day prove to be safer, Plaintiffs concede that this "fact didn't make TDF itself defective in design—looking at do[] those risks outweigh the benefits" (Tr.40:11-13), and thus could not establish that Gilead knew or should have known that TDF was defective.

IV. There Is No Duty To Develop A Different Product, Especially In This Category Of Cases.

A. There is no duty to develop a different product when the existing product is not defective.

The first part of Question 4 asks: "what must [Plaintiffs] prove Gilead knew or reasonably should have known about TAF relative to TDF to establish that Gilead's duty of care required it to continue development of TAF?" There is nothing a plaintiff could prove that would require any manufacturer to continue developing a product, especially a prescription drug, where the product on the market is reasonably safe.

Since Plaintiffs do not claim that TDF is unreasonably unsafe, improperly manufactured, or lacking proper warnings, Gilead has satisfied any duty it owed to Plaintiffs as consumers of its medicines. (See Pet. 39-48; Reply 21-24, 28-29.) Even if this Court holds open the possibility of imposing on manufacturers duties beyond those prescribed by product-liability law, those duties could not include an obligation to invest enormous time and resources to develop a new product to replace a reasonably safe product with a safer one.

Such a duty would replace product-liability law with "perfect-product law." Giving dispositive weight to a safer feasible *existing* alternative is impermissible in the design-defect analysis because it would mean a manufacturer is obliged to produce the safest feasible product. (*Ante* 16-17.) Even insofar as feasible alternatives are considered in the design-defect analysis, this has never encompassed a duty to bring a completely new product to market. Plaintiffs' proposed duty here goes much further, requiring a manufacturer to commit tremendous resources to develop a product, just because there is reason to think it might be safer for some small subset of patients.

Existing product-liability rules have developed to properly balance burdens and protections. Manufacturers are not treated as "insurers" against all harms (including foreseeable harms) that their products might cause; they "are liable in tort only when 'defects' in their products cause injury." (*Soule*, *supra*, 8 Cal.4th at 568 fn.5.) Accordingly, the existing regime incentivizes manufacturers to develop reasonably safe products with adequate

warnings. (See Pet. 39-42, 49; Reply 21-23.) They are not required to develop (or maintain) research programs to devise improvements or new products. Otherwise, tort law would place an intolerable burden on manufacturers, increasing the costs consumers pay and diminishing the number of products available.

A duty to develop a new product would displace design-defect law and upset the existing balance. A manufacturer could no longer satisfy its duty by ensuring that its product is reasonably safe. And existing limitations regarding what constitutes a defective product, or what qualifies as a feasible safer alternative, would become irrelevant. Rather, manufacturers would be placed under an endless obligation to pursue *ever-better* new products or improvements to existing products. (See Pet. 49-52.) Differently put, the new duty would alter the standard of care manufacturers owe consumers—reasonably safe would not be safe enough. No plaintiff would ever bring a design-defect claim if she could just assert that the manufacturer failed to exercise reasonable care under this lesser standard. Indeed, as Justice Burns suggested at oral argument, if such a low standard were available, these claims would have long ago proliferated. (Tr.35:9-15.)

Rewriting product-liability law as Plaintiffs propose would be particularly problematic in the prescription-drug context. Even assuming that safer, feasible alternatives could *factor* into the analysis of whether a drug were defective after *Brown*, it is still important to respect *Brown*'s warning against the intolerable

policy consequences that would result if a safer, feasible alternative *alone* could subject a manufacturer to liability: diminishing the availability and increasing the cost of essential medicines. It would make no sense to revive those very same consequences in the form of an independent and novel duty to develop a new drug anytime *some* patient population of whatever size might benefit from it as compared to an existing, non-defective medicine.

As *Brown* acknowledged, "harm to some users from prescription drugs is unavoidable"—meaning drug manufacturers are already at a greater risk of incurring liability than manufacturers of other products. (44 Cal.3d at 1063.) Yet "[p]ublic policy favors the development and marketing of beneficial new drugs," because "drugs can save lives and reduce pain and suffering." (*Ibid.*) So courts must be especially careful not to impose additional burdens on manufacturers of essential medications.

On the other side of the ledger, overhauling existing product-liability law is unnecessary given the extensive regulatory regime that already protects patients. (See *id.* at 1069 fn.12 ["[C]onsumers of prescription drugs are afforded greater protection against defects than consumers of other products."].) A manufacturer cannot simply begin marketing its medicine as soon as it has proof of concept and promising leads. It must undergo a lengthy process of laboratory testing followed by years of phased clinical trials. (2022 PhRMA Br. 20-21.) Plus, a prescribing doctor serves as a learned intermediary, responsible

for "independent[ly] judg[ing]" the safety of a prescription drug for a particular patient. (*Gall v. Smith & Nephew, Inc.* (2021) 71 Cal.App.5th 117, 122.) And FDA continues to monitor medicines after approval and requires disclosure of all known side effects—even later-arising ones. (21 C.F.R. § 201.57(c)(6)-(7).) Ongoing monitoring and disclosure further reduce "the likelihood that harm will occur." (*Hansen*, *supra*, 55 Cal.App.4th at 1512.) Patients do not need, as an added layer of protection, lay juries acting as ad hoc drug development boards or regulators.

B. If there could ever be a duty to develop a new product, it could not apply to this category of cases.

Gilead maintains that there is no case in which any manufacturer—especially a drug manufacturer—has a duty to bring a new product to market where its current product is non-defective. But if there were, it cannot be in cases like this, nor can it be the duty Plaintiffs articulate: Under Plaintiffs' rule, every product development decision for any manufacturer is subject to challenge in litigation, years later, on the ground that the manufacturer should have known that an experimental product would prove safer than an existing, non-defective product. That cannot be the rule for three reasons: (1) Plaintiffs offer no line that would guide manufacturers; (2) Plaintiffs' proposed duty would reach decisions made far too early in the development cycle to warrant a duty; and (3) Plaintiffs' proposed scienter standard is not sufficiently protective.

1. Clear legal rules are essential, but Plaintiffs' definition of the duty offers no line.

The Court asks whether "the expense and uncertainty associated with drug development and approval require clear rules establishing when such a duty [to continue developing a drug] arises." The answer is yes, but manufacturers need clarity on more than just the timing. They need clear rules demarcating the categories of conduct that will lead to liability, and those that will not. Plaintiffs' proposed rule is far too nebulous and expansive to provide guidance on any dimension.

Plaintiffs have never contested amici's statistics, confirming that developing a new medicine is a massive and uncertain endeavor—typically "tak[ing] 10 to 15 years and cost[ing] $2.6 billion." (2022 PhRMA Br. 21.) As noted, a manufacturer will have thousands of drug candidates for any one that secures FDA approval. (*Ante* 12.) And securing FDA approval is "onerous" (*Mutual Pharmaceutical Co. v. Bartlett* (2013) 570 U.S. 472, 476), involving hundreds of thousands of pages of test results and exacting scrutiny by top scientists (*ante* 12-13).

Drug manufacturers are constantly investigating multiple portfolios of potentially beneficial new drugs—even for patient populations already served by reasonably safe medicines. (2022 PhRMA Br. 26.) If a company has a duty to pursue this arduous and costly exercise, the company must at least know precisely when that duty arises and for which of its many drug candidates. Manufacturers will conduct themselves very differently if, for example, the duty to bring a safer drug to market arises once

that drug has obtained FDA approval versus anytime a drug candidate seems promising based on results in a test-tube or an early human trial (which was all Gilead had when it made the TAF decision challenged here).

Basic tort doctrine confirms that courts must tell manufacturers the governing rules. The whole point of imposing a "duty" in tort is to communicate "the fact that the actor is required to conduct himself in a particular manner at the risk that if he does not do so he may become liable to another." (Rest.1st Torts, § 4.) A duty is akin to a "legal rule" that governs parties in conducting their affairs—"'imposing a significant precautionary obligation on a class of actors.'" (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 773 & fn.3.) An unclear rule cannot adequately shape future conduct.

Plaintiffs' proposed rule provides no guidance at all. It is not enough to ask, as Plaintiffs propose, whether a reasonable manufacturer "would have acted differently" (Tr.38:10-14), and leave the "standard of care" to be fashioned only in a jury's retrospective assessment of breach (Tr.38:15-40:2; see Tr.46:6-19.)

Such a vague liability standard would leave manufacturers no choice but to behave as if every bit of information they obtain about possible drug candidates will subject them to future liability. That, in turn, will yield disincentives to investigate and develop beneficial new medicines. (*Post* 60-62.) The financial costs of guarding against such potential liability would increase the price of medicines. But that cost would pale in comparison to

the imponderable loss of research abandoned and medicines not developed.

Manufacturers also need clarity along other dimensions. For example, how would motive be judged? To what extent could a manufacturer consider profit against the colossal investment product development requires before a jury could find that the manufacturer illicitly considered profits over patients? Next, what is the applicable standard of safety? Must the developmental product be safer than the original product for all users, or just a subset? What if the developmental product has *different* side effects; is there still a duty to develop that product?

These unanswerable questions provide an additional reason not to recognize any duty. But if the Court does, it owes the industry and patients bright-line rules.

2. Plaintiffs' proposed duty imposes liability far too early in the drug development timeline.

a. Plaintiffs' basic premise is that a drug manufacturer can be liable if it stopped developing an investigational compound despite knowing (or having reason to know) that the potential drug could be safer than, and as effective as, a current drug. But their proposed standard is so nebulous that it is bound to impose liability on a manufacturer long before the typical manufacturer could plausibly be accused of attaining that knowledge. Here, for example, it would impose a duty on Gilead based on nothing more than preclinical studies and a single small Phase I/II study that *did not* conclude TAF was safer than TDF. Regardless of what it showed, at that early stage of drug development where Plaintiffs'

proposed duty would arise, the most a manufacturer could typically have is a *hypothesis* regarding a potential drug's safety profile.

For reasons described above (*ante* 12-14), a drug manufacturer generally could not even make a defensible assertion—much less *know*—that a drug candidate is as effective as a drug already on the market before identifying the specific form of the compound to use, determining the dose, and completing Phase III and head-to-head clinical trials. Nor could the drug manufacturer know until that point that a new drug that seems safe on one dimension does not cause other—possibly more dangerous—side effects.

Notably, Phase III clinical trials do not necessarily establish that a new drug is *safer* than an existing medicine, an essential component of Plaintiffs' proposed duty. That is because FDA will approve a drug if it is *equally* as effective and safe as another drug—that is, "non-inferior." (PhRMA Suppl. Ltr.) To support the hypothesis that a medicine is safer than an existing medicine, the manufacturer must conduct a lengthy head-to-head trial comparing the two medicines in a large patient population. (*Ibid.*)

Such studies are so essential to establishing comparative safety that it is generally illegal for a drug manufacturer to tell prescribing doctors that a medicine is "better, more effective," or "safer" than another drug before securing FDA approval (based on Phase III studies) *and* performing head-to-head comparisons in a large population. Such a claim is illegal absent "substantial

evidence" (21 C.F.R. § 202.1(e)(6)(i), (xvi); 21 U.S.C. § 331), which typically requires at least two Phase III studies (2App.414-15 [Pence Dep.]; see also 1App.203 [Egan Decl.]). And, as Plaintiffs' expert testified, there would need to be double-blind, randomized studies comparing TDF and TAF head-to-head, in at least 500 subjects, tracked over 24-48 weeks. (2App.417-18.) Making any comparative safety claim before such studies are complete could subject a manufacturer to civil and criminal penalties.

If it would be illegal for a manufacturer to even *suggest* that a drug candidate might be safer, then it would be incongruous for a court to impose liability where the manufacturer fails to invest the funds and human resources necessary to even plausibly *know* it is safer.

b. This case perfectly illustrates why no duty could ever be imposed for stopping drug development at the early point Plaintiffs propose.

From preclinical studies, Gilead had evidence that TAF might be distributed *differently* than TDF—enabling more tenofovir to reach targeted cells—but that did not establish it was safer, or that it did not cause different side effects. (7App.2292; 5App.1717-21.) Rather, countervailing evidence also emerged from the preclinical studies: A member of the development team assessing TAF warned of TAF's "potential toxicity" because of its active accumulation in the bone and metabolism in skeletal muscle. (5App.1723.)

Notably, Plaintiffs do not suggest that Gilead's preclinical work was enough to show Gilead knew or should have known

that TAF was safer in humans. Their claim centers around the only clinical study conducted in humans, the 1101 Study. Gilead conducted that study because preclinical studies suggested that TAF was promising enough to try out on humans. (6App.1891.) As noted (*ante* 14), Study 1101 was a Phase I/II study, in which 20 patients received a 14-day regimen of TAF and 10 received TDF. (7App.2280, 2286.) Although Study 1101's findings "support[ed] preclinical data" regarding TAF's "increase[d] cellular distribution," it did *not* show TAF to be safer than TDF. (7App.2301.) Rather, as mentioned previously, it concluded only that TAF's safety profile was "similar" to TDF's. (*Ibid.*)

Meanwhile, Gilead conducted more animal studies, including a nine-month toxicology study in dogs. That study reinforced earlier questions about TAF's different distribution, again "suggest[ing] that … [TAF] may have the potential for long term safety issues." (7App.2305.) In particular, TAF caused cardiovascular and thyroid side effects, and was "not well tolerated" at high doses. (7App.2304.)

It is no wonder then, that Plaintiffs' own expert concedes that TAF was not "*known* to be safer than TDF" in 2004 or 2010. (2App.444-46 [italics added].) Nor could Gilead have believed otherwise. Gilead had not completed any Phase III studies. As Plaintiffs concede, Gilead did not know enough about TAF to even apply for FDA approval. (10App.3106.) And it was not until 2014 that Gilead completed the first large-scale head-to-head study of TDF and TAF, which Plaintiffs' own expert agreed (*ante*

44) was necessary to support a conclusion that TAF was safer for any sub-population of patients. (10App.3109, 3114.)

Back in 2004, Gilead estimated that the cost of conducting further clinical studies to secure FDA approval would be between $82-135 million. (7App.2204, 2313.) Even so, the contemporaneous notes from the Gilead committee that discontinued TAF development show that its decision was not driven by financial analysis but by TAF's failure to distinguish itself from already-approved TDF, including a failure to reach preestablished benchmarks demonstrating materially greater efficacy or a superior safety profile. (7App.2321.)

Nevertheless, Plaintiffs propose a duty that would allow it to try to a jury a claim that Gilead violated its duty to develop TAF in 2004. Even if it would be possible to provoke a credulous jury into reaching that conclusion, the consequences of allowing such a lawsuit to proceed far outweigh any benefits. (*Post* 60-64.)

c. While Gilead believes that there should never be a duty to develop a new product where an existing product is reasonably safe, this Court need not definitively decide that question now. It can dispose of this case with the narrow ruling that no such duty can attach this early in the drug-development cycle. If the Court does recognize a duty in some future case, it can decide then where to draw the clear line that is so critical to guiding manufacturers. Logically, at a minimum, no duty may arise before the manufacturer conducts head-to-head studies and secures FDA approval because that is when the earliest point at which a drug candidate can be known to be safe and effective and

can be legally compared to the existing drug. But wherever the line is drawn, the Court should designate the precise point in the drug-development cycle that triggers the duty, tethered to when a drug manufacturer typically amasses enough proof to know the facts on which Plaintiffs' proposed duty is premised (i.e., as effective and safer, with no countervailing side effects).

3. Constructive knowledge is not sufficiently protective of intricate drug-development decisions.

Another flaw in Plaintiffs' proposed duty is that its scienter standard—the "knew or should have known" negligence standard—is too lax in imposing liability. Wherever in the drug-development cycle a duty attaches, it cannot impose liability anytime a plaintiff can persuade a jury that a manufacturer *should have* known that a drug candidate had the requisite safety attributes. Plaintiffs' negligence theory would reach not only deliberate decisions to delay development for profit, but also instances where a company acts in good faith and yet a plaintiff can claim that it should have known that a drug candidate would have prevented injuries if had been developed or should have brought the drug to market faster through the exercise of due care. But Plaintiffs have never attempted to defend applying their duty to such situations—presumably because it would impose intolerable social costs and enormous burdens (see *post* 60-64).

There would be nothing unusual in imposing a higher scienter standard for a tort duty. Courts frequently temper "the negligence standard [where it] would operate too harshly on

defendants or would entail inappropriate social results." (Rest.3d Torts: Phys. & Emot. Harm, § 2 com. b.) In such circumstances, courts look for "willful misconduct"—for example, "'disregard of a risk *known* … or so obvious that [the defendant] must be taken to have been aware of it, and so great as to make it highly probable that harm would follow.'" (*Calvillo-Silva v. Home Grocery* (1998) 19 Cal.4th 714, 728 [italics added].) Courts apply that heightened standard, for example, in cases where plaintiffs engage in activity that is "inherently dangerous" but socially desirable—which certainly describes lifesaving medicines. (*Knight v. Jewett* (1992) 3 Cal.4th 296, 308, 318 [requiring plaintiff to prove "reckless conduct … totally outside the range of the ordinary activity."]; see *Patterson v. Sacramento City Unified School Dist.* (2007) 155 Cal.App.4th 821, 839.)

Tellingly, a heightened scienter standard aligns with how Plaintiffs couch their position. Even though Plaintiffs ground their claim in a negligence statute, the *first page* of Plaintiffs' Return refers to knowledge and uses the term "appalling" twice, plus "deliberate," "calculated," and "deplorable." (Ret. 8.) In oral argument, Plaintiffs pinned their proposed duty to the moment "Gilead *knew* TAF was a safer alternative, *knew* it did not have [the] side effects [caused by TDF], and yet *intended* to press pause." (Tr.44:10-15 [italics added].) In short, Plaintiffs seek to hold Gilead liable for intentionally disregarding a *known* risk.

A heightened standard also addresses the scenarios that appeared to most trouble this Court. Justice Burns asked about a manufacturer that could "calculate[] precisely how many people

would be injured by their product" if they failed to develop a new one, wondering whether tort law could reach such "egregious" conduct. (Tr.60:10-22, Tr.62:10-63:11.) An actual-knowledge/willful-disregard standard would reach that conduct, where a drug candidate (unlike TAF) was sufficiently far enough along to consider exposing a manufacturer liability for failure to develop it.

V. If *Rowland* Applies, This Court Should Recognize An Exception Under The *Rowland* Factors.

The Court's final question involves the framework for recognizing an exception to an existing duty under *Rowland v. Christian* (1968) 69 Cal.2d 108. Gilead continues to maintain that *Rowland* does not apply because Plaintiffs have proposed a new duty, as already explained at length (Reply 37-39; Tr.8:4-10:15). But ultimately, *Rowland* does not change the outcome. It makes little difference whether Plaintiffs must establish a duty or Gilead must establish an exception. (Tr.59:15-60:5.) Applying the *Rowland* factors, there must be an exception that covers at least this category of cases.

A. If the *Rowland* factors apply, this Court should address them.

This Court asks whether it should "examine the *Rowland* factors [if *Rowland* applies] notwithstanding Gilead's prior disavowal of an argument under that framework." The answer is yes.

As a threshold matter, however, there was no disavowal—and certainly none as persistent, emphatic, and intentional as

Plaintiffs' disavowal of their design-defect claim. Both below and on appeal, Gilead has consistently maintained that *Rowland* does not apply, but it did so with arguments that map neatly onto the *Rowland* factors. (See Pet. 49-52; Reply 18, 23-24, 40-45; see also 1App.133-34; 10App.3147-48.) On appeal, in particular, Gilead explained that it had "addressed the *Rowland* factors, just under a different heading," pointing to the places in prior briefing that had addressed them. (Reply 39-40 fn.4.) Plaintiffs agreed, noting that "an entire section of Gilead's Petition" raised "policy arguments" and declared that "although Gilead posits that it need not 'resort' to a *Rowland* analysis, that is *precisely what it seeks to do*." (Ret. 46-47 [italics added]; accord Ret. 48 [acknowledging that Gilead argued the "*burden to Gilead* and potential consequences to the community" factor].) That is precisely right. Amici also weighed in with extensive arguments addressing the *Rowland* factors (see PLAC Br. 20-29), which Plaintiffs then addressed (Pls.' Resp. to Amici 24-28). Then, in oral argument, Gilead continued to press the position that it has already addressed, and prevails under, the *Rowland* factors. (Tr.59:15-60:5.)

Regardless, as noted above (*ante* 32), this Court has the discretion to overlook an earlier disavowal and it should exercise that discretion as necessary to fully address the legal claims in this appeal. Several considerations support doing so here. First, the decision whether to adopt an exception under *Rowland* is a question of law decided without regard to the facts of this case. It calls for a "'clear, categorical, bright-line'" for a "'general class of

cases'" (*Cabral*, *supra*, 51 Cal.4th at 773-74 fn.3) covering "innumerable, unknowable future circumstances"—not just the precise "circumstances alleged here" (contra Ret. 51). So this Court does not need the trial court's guidance in parsing the record of the case. Second, as noted, the parties actually addressed most of the factors under a different framework. (See Reply 39-40 fn.4.) Third, the question of duty here is a matter of extraordinary public importance, as evidenced by the numerous amicus briefs in this case. (See *Sea & Sage Audubon Soc'y, Inc. v. Planning Com.* (1983) 34 Cal.3d 412, 417.) Fourth, no future panel will be better equipped to resolve this case. This Court has the benefit of 11 briefs from the parties plus five amicus briefs (and counting) devoted to whether a duty exists—including four supplemental briefs focused specifically on the *Rowland* factors. Manufacturers across a vast swath of business are watching this case and seeking this Court's guidance on whether they have a duty to develop new products when an existing product is already reasonably safe.

B. Under the *Rowland* factors, there must be an exception that covers at least this category of cases.

If *Rowland* applies, there should be an exception that applies to all decisions not to develop a new or improved product where the existing product is not defective. Recognizing that exception now would avoid a lot of mischief and wrangling over the scope of an exception that should be categorical. But here, again, this Court can dispose of this appeal with a narrower exception that covers the "general class of cases" before it and

leaves other scenarios for another day. (*Cabral*, *supra*, 51 Cal.4th at 773, fn.3.) Whatever this Court does in future cases, it should hold that Gilead could not have had a duty because it had not even started Phase III trials, much less conducted the sort of head-to-head studies necessary to possibly supply knowledge of the comparative safety of TAF over TDF. In some future case, this Court can decide to adopt the complete exception, or to limit the exception to certain later points in the development cycle.

The *Rowland* factors are commonly divided into "two categories": foreseeability and public policy. (*Regents of Univ. of Calif. v. Super. Ct.* (2018) 4 Cal.5th 607, 629.) Both categories favor an exception.

1. The foreseeability factors favor an exception.

The interconnected foreseeability factors assess 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 772.) "[T]he degree of foreseeability [must be] high enough to charge the defendant with the duty to act on it"—i.e., "reasonable" foreseeability, not mere possibility. (*Sturgeon v. Curnutt* (1994) 29 Cal.App.4th 301, 306-07.) The foreseeability factors counsel against imposing any duty to develop a drug here.

Foreseeability of harm to the plaintiff. The first factor addresses whether harm is a "reasonabl[y]" foreseeable consequence of the alleged negligence. (*Id.* at 306.) Because

without reasonable foreseeability, "there [is] no duty," this factor alone requires an exception. (*Ibid.*)

It goes without saying that the disclosed side effects of any medication already on the market are foreseeable. The drug manufacturer displays them prominently on the label and prescribing doctors (serving as learned intermediaries) weigh the benefits and risks for a particular patient. But where a drug on the market is reasonably safe and prescribed by a doctor, the fact that it will foreseeably cause side effects cannot weigh into the *Rowland* analysis. Counting the foreseeability of those injuries against the drug manufacturer would fly in the face of *Brown*'s holding that it is improper to impose liability on a manufacturer for the foreseeable (and disclosed) injuries from a non-defective drug.

Rather, because Plaintiffs' proposed duty is to develop (or continue developing) a different product to avoid the injuries associated with an existing, non-defective medicine, the question is whether it is foreseeable that an abandoned developmental candidate would *prevent* those injuries. The less information that a manufacturer has about the drug candidate, the less foreseeable it is that the candidate would prevent injuries that another medicine would cause. In the category of cases currently before the Court—long before even Phase III trials have started—there are far too many unknowns, and far too many steps in the chain of causation to treat that scenario as reasonably foreseeable. Of course, "[o]n a clear day, you can foresee forever," but a duty requires more than mere possibility.

(*Sturgeon*, *supra*, 29 Cal.App.4th at 306-07.) After devising a hypothesis that a developmental drug could be equally effective and safer without countervailing side effects, the manufacturer would still have to determine:

- whether and how much the developmental candidate actually prevents the known side effects;
- whether it is as effective;
- whether it introduces different side effects and how dangerous those are;
- whether, in light of the answers to those questions, patient welfare is best maximized by pursuing this path or another;
- whether FDA will approve the developmental drug; and
- whether doctors will prescribe it over the existing medicine.

This causal chain is too contingent, conjectural, and unknowable to be foreseeable. (See PLAC Br. 22-24 & fn.2 [manufacturer's lack of "control" weighs against foreseeability].) And it is far more remote than other cases where courts have declined to recognize an exception. For example, in *T.H. v. Novartis Pharmaceuticals Corp.*, which Plaintiffs highlighted at oral argument, the manufacturer "kn[ew] to a legal certainty" that any negligence in the labeling of a brand-name drug would mislead physicians as to whether it could safely prescribe a generic bioequivalent. ((2017) 4 Cal.5th 145, 166.)

The 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 studies.

Closeness of connection between defendant's conduct and plaintiff's injury. The next factor is "strongly related" to the foreseeability analysis. (*Cabral*, *supra*, 51 Cal.4th at 779.) The extended chain of causation described above highly attenuates the connection between injury from a non-defective medicine and asserted negligence in failing to develop a hypothetically safer drug candidate.

The connection is further attenuated because the purportedly negligent conduct is *not* the "manufacture, [sale], or supply" of the allegedly injurious product. (*O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 365.) In *O'Neil*, the plaintiffs claimed that the defendant's products would foreseeably expose consumers to *other* accessory products containing asbestos. (*Id.* at 342.) The Court determined that the manufacturer's conduct with respect to the marketing of its product had an "extremely remote" connection to injuries caused by another product—even assuming those injuries were foreseeable. (*Id.* at 364-65.) While the Court's analysis partly depended on the defendant's lack of control over the asbestos-containing products, which were produced by another manufacturer, it suggested generally that whenever the purported negligence concerns the development or manufacturing of a product *other* than the allegedly injurious product itself, the connection factor cannot be satisfied. (*Id.* at 365.)

Degree of certainty of plaintiff's injury. The final foreseeability factor generally does not come into play unless "the

only claimed injury is intangible harm." (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1023.) Because Plaintiffs' asserted injuries are physical, this factor bears no relevance.

2. The policy factors favor an exception.

Even when the foreseeability factors fully favor a duty, "policy considerations [may] ultimately require an exception to the general duty of care." (*Kuciemba*, *supra*, 14 Cal.5th at 1022; accord *O'Neil*, *supra*, 53 Cal.4th at 362 ["'foreseeability alone is not sufficient to create an independent tort duty'"].) The second category of *Rowland* factors, which analyze policy considerations, decisively requires an exception here.

Moral blame. "'[T]he moral blame that attends ordinary negligence is generally not sufficient to'" weigh against an exception. (*Martinez v. Bank of Am. Nat. Trust & Savings Assn.* (2000) 82 Cal.App.4th 883, 896.) Courts reserve moral blame for the categories of cases where defendants intentionally cause harm or act with bad faith. (*Ibid.*)

Drug development decisions generally do not warrant moral blame. These are intricate decisions that account for finite resources, numerous possible research paths, and endless patient needs, all assessed with limited information in the context of highly unpredictable outcomes. Plaintiffs' lawyers with the benefit of hindsight could find fault with any such decision, and hurl invectives like "egregious" and "appalling." But "the hindsight of the judicial process is an imperfect device for evaluating business decisions" like these. (*Lamden v. La Jolla Shores Clubdominium Homeowners Assn.* (1999) 21 Cal.4th 249,

259.) And rarely—if ever—would it be considered immoral to opt against dedicating immense financial and human resources toward improving upon the safety profile of an already reasonably safe medicine. Nor is it immoral, even after collecting promising initial data, not to further pursue an arduous and highly uncertain effort to secure FDA approval.

Several legal principles support that intuition. First, a decision not to conduct a massive research and development program (or not to invest in a huge regulatory undertaking) is a decision not to act, which Code of Civil Procedure § 1714 ordinarily does not reach. (See Reply 24.) Second, "little moral blame can attach" where a manufacturer does not affirmatively mitigate "dangerous aspects of *other* … products." (*O'Neil*, *supra*, 53 Cal.4th at 365.) That conclusion applies with special force where, as here, the injurious "other … products" are reasonably safe. Third, the heavy uncertainty regarding whether a developmental drug will ever prevent a single injury diminishes any moral blame. Fourth, a manufacturer declining to pursue one path generally does so to pursue another, directing its finite resources toward other patient needs. And finally, the blameworthiness factor weighs *against* a duty where "there can be little doubt that defendants' conduct"—developing lifesaving medicines—is "of high social utility." (*Ibid.* & fn.13 [quotation marks omitted].)

The record here powerfully illustrates the absence of moral culpability in decisions (like this one) to stop development of even

promising drug candidates, especially in favor of other, potentially beneficial development paths:

- TDF is a lifesaving medicine that was—and remains—remarkably safe and effective. (3App.991-95, 1017-19; 9App.2893.) The Development Committee emphasized TDF's safety profile in deciding to focus on TDF-based fixed dose combination medicines rather than proceed with the unproven TAF. (2App.462; 7App.2321.)

- When Gilead discontinued TAF research in 2004, no one knew that TDF would prolong lives by decades, which is what yielded a patient population more susceptible to bone and kidney issues. (See 8App.2653; 9App.2832, 2835, 2928.)

- Early data concerning TAF's safety profile pointed in different directions: The only clinical study found that TAF had a "similar" safety profile to TDF, not a superior one. (7App.2301.) Non-clinical studies revealed the potential for new cardiac and thyroid side effects—which was resolved only after another five years of study. (See 7App.2304-05.)

- The side effects that TAF might have been able to prevent affected a small proportion of patients, on the order of 2 out of 100,000 per year (for bones) and 11 out of 10,000 (for kidneys). (*Ante* 19.)

- TAF development would have taken years and cost at least $82 million. (7App.2204, 2313.)

- Gilead instead devoted its resources to (successfully) devising a "watershed" once-a-day pill that benefited the entire population of HIV/AIDS patients. (See *ante* 20; Reply 16-17.)

Also illustrative is the ease with which creative counsel can accuse a drug manufacturer of "appalling" conduct that "put[s] profits over people." (Ret. 8, 27.) Here, those invectives

principally revolve around a single document: a "quick and dirty" analysis performed by a junior financial analyst who was *not* involved in the Development Committee's deliberations. (6App.2084, 2087-90; 7App.2135-50, 2202-09.) And the analysis—conducted before anyone could know TAF's actual safety profile—was explicitly premised on the "[k]ey [a]ssumption[]" that the "safety profile of [TAF] [wa]s *comparable* to TDF's safety profile." (7App.2203-04 [italics added].) Plaintiffs' entire narrative insists on the opposite, that Gilead "knew" something no drug company could know at the time: that TAF was equally effective as and safer than TDF, with no additional side effects. (See *ante* 48.) The reality, as Plaintiffs' own cherry-picked documents demonstrate, is that the Development Committee stopped TAF development precisely because TAF failed to meet concrete, patient-oriented benchmarks regarding safety and efficacy that they had set years earlier (6App.1901, 1903; 7App.2196, 2286)—along with unpredictability about TAF's safety profile. (7App.2304-06, 2321.)

Because drug manufacturers will always have to make choices constrained by finite resources, creative lawyers will always be able to spin a preferred narrative. (See Pet. 52; Reply 41.) But apart from ignoring the realities of drug-development decisions, turning financial analysis into a basis for moral culpability is an exercise in distortion. Consider, for example, that the greater the population that a drug serves, the more profit a company would make. But casting blame on manufacturers for widespread treatment gets the morality calculus backward. In short, the fact that drug-development

decisions are informed by financial considerations cannot be cause for moral opprobrium.

Policy of preventing future harm. This factor "examines both the positive and negative societal consequences of recognizing a tort duty." (*Kuciemba*, *supra*, 14 Cal.5th at 1026.)

Plaintiffs' proposed duty will have profoundly negative consequences. (See Pet. 50-52; Reply 42-46.) To start, it would *disincentivize* manufacturers from improving on existing, reasonably safe medicines because attempts at improvement provide the basis for liability. Additionally, preliminary investigations could trigger a multi-billion-dollar obligation to take a promising drug candidate through further clinical studies and to FDA approval (or rejection)—even if resources would be better used elsewhere. This would discourage manufacturers from even beginning to investigate possible improvements. A manufacturer could not start an investigation of a new product or improvement unless it *knew*, with certainty, that it would take the product all the way to market. Altogether, it would reduce the number of beneficial medicines available for consumers. (See 2022 PhRMA Br. 27-34 [discussing the chilling effect of Plaintiffs' proposed duty on innovation]; 2022 Chamber Br. 25-26 [discussing examples].)

This case illustrates the policy dangers. If Gilead had never investigated TAF, Plaintiffs could impose no duty here. Ironically, the decision in 2010 to develop TAF, conduct Phase III studies, and bring TAF to market is what furnished Plaintiffs' best evidence of TAF's ultimate safety profile—supplying the

basis for this lawsuit. If Gilead had Plaintiffs' duty in mind in 2001 (when the first TDF medicine was approved), Gilead might have thought twice about continuing to investigate TAF. Same for the decision to conduct Phase III studies in 2010 and the later decision to bring TAF to market. Those activities should plainly be encouraged but are discouraged under Plaintiffs' proposed duty. (See *Brown*, *supra*, 44 Cal.3d at 1063.)

Once a drug manufacturer has produced some data suggesting the drug candidate is safer, the prospect of litigation would also perversely skew the manufacturer's development priorities. Consider the choice between developing Medicine A for an otherwise incurable disease afflicting a vast patient population versus Medicine B to improve on outlier side effects associated with an existing, FDA-approved medicine. While Medicine A may have greater potential to reduce overall suffering, pursuing it at the expense of Medicine B could yield massive liability under Plaintiffs' proposed duty. To optimize health outcomes for *all* patient populations, manufacturers should focus on developing reasonably safe medicines—not on which development path may expose them to liability.

On the other hand, the uncertainty of drug development and of FDA approval undermines any purported beneficial consequences of Plaintiffs' proposed duty. (*Ante* 12-13, 43-44, 54.) It is only ever with the benefit of hindsight that a plaintiff would be able to say that a drug manufacturer should have known whether to pursue one investigational compound over another. "To impose liability on a defendant for choosing the wrong side in

a scientific debate"—or the wrong path at a development crossroads—"does not further the goal of preventing future harm. The very nature of scientific debate is that the 'right' answer has not yet emerged." (*N.N.V. v. Am. Assn. of Blood Banks* (1999) 75 Cal.App.4th 1358, 1383-84.) Simply put, while stopping development of a drug candidate may not imperil patient safety, creating liability for that decision certainly will.

Extent of the burden to defendant and consequences to community. Even if the other *Rowland* factors did not weigh in favor of a no-duty rule, "[s]ome factors may be so weighty as to tip the balance one way or the other," and a "significant and unpredictable burden" on defendants and the community suffices. (*Kuciemba*, *supra*, 14 Cal.5th at 1031.) Because Plaintiffs' duty presents such a burden, this factor necessitates an exception.

A duty here would "throw open the courthouse doors to a deluge of lawsuits" (*Kuciemba*, *supra*, 14 Cal.5th at 1031; accord *Bily*, *v. Arthur Young & Co.* (1992) 3 Cal.4th 370, 400 [declining to recognize a duty that would "raise[] the spectre of vast numbers of suits and limitless financial exposure"].) Every development decision yields multiple classes of plaintiffs who would have benefited if the company had invested its resources elsewhere. (Reply 44.) Every improved medicine a manufacturer releases gives birth to a class of plaintiffs who can claim that it should have been developed and released sooner. For example, if Gilead had delayed the development of its TDF-based once-a-day pill so that it could secure FDA approval of TAF, the millions of

beneficiaries of the improved regimen (including these same Plaintiffs) could have sued for delaying that improvement.

Indeed, while manufacturers assess whether to undertake the expense of drug development or regulatory approval under conditions of extreme uncertainty, with partial scientific knowledge and billions of investment dollars on the line (see Pet. 51-52; Reply 41), it will always be possible to craft a "revisionist" narrative in which the best path for one particular patient was obviously right all along—but was ignored by short-sighted and profit-oriented executives. (*Bily*, *supra*, 3 Cal.4th at 401 [explaining that susceptibility to "plaintiffs' litigation-focused attention" might lead to liability disproportionate with fault].) It is much more difficult in the moment to predict which promising paths will pan out (*ante* __), or how best to keep a company competitive and answerable to shareholders.

Drug manufacturers should not be subjected to such "enormous and unprecedented financial burdens … in potential damages awards and litigation costs." (*Kuciemba*, *supra*, 14 Cal.5th at 1027.) Litigation costs aside, drug manufacturers should not be forced to absorb the costs of complying with Plaintiffs' proposed duty. (See *Kesner v. Super. Ct.*, (2016) 1 Cal.5th 1132, 1152.) The obligation to follow every promising lead surfaced in research and development would be incalculably expensive. (*Ante* __.)

The immense burden placed on drug manufacturers would ultimately burden the community at large. Increased expense—whether in future damages awards or the dedication of resources

toward potentially fruitless developmental leads—would divert resources from drug development and increase the cost of medicines, placing them "beyond the reach of those who need [them] most." (*Brown*, *supra*, 44 Cal.3d at 1063.) The duty would also "deter [the] socially beneficial behavior" of improving existing prescription drugs. (*Kuciemba*, 14 Cal.5th at 1028.) And some drug manufacturers may simply "shut down"—depriving consumers of the "essential" lifesaving medicines that these companies develop. (*Ibid.*; see 2022 PhRMA Br. 34-35 [prospect of expanded liability "might well contract" pharmaceutical industry].) These extraordinarily "negative consequence[s] to the community, while hypothetical, cannot be ignored." (*Kuciemba,* 14 Cal.5th at 1028 [alterations and citations omitted].)

Availability and cost of insurance. Manufacturers cannot insure every "unknowable" risk "lurking" in products. (*O'Neil*, *supra*, 53 Cal.4th at 365.) Plaintiffs' proposed duty would massively expand manufacturers' existing exposure to liability. That, in turn, would greatly increase the cost of commercial- and products-liability insurance—if it were available at all—tightening budgets for research and development and making prescription drugs more expensive and inaccessible. (See *Brown*, *supra*, 44 Cal.3d at 1062-63.)

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A "duty of care will not be held to exist even as to foreseeable injuries … where the social utility of the activity concerned is so great, and the avoidance of the injuries so burdensome to society, as to outweigh the compensatory and cost-

internalization values of negligence liability." (*Merrill*, *supra*, 26 Cal.4th at 502; accord *Kuciemba*, *supra*, 14 Cal.5th at 1025.) That is the case here: The policy factors confirm "the significant and unpredictable burden that recognizing a duty of care would impose on" research and development, the court system, and "the community at large." (*Kuciemba*, 14 Cal.5th at 1031.)

If *Rowland* applies, this Court should hold that there is an exception for any decision not to proceed with research or regulatory approval of a drug candidate, or at a minimum that an exception applies to the category of cases arising this early in the development timeline.

CONCLUSION

This Court should grant Gilead's Writ.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

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