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

PETITIONER'S REPLY SUPPLEMENTAL BRIEF

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INTRODUCTION[1]

Although Plaintiffs' Supplemental Brief declines to answer several of the Court's questions, it does vastly simplify things by mooting the design-defect issues. So the question posed in Gilead's Petition is cleanly presented: Even if a drug manufacturer has satisfied its duty of care to provide consumers a reasonably safe medicine with adequate warnings, can it still be held liable for injuries arising from that product on the ground that the manufacturer should have more quickly developed a different drug to give consumers a "choice" about which drug to take? The answer is no: This Court should reject that duty—especially in the category of cases like this one, before a drug candidate has even begun the Phase III and head-to-head clinical studies that could establish that it is actually safer and equally effective without any worse side-effects.

Plaintiffs confirm that their proposed duty is both nebulous and boundless. The only direction they are prepared to give this Court—or manufacturers—is that the duty is to "act reasonably" and individual juries will decide what that means. That means that a jury is free to decide that a drug manufacturer behaved unreasonably because it opted not to pursue drug development after test-tube or animal studies showed some promise.

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[1] This brief cites Gilead's Supplemental Brief as "GSB", Plaintiffs' Supplemental Brief as "PSB", Gilead's Writ Petition as "Pet.", Plaintiffs' Return as "Ret.", Gilead's Reply to Plaintiffs' Return as "Reply." Merits stage amicus briefs are cited as "2022 _____ Br.", and supplemental amicus briefs as "____ Suppl. Br.", both according to the lead amicus.

That is no exaggeration—it is what Plaintiffs point to in this very case. They had previously been saying that Gilead knew TAF was safer and as effective because of one, very preliminary and very small clinical study. But in the face of evidence that the study found TAF to be no safer than TDF, they now retreat to arguing that the (conflicting) evidence from test-tube and animal studies sufficed to prove that Gilead "knew" TAF was safer in humans.

Such a vague and expansive standard will be of no use to manufacturers and will affirmatively harm consumers. Manufacturers will have to overcompensate by taking precautions not to learn too much to avoid the risk of retrospective damages awards. And all manufacturers, including those outside the pharmaceutical context, will have a disincentive to develop new products and improvements on existing ones because those later innovations could be used against them as a basis for free-floating negligence liability. That is bad for consumers across every sector. In the pharmaceutical space, it would be devastating. It would mean fewer scientific breakthroughs and fewer life-saving medicines.

With extensive briefing, this Court is now well-equipped to address Plaintiffs' novel duty, whether the inquiry is couched as adopting a new duty or carving out an exception to an existing one. Under either rubric, this Court should reject Plaintiffs' proposed duty.

ARGUMENT

This brief begins by correcting the flawed factual narrative that underlies Plaintiffs' answers to all this Court's questions. § I. The brief then turns to the two questions that remain in dispute. Part II addresses Question 4 and argues that no duty of care should apply in this category of cases. Part III addresses Question 5 and demonstrates that, even if this Court were to approach the duty under *Rowland*, *Rowland*'s factors demand an exception. Part IV assesses the consequences of Plaintiffs' concessions on Questions 1-3. Part V addresses a recent decision in the related federal litigation.

I. Plaintiffs Build Their Argument For A New Duty Around A False Narrative.

The questions of the existence of a duty and the propriety of an exception are both questions of law that must be resolved for "'an entire category of cases.'" (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1021.) Neither is based on "'the facts of the particular case before'" the Court. (*Ibid.*) The facts can be relevant context for framing a duty or specifying the category. But that is not how Plaintiffs use them. At every turn, Plaintiffs improperly pin their arguments about whether there is a duty to the "specific facts" of this case. (PSB35.) Plaintiffs do so in assuring this Court that their proposed duty is not boundless (*post* 20), in explaining why a duty is needed under the "circumstances alleged here" (PSB10; *post* 27), and in discussing almost every foreseeability and public-policy factor of the *Rowland* analysis (*post* 39-40, 41, 43, 44, 49).

That approach is legally wrong. But it is especially problematic because Plaintiffs' arguments—most notably their answers to Questions 4 and 5—revolve around three false themes: (1) that Gilead "knew" in 2004 that TAF was safer than TDF; (2) that Gilead had "already innovated, [and] already developed" TAF by then; and (3) that Gilead stopped TAF development for purely financial reasons unrelated to patient needs. (See, e.g., PSB37, 21, 35.) Plaintiffs appear to believe that Gilead's decision to tee up a pure legal issue—by not disputing specific facts—allows them to take liberties with characterizing the record.

To the extent the Court considers the facts of this case, it should understand that the record flatly contradicts each of Plaintiffs' themes. Clarifying the record is also instructive because Plaintiffs' spin is an object lesson on how easy it is to portray good-faith drug-development decisions as nefarious and because it exposes the sheer breadth of Plaintiffs' proposed duty.

A. Gilead stopped TAF development before it could know that TAF would be safer than TDF.

The Court's request for supplemental briefing placed front-and-center the question of what a manufacturer generally needs to *know* about a drug candidate in order for a duty to develop that drug to arise. As Gilead has consistently demonstrated, Plaintiffs' theory of negligence would impose liability regardless of what a manufacturer actually knows (Reply 45, GSB47-49) and reaches a drug manufacturer's development decisions long before it *could* know of a drug candidate's actual or comparative safety

profile (GSB42-46). Plaintiffs obscure the consequences of their proposed rule by repeatedly skewing the facts to suggest that a duty should be imposed here *precisely because* of Gilead's purported knowledge. The theme is so central to Plaintiffs' legal argument that they repeat 11 times that Gilead knew TAF was safer than TDF. (PSB8, 10-11, 13, 21-22, 26, 35, 42-43, 45, 49.) How Plaintiffs draw *that* inference from *this* record is instructive in laying bare how easy it will be to assert knowledge in future cases under the duty that Plaintiffs propose.

This is how Plaintiffs describe Gilead's knowledge in 2004: "By the time Gilead made the decision to shelve TAF … [t]here was no question whether TAF was effective or capable of alleviating the risks of bone and kidney damage inherent in TDF. Those questions had *already* been answered." (PSB45.) That is a shift. Until now, Plaintiffs had framed Gilead's negligence as the failure to "continue[] TAF development"—including "conduct[ing] the additional studies needed" to establish its safety and effectiveness. (10App.3106.) Their own expert admitted that TAF was not "known to be safer than TDF" in 2004. (2App.444-46.) Now Plaintiffs assert that Gilead did not need to do anything further to *know* TAF was safer. The undisputed factual record—and realities of drug development Gilead and amici have recounted—refute this framing.

Gilead has already described exactly what it knew in 2004 when it stopped TAF development. (GSB44-46; Reply 14-16.) To summarize, TAF's *pre*clinical data supported a hypothesis that TAF might be distributed *differently* than TDF: More tenofovir

appeared to reach targeted cells (which could be good), but more tenofovir also reached cells that were not targeted (which could be bad). (5App.1666, 1717-21; 7App.2292.) Also on the negative side of the ledger was a dog study that raised questions (eventually dispelled a decade later by clinical testing) about whether TAF might cause other side effects—including potential cardiac and thyroid complications. (7App.2304.) The only clinical data Gilead had was Study 1101, the single 14-day Phase I/II clinical study—very early in the development cycle—in which just 20 patients received TAF and 10 received TDF. (7App.2280, 2286.)

Plaintiffs' earlier briefs emphasized Study 1101 to establish Gilead's knowledge. That study, Plaintiffs insisted, was what gave Gilead the "*proof of concept*" that TAF is safer than TDF. (Ret. 14.) The fallacy, which Gilead repeatedly emphasized (e.g., Reply 14-15), is that Study 1101 did *not* establish any safety improvement over TDF—finding only a "similar" safety profile. (7App.2301, 2305, 2308.)

So Plaintiffs have now executed another shift: Study 1101 is completely absent from their Supplemental Brief. Plaintiffs have moved their claim of knowledge even *earlier* in the development cycle. Plaintiffs now cite to two *preclinical studies*—animal and test-tube studies—to claim that Gilead knew TAF was safer than TDF because "TAF … achieved the same antiretroviral effect as TDF but with roughly 90% less toxic tenofovir in the blood." (PSB22 [citing 5App.1662-70, 1717-24].) Neither preclinical test determined that TAF was safer than

TDF. (See, e.g., 5App.1688 ("[TAF] is marginally *more toxic* than [TDF] in the dog and *significantly more toxic* in the rat" [italics added].)

That is it. Plaintiffs cite no further scientific data to substantiate their claim that Gilead knew TAF was safer than TDF in 2004.

Beyond that, Plaintiffs invoke a commercial evaluation from 2002, based on those same preclinical studies, citing TAF's safety "*potential*." (6App.1898 [italics added]; see 6App.1896-911 [referring to "potential" outcomes eight times].) And Plaintiffs cite a 2008 email in which a Gilead scientist mentions the "spectacular success" of TAF's "*preclinical* program." (5App.1713 [italics added].) That same email explains that Gilead had stopped TAF development in 2004 because TDF had proven itself remarkably safe, and Gilead concluded it would be "very difficult to show a clinical difference between the drugs." (5App.1713.)

If some promising (but mixed) preclinical results are enough to impose a legal duty on a manufacturer to continue a drug's development through the gauntlet of human clinical trials and FDA approval (or rejection), then Plaintiffs' duty truly is boundless.

B. Gilead had neither "innovated" nor "developed" TAF by 2004.

Plaintiffs' misstatement about knowledge is the quicksand foundation for its equally false assertions that Gilead had "*already* innovated" and "already developed" TAF by 2004. (PSB45-46; see PSB37, 49, 50.) That, too, is a shift. At oral

argument, Plaintiffs acknowledged that TAF "was still in development" in 2004. (Tr.42:20-22). Now Plaintiffs insinuate that Gilead was on the verge of approval, with TAF medicines waiting to be shipped. The undisputed record establishes that TAF was years and tens of millions of dollars away from that point in the highly uncertain drug-development cycle.

Plaintiffs try to support their "already innovated" narrative with two sleights of hand. The first is the unexplained assertion that "[b]y the time Gilead made the decision to shelve TAF, it had already been submitted to the FDA for an IND and begun the approval process." (PSB45.) An IND is an "Investigational New Drug" application. A drug manufacturer must file an IND before testing the drug on a single human. (21 C.F.R. §§ 312.20, 312.22.) An IND indicates nothing more than baseline assurance that the compound seems safe enough to risk human testing. (GSB12.)

In other words, far from signaling imminent approval, the IND is just a prerequisite to the long, expensive, and highly uncertain clinical process previously described. (See GSB12-13; 2022 PhRMA Br.20-21 [distinguishing an IND from a New Drug Application (NDA) seeking approval of a new drug].) It was a necessary step before Gilead could embark on a multi-year $82-million-plus venture with an 88% failure rate. (GSB22 [citing 7App.2313]; GSB13 [citing 2022 PhRMA Br. 21-22].)

Plaintiffs' second narrative sleight of hand is the related assertion that Gilead had "planned a timeline for FDA approval and release of TAF." (PSB45.) But a timeline is not some firm commitment to develop a drug. It is a piece of paper. No drug

manufacturer devotes huge resources to a drug candidate without laying out when the costs will be incurred and when potential offsetting revenues *might* start (assuming that all the studies pan out and regulatory approvals are secured).

If development had been completed by the time Gilead made its decision in 2004, Plaintiffs would not have conceded that TAF was still years away from the market. (1App.304; 2App.416-17.) And it would not have taken Gilead five years of additional study to obtain FDA approval after Gilead revived TAF development in 2010. (10App.3108, 3114.) The time and expense were necessary to bridge the gulf between the knowledge on TAF in 2004 and the scientific proof necessary to secure FDA approval.

C. Patient needs, not money, motivated Gilead's decision to stop TAF development.

Despite purporting to ground their cause of action in negligence, Plaintiffs' brief revolves around the allegation that Gilead "deliberately delay[ed]" or "intentionally" withheld TAF (PSB8, 10-11, 19, 21-22, 24, 26, 31, 42-43, 52), and did so "*solely* to make money and at the expense of patient safety" (PSB45 [italics added]). Gilead has explained how Plaintiffs' cherry-picked documents belie that assertion. (Reply 15-16.) Here is a bit more detail:

As an initial matter, contrary to Plaintiffs' repeated assertion that the decision to stop TAF's development was made "not in the laboratory but in the boardroom" (PSB11), the record is clear that a scientist made that decision—specifically, Dr.

Norbert Bischofberger, Gilead's Senior Vice President of Research and Development. (2App.462.) And his decision was about the science—most notably that the data from tens of thousands of real-world patients established that TDF is safe, effective, and well-tolerated while an early clinical study had shown that TAF showed no meaningful improvement over TDF. (2App.462.)

The documents Plaintiffs presented provide all the necessary background: Long before Gilead made the decision to discontinue TAF development, the development team identified specific, measurable "go/no go" criteria based on TAF's clinical value. For example, TAF development would not proceed unless a Phase I/II study established a materially greater viral load reduction compared to the first TDF-medicine (Viread®) (i.e., "1 log more," a ten-fold increase). (6App.1903.) That was because Viread® had already been approved and marketed, so it was "critical that [TAF] be more than [a] mere replacement for Viread but also provide significant benefits." (6App.1901; see also 5App.1670.)

Study 1101 was the study designed to test whether TAF met that threshold, and TAF fell short. (7App.2289; see also 7App.2196 ["one log difference in viral load between [TDF] and [TAF], was not met"].) And—as repeatedly noted—TAF "showed a safety profile similar" to TDF, not safer than TDF. (7App.2290, 2301.) Gilead decisionmakers cited those results in internal communications about whether to stop TAF development: TAF did not "appear to be sufficiently differentiated from Viread," while TAF's different "distribution profile" made any "predic[tion]

of [its] safety impossible." (7App.2321.) That was critical. Dr. Bischofberger, the final decision-maker, summed up the view of patient need as follows: "TDF was safe, was well-tolerated, was great in the regimens…. [TAF] was not differentiated. You know, there was not an identifiable patient population where TDF is not useful which [TAF] would be useful." (2App.462.)

TAF's failure to differentiate itself from TDF on any key metric also explains the "patent extension" concept reflected in a memo by a financial analyst. Gilead's TAF development plans explicitly described two alternative paths based entirely on how TAF performed. Path 1 was if TAF met the benchmarks reflecting a *meaningful improvement* over TDF. (6App.1901; 7App.2314.) If so, Gilead would proceed with a full development strategy. Gilead projected that an improved medicine could yield an extra $1 billion over existing TDF sales between 2008 and 2013 alone. (7App.2314-15.) The operating assumption was that TAF would replace (i.e., "cannibalize") TDF's market share and expand it to new patients. (6App.1901, 1922; 7App.2204.) "Cannibalize" is not a bad word among drug manufacturers; it means that, if doctors decide to switch patients from the existing medicine to the improved medicine, the company will retain that revenue—and reap the additional revenues from new patients. (6App.1945; 7App.2268-69.)[2]

[2] Plaintiffs repeatedly assert that the delay of TAF yielded an "additional" $27 billion in "profits." (E.g., PSB8.) They have never explained that number. No such figure appears in the document they cite (which, anyway, is about *revenues*—not profits).

Path 2 was if TAF turned out not to be materially more effective or safer than TDF. (See 7App.2203-04 ["safety profile … comparable to TDF's safety profile"].) In that scenario, there was no reason to rush TAF to market; all it would do is "cannibalize Viread" (7App.2153) without offering patients added benefits. In that scenario, TAF's only potential value lay in the possibility that it might be covered by patents that expired later than the TDF patents. (*Ibid.*; 7App.2276.) In contrast to the billion dollars of extra revenue Gilead projected to gain between 2008 and 2013 from a full development path (Path 1) (7App.7314-15), Gilead would see *no* revenue from TAF under the so-called "patent extension" path (Path 2) in that same six-year period. (7App.2209 [projecting no revenue from TAF in years 2008-2013]; 7App.2153.) And there was no predicting when, if ever, any franchise extension could materialize, because the approval and timing of patents on variations and combinations of existing and future medicines is too uncertain—especially at such an early stage of development. As it turned out, TDF-based medicines are still protected by patents to this day—extending well beyond the 2017 horizon the financial analyst had in mind. (See, e.g., U.S. Patent Nos. 8,592,397, 8,716,264 [both expiring January 2024].)

There is not a single document in the 15-year record of TAF development that ever suggested it would be a good idea to delay TAF development if TAF was known to be safer, much less that it

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(6App.2003.) They have never offered any evidence that Gilead *profited* or even generated more revenue from not offering doctors the choice between TAF and TDF sooner.

was advisable to sacrifice patient interests and an immediate $1 billion in pursuit of a highly speculative strategy that might or might not yield benefits 13 years later.

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As the foregoing illustrates, Plaintiffs' narrative is classic hindsight revisionism. In 2004, Gilead could not have known TAF would have a better safety profile, had not fully innovated TAF, and did not base its 2004 development decision on greed rather than patient care. That is the actual context for deciding whether a duty is needed and what category of cases it might cover.

II. The Court Should Reject Plaintiffs' Boundless Reasonableness Standard And Hold That No Duty Of Care Applies, At Least To This Category Of Cases.

Plaintiffs insist that the Court need not provide any guidance or clarity to manufacturers regarding when and how a duty to develop a new product may arise. Plaintiffs instead argue that the "duty of care owed is simply to *act reasonably*" in accordance with § 1714. (PSB35.) In Plaintiffs' view, any further questions are reserved for the jury in its evaluation of breach. (PSB37-38.) Yet product-liability law already provides manufacturers with very clear guidance on what it means to act reasonably toward the consumers of their products: ensure their product is not defective and contains adequate warnings. To the extent anything more is required, that obligation must be articulated at a categorical level and in clear terms.

Plaintiffs resist any such clarity. All they are willing to say is that the "specific facts" of "specific foreseeability" justify imposing a duty of care *here*. (PSB35, 37.) That is not how tort

duties work. This Court cannot leave manufacturers rudderless to navigate the new and limitless liability that Plaintiffs would impose. At a minimum, it should not recognize a duty to develop a new product in the category of cases, like this one, that arise so early in the development cycle.

A. Plaintiffs' "act reasonably" edict would supplant existing product-liability law.

Everyone agrees that a duty of care "applies to a manufacturer of prescription drugs … to avoid causing harm to Plaintiffs" as consumers of its products. (PSB35.) This duty has been defined over decades of product-liability caselaw. (See GSB36-37.) Under that governing precedent, a manufacturer acts reasonably insofar as it ensures that its products are reasonably safe and accompanied by adequate warnings. (See *Milwaukee Electric Tool Corp. v. Super. Ct.* (1993) 15 Cal.App.4th 547, 551; see Reply 21-23.) This is explicit in the case Plaintiffs feature in the second paragraph of their brief (PSB8): The "duty" that "a manufacturer *already* owes" is the "duty to design [a] product so it is safe for intended use" and the "duty to warn of risks of using [the] product." (*Bettencourt v. Hennessy Industries, Inc.* (2012) 205 Cal.App.4th 1103, 1118.)

The dispute laid out in the Supplemental Briefs is whether to recognize the specific duty Plaintiffs propose: a duty to supplement a reasonably safe product by giving consumers the "*choice*" of a potentially safer product. (PSB8, 22, 26, 32.) Plaintiffs insist that anytime a manufacturer "could have acted differently" by developing a product to avoid harms stemming

from its non-defective products (PSB21), a jury can decide, in its unbounded discretion and long after the fact, that the manufacturer's actions or inactions were unreasonable. (PSB37-38).

Plaintiffs confirm how broad and nebulous their proposed duty is. They say it does not matter whether their claims would be flatly foreclosed by product-liability law, because this duty to "act reasonably" is not "constrained" by any of the traditional limits on a manufacturer's duty of care. (PSB11.) They "need only show that Gilead knew TDF caused injuries and failed to take actions *outside the design of TDF* to avoid the same." (PSB10 [italics added].) The added duty applies even if the benefits of the existing product not only outweigh the harms, but vastly outweigh them. It attaches even if the manufacturer's product is not only safe, but the safest product on the market—as long as a jury could find it was possible to make it safer still. The duty attaches even if it would consume enormous resources and time to bring the alternative product to market—in other words, even if design-defect law would not consider that new product to be feasible. (See PSB20.) The duty attaches "'*regardless* of whether" the manufacturer undertook "'careful assessment of feasibility, practicality, risk, and benefit' … in the design of [its product]"; according to Plaintiffs, the manufacturer "may [still] be found negligent" for the injuries caused by its product. (PSB24 [some italics omitted].) Plaintiffs treat all these considerations as "questions of breach" for the jury. (PSB37-38.)

Plaintiffs never explain how the duty to "act reasonably" in developing new products would subsist alongside the existing product-liability framework. That's because it wouldn't. Plaintiffs never deny, for example, that their new duty would not just supplement design-defect law, but supplant it—with perfect-product law. (GSB15-17, 36-39.) A manufacturer could be held liable whenever another existing product or could-be-developed product would be safer—creating an endless obligation to produce the safest possible product. Unless a manufacturer produced the safest product feasible, its reasonably safe product would not be considered safe enough *anytime* a consumer was injured. Relatedly, a design-defect claim requires a balancing of numerous factors, only one of which is a safer feasible alternative (GSB14-16), and a negligent-design-defect claim requires proof of negligence on top of design defect (GSB33-34). There is no reason a plaintiff would undertake to prove all these extra elements when it would suffice just to assert that there was a safer, feasible alternative that either exists or could be developed (at whatever cost).

All of this raises a corollary to Justice Burns's question (Tr.35:9-15) about why there have not been more cases pressing this duty if it really existed: Why have courts expended so much energy narrowly defining design defects and safer feasible alternatives, if none of those constraints matter?

B. Plaintiffs' abstract "reasonableness" standard provides no guidance to manufacturers, courts, or juries.

1. While obliterating the product-liability standards that have guided manufacturers for decades, Plaintiffs offer no guidance in their stead. Plaintiffs refuse to answer this Court's question whether "clear legal rules" are necessary for "establishing when such a duty arises" or what those rules are. (Question 4.) They refuse to say, "what amount of information is enough to establish a foreseeable risk of harm to patients" and "at what point a manufacturer should have acted upon that knowledge." (PSB38.)

That is because the answers are entirely unsatisfactory: Under Plaintiffs' approach, there are no rules at all, much less "clear" ones. Plaintiffs see no role for this Court in determining the existence and contours of a legal duty. They relegate the line-drawing to each jury's retrospective evaluation of the "reasonableness of [the manufacturer's] conduct" (PSB48), based on the specific facts of the case. (PSB36-37.) That idiosyncratic and unpredictable measure of "reasonableness" provides manufacturers no "'*forward-looking*'" guidance. (Contra PSB49.) No guidance as to when a consumer of a non-defective medicine is entitled to the "*choice*" of a completely different product. (PSB32.) Or what turns legitimate consideration of financial factors into an "unreasonabl[e]" effort to "maximize profits." (PSB31.) Or how quickly a drug manufacturer must make a drug candidate "timely available alongside" an existing, non-defective medicine. (PSB26.)

Simply put, "act reasonably" is not a legal standard or a practical norm to which a manufacturer can conform its conduct.

2. Plaintiffs acknowledge that there must be *some* "limiting principle" before a duty of care can be recognized in a given case. (PSB36.) Yet the only one they offer is the "foreseeability of harm" flowing from the *particular* defendant's conduct. (*Ibid.*) Plaintiffs explain: A manufacturer has a "duty to act reasonably" where "the foreseeability of catastrophic harm" from failing to develop a new product is "obvious," although "*may*[*be*] not" where the "specific foreseeability of catastrophic harm is not present." (PSB35-36 [italics added].)

That is a meaningless limitation—especially in the pharmaceutical context. Just about every prescription drug entails "some risks, perhaps serious ones." (*Brown v. Super. Ct.* (1988) 44 Cal.3d 1049, 1063.) Those risks are displayed prominently on the label and inform doctors' prescribing decisions. (See, e.g., PSB42 [arguing foreseeability because "FDA approved labels for each … TDF medication[] have from their onset included information regarding renal (kidney) and bone risks"].) Side effects listed on the label are not only foreseeable, but scientifically proven. (21 C.F.R. §§ 201.57(c)(6)(i); 71 Fed. Reg. 3922, 3935 (FDA Jan. 24, 2006) [labeling should only include side effects "well-grounded in scientific evidence"].) So if foreseeability is the only limit on a drug manufacturer's obligation to develop a drug candidate that might plausibly mitigate side effects, there is no limit at all.

Nor does it narrow things to add the qualifier "catastrophic" to "foreseeable harm." (PSB35.) As Plaintiffs emphasize, "[t]he circumstances in which pharmaceutical manufacturers operate are those that directly involve *risks to human life*": the development of *lifesaving* medicines. (PSB21.) So the harms in this context are often by definition "catastrophic"—particularly to a jury confronted with a plaintiff who presents only the downside consequence of a development path not taken. (See GSB19.)

A key reason foreseeability cannot serve as a limiting principle is that it is so amenable to hindsight bias. Plaintiffs prove the point by waving around an article published in *2018* purporting to quantify injuries that TAF could avoid, under various questionable assumptions. (PSB43 [citing 9App.2849-919].) That article issued *14* years after the challenged decision, after Phase III and head-to-head clinical studies comparing TAF and TDF, and after FDA approval of four TAF medicines. Plaintiffs cite to this as circumstantial evidence that Gilead's decision to stop TAF development caused Plaintiffs' alleged injuries (PSB43). Only the most extraordinary juror would be able to resist relying on such evidence (erroneously) to find the injuries foreseeable in hindsight. (Cf. *Chavez v. City of Los Angeles* (2010) 47 Cal.4th 970, 986-87 [courts should "avoid … the recognized tendency for individuals to overestimate or exaggerate the predictability of events after they have occurred"].)

In any event, courts have rejected foreseeability as the sole limit on when the general duty of care applies: "On a clear day,

you can foresee forever"—it is effectively no standard at all. (*Sturgeon v. Curnutt* (1994) 29 Cal.App.4th 301, 307.) Moreover, "in strict liability as in negligence, 'foreseeability alone is not sufficient to create … duty.'" (*O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 362.) And Plaintiffs' case-by-case approach to foreseeability is inconsistent with the categorical approach courts are required to take to determining whether to recognize a duty. As the Supreme Court explained, "duty differs from the other elements of a tort" in that it must be "analyz[ed] … at a higher level of generality." (*Vasilenko v. Grace Family Church* (2017) 3 Cal.5th 1077, 1084.) Thus, the court decides not "'whether a *particular* plaintiff's injury was reasonably foreseeable in light of a *particular* defendant's conduct,'" but 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 v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 772.) Foreseeability thus cannot "bridge[]" the general duty of care to specific circumstances. (Contra PSB36.) The "facts of specific foreseeability" never "support liability" alone. (Contra PSB37.)

Plaintiffs never address whether injury is foreseeable in the category of cases before the Court: that is, cases where a manufacturer who markets a reasonably safe medicine stops developing a drug candidate barely into clinical testing—long before Phase III or large-scale head-to-head clinical studies establish the candidate's absolute or comparative safety profile. As discussed at length in Gilead's Supplemental Brief (GSB52-

55), and in further detail below (*post* 40-42), harm from such a decision is not reasonably foreseeable. So even if the Court were to accept Plaintiffs' flawed premise that foreseeability alone could give rise to a duty of care, that component would not be sufficient for this category of cases.

3. For similar reasons, Plaintiffs do not move the ball by insisting that "the specific facts that Gilead *knew* here, its knowledge that TAF would alleviate the toxic side effects of TDF, and its intent to disregard such foreseeable harm simply to make money … is what makes Plaintiffs' claims actionable in negligence." (PSB35.) That, too, defies the Supreme Court's command to "analy[ze] … duty … at a higher level of generality." (*Vasilenko*, *supra*, 3 Cal.5th at 1084.) And those purported features cannot be what "makes Plaintiffs' claims actionable in negligence," which applies without regard to actual knowledge, intent, or profit motive.

As to knowledge, although Plaintiffs assert nearly a dozen times that Gilead actually "knew" TAF was safer than TDF (*ante* 11), they concede actual knowledge is not an element of their proposed duty (PSB35). After all, if this is really a negligence claim, negligence can be based on constructive knowledge (i.e., should have known) (see *John B. v. Super. Ct.* (2006) 38 Cal.4th 1177, 1190)—which even Plaintiffs will not defend as a workable standard here.

Plaintiffs also implicitly concede that intent and profit motive are not elements of their proposed negligence claim. (PSB48.) A plaintiff can prove negligence by pointing to purely

"accidental conduct" with the most altruistic of motives. (*Patarak v. Williams* (2001) 91 Cal.App.4th 826, 829; see *Bigler-Engler v. Breg, Inc.* (2017) 7 Cal.App.5th 276, 321 [claim resting on the failure to "meet the prevailing standard of care[] … does not require proof of an improper motive"].) So for every manufacturer held liable for failing to "timely" bring a new product to market for some nefarious reason (PSB26), countless manufacturers would be held liable for good-faith decisions, that a jury could later find to have unreasonably delayed a product getting to market. In the drug-development context, for example, that could mean liability for a delay in bringing a beneficial drug to market because the manufacturer conducted one extra study or designed a study to include more people than required.

Especially vulnerable is the manufacturer who declines to take a development path because it believes its finite resources would be better placed developing a different drug for a different patient population. Confronted with a plaintiff injured by that decision, but not the legions of patients benefited, a jury could easily find that choice unreasonable. (See GSB19 [discussing skew of feasible-alternative analysis from focusing on the plaintiff].)

Even if knowledge and motive could somehow limit Plaintiffs' proposed duty, it is too easy to manipulate the evidence to reach (and persuade) a jury on both. As mentioned above, this case is an object lesson in the ease of factual manipulation. (*Ante* 10.) No manufacturer could know that a drug candidate is safe and effective, let alone safer than a drug on the market, before

conducting Phase III head-to-head comparative studies. Yet Plaintiffs have crafted a narrative that Gilead knew in 2004 that failure to develop TAF would lead directly to injuries arising from TDF medicines. Similarly, Plaintiffs persist in a narrative that Gilead's decision to stop TAF development was based purely on profit considerations. Yet the evidence establishes that Gilead's decision was based on TAF's failure to meet preset scientific benchmarks—whereas if TAF *had* met those benchmarks, Gilead would have proceeded with TAF and reaped an additional billion dollars. (*Ante* 17.)

If Plaintiffs can get to a jury on this record, then future plaintiffs will be able to challenge most any decision, regardless of how early it is in drug development. It is far too easy for any plaintiff to declare that "the specific facts that [a drug manufacturer] *knew* … and its intent to disregard such foreseeable harm simply to make money … is … actionable in negligence." (PSB35.) Meanwhile, Plaintiffs have said nothing to undermine Gilead's point that their proposed duty would expose to liability decisions made way too early in the drug-development cycle—long before a drug company could possibly know that a drug candidate would be safe or safer in the human body. (GSB42-44.)

4. In light of all this, even the answers Plaintiffs do purport to give are unedifying. Plaintiffs assure the Court that a manufacturer *may* consider the financial obligation it owes to its shareholders. (PSB47.) They maintain that a manufacturer is under no obligation to develop *every* promising drug candidate

that might prove to be safer than an existing, non-defective product. (PSB48.) Says who? Their reasonableness standard provides no such clarity, because in Plaintiffs' view, courts cannot enforce those lines. As Plaintiffs acknowledge, a manufacturer cannot even safely dedicate its "finite resources" toward one development path over another purely because "it believes that investment will save more lives"—as Gilead did here—because a jury is free to find that decision unreasonable. (PSB48.)

C. The indefiniteness of Plaintiffs' proposed duty is untenable.

The nebulousness of Plaintiffs' proposed duty and its extraordinary breadth are the best backdrop to this Court's question whether "clear legal rules" are necessary for "establishing when such a duty arises" and what those rules are. (Question 4.) The answer has to be yes.

As explained (GSB41), recognizing a duty is akin to formulating a "legal rule" that may guide lawful conduct going forward (*Cabral*, 51 Cal.4th at 773). That is especially so in product-liability law. Though there is a compensatory element, the principal aim is to prevent *future* injuries altogether by motivating manufacturers not to market defective products. (See *Nelson v. Super. Ct.* (2007) 144 Cal.App.4th 689, 696 [strict liability "'provide[s] an economic incentive for improved product safety'" and "'induce[s] the reallocation of resources toward safer products'"].)

Plaintiffs do not suggest that their amorphous rule could achieve the goal of injury-prevention. Nor do they challenge the

Court's premise that the extraordinarily high costs and uncertainty of drug development (see GSB12-14) put more of a premium on clarity. Plaintiffs' view is that there is no "social value" in drawing any "bright line" to guide conduct going forward. (PSB10.) That is contrary to the purpose of tort law. Plaintiffs would have manufacturers scrambling to protect themselves against expansive liability without any ability to gauge whether liability would be imposed, on the one hand, and subject to completely arbitrary damages awards, on the other.

Plaintiffs also fail to address the inevitable consequences of such a vague rule on the behavior of drug manufacturers. The effort to conform to an unclear standard leads to deadweight social costs. The only upshot of leaving that boundary undefined would be to impose an excessive "'precautionary obligation'" on manufacturers. (*Cabral*, 51 Cal.4th at 773 fn.3.)

Gilead has already outlined the skewed incentives that would come into play if a duty of care could be recognized in the category of cases presented here. (GSB36-39; 60-64.) Under Plaintiffs' rule, manufacturers—in every industry—would have to guard against any narrative plaintiffs' counsel could craft in retrospect about how it "could have acted differently" to avoid injury from its non-defective products. (PSB21.) Take the car industry. A truck manufacturer could face a claim for *selling* a vehicle capable of going off-road—given the risks of off-road driving. Or a manufacturer might be liable for selling a sportscar that goes too fast. In fact, a manufacturer could be held liable for failing to implement technology that caps every car at the speed

limit—in light of extensive evidence that speed kills. Attempting to address such expansive potential liability would be paralyzing. (See generally 2022 Chamber Br. 30.)

Plaintiffs argue that the vagueness is tolerable because juries have been "evaluating the reasonableness of conduct for centuries." (PSB48.) Not conduct like this. The "corporate, executive level, strategic decision[s]" Plaintiffs target here (PSB11) are *not* the sorts of decisions usually entrusted to juries. That is because courts and juries lack the expertise to "'scrutinize … decision[s] made by business persons who are likely more competent in the particular business matters at issue.'" (*Hill v. State Farm Mutual Automobile Ins. Co.* (2008) 166 Cal.App.4th 1438, 1492.) Courts have gone so far as to devise a presumption that corporate, strategic decisions "are based on sound business judgment" (*Berg & Berg Enterprises, LLC v. Boyle* (2009) 178 Cal.App.4th 1020, 1045), and refuse to invalidate them based on allegations of negligence alone (see *Hill*, 166 Cal.App.4th at 1449 [business decisions valid absent evidence of "fraud, oppression, illegality, or the like"]). (See also Chamber Suppl. Br. 28.) In short, juries are ill-equipped to evaluate "what a reasonable pharmaceutical company would have done." (PSB37.)

The sorts of business decisions that are subject to Plaintiffs' proposed duty are especially impervious to principled assessment. The trial court's *Sargon* decisions explained it well: There are no measurable standards against which to assess these decisions, like "professional negligence" or "malpractice" or "compliance with standards for clinical trials, … FDA

regulations, or the safety of an assertedly defective product." (10App.3275.) At issue instead are intricate "business decision[s] … informed by medical *and* financial concepts." (*Ibid.* [italics added].)

If anything, that understates matters. Plaintiffs do not dispute that these decisions involve determining which product-development paths may best maximize the manufacturer's resources, withstand the grueling FDA approval process, and beat out existing medicines to reach consumers through prescribing doctors. They are rarely binary decisions, but choices among multiple competing paths, often involving different patient populations suffering with different diseases, and necessarily based on limited information. Each choice implicates a road-not-taken—including a patient population who might have benefited from an alternative path. (See, e.g., GSB19-20 [Gilead's decision to pursue a once-a-day combination pill built off TDF].) These are not the sorts of decisions that should be given to a jury.

D. The Court is free to rule on narrower grounds.

Plaintiffs present this Court with an all-or-nothing choice: Either rule that there is a duty for all drug-development decisions or none. They raise the prospect of a drug manufacturer that has complete knowledge that an alternative is as effective and safer, with no countervailing side-effects, and declines to proceed purely out of greed. We address later, whether a new duty is even necessary to cover that scenario. (*Post* 45-46.) But the direct answer here is that this Court is free to decide this case on narrower grounds that do not cover that scenario. As

discussed, this Court can rule that a manufacturer has no duty to invest in developing a new drug candidate when the candidate is this early in the development cycle, and leave for another day whether to recognize a duty when the candidate is much further along. (GSB42-47.) Nothing Plaintiffs have said forecloses that option.

For example, Plaintiffs have said nothing to cast doubt on the descriptions of the typical drug-development process that Gilead and amici have provided. (See, e.g., GSB12-14, 42-47; 2022 PhrMA Br. 20-26.) In particular, they do not deny that drug development takes a well-defined path with stop-and-go checkpoints throughout. Nor have they responded to the point that when a manufacturer is equipped with only preclinical and limited Phase I or II clinical studies, it cannot possess the requisite knowledge.

To repeat, Gilead maintains that no duty to develop a new product should be imposed where an existing product is already reasonably safe. (GB35-39.) Should this Court ever recognize such a duty, the least it must do is draw a clear line, tethered to the point in the drug-development cycle where a manufacturer typically has enough evidence to know that a drug candidate is actually effective and safer than an existing medicine without countervailing side effects. (GB46-47.) But this case does not have to be, and should not be, the case in which that line is drawn.

E. *Brown* and *Mexicali Rose* do not support Plaintiffs' proposed duty.

1. Plaintiffs cannot find support for their proposed duty in *Brown*, *supra*, 44 Cal.3d 1049, nor invoke the case to avoid the eviscerating impact of their theory on product-liability law. (PSB16.) The most important thing to note about *Brown* is that it did not come close to condoning the expansive new duty Plaintiffs propose here—and Plaintiffs do not contend it did.

Plaintiffs invoke footnote 12 only in support of the threshold question whether a manufacturer has any duties with respect to its products beyond those prescribed by product-liability law. Plaintiffs contend that the footnote makes "explicitly clear that drug manufacturers are *not* exempt from liability for ordinary negligence." (*Ibid.*) To the contrary, what the footnote makes explicitly clear is that it was focused on "ordinary negligence" in connection with a defective product. (See Pet. 45-46.) The footnote assures the reader that "drug manufacturers are [not] free [from] all liability for *defective* drugs." (*Brown*, 44 Cal.3d at 1069 fn.12 [italics added].) It then catalogs the remaining ways in which "defective drugs" are still "subject to liability for [1] manufacturing defects, as well as [2] under general principles of negligence, and [3] for failure to warn of known or reasonably knowable side effects." (*Ibid.*) *Brown*'s reference to "general principles of negligence" clarifies that its holding—"that a manufacturer is not *strictly liable* for injuries caused by" a defective drug (*id.* at 1069 [italics added])—does not also bar a claim for negligent-design-defect. (See *Scott v. C.R. Bard, Inc.* (2014) 231 Cal.App.4th 763, 773-74 [cited at

PSB32] [relying on *Brown*'s footnote to say that drug manufacturers are not "free of liability for *defective drugs*" and can be liable "'under general principles of negligence'" for "negligent[] design[]" [italics altered].)

Misreading *Brown*'s footnote, as Plaintiffs do, undermines *Brown*'s central goal. The whole point of rejecting strict-liability design-defect claims for prescription drugs was to accommodate medicines that are "necessary to alleviate pain and suffering or to sustain life" yet "unavoidabl[y]" cause "harm to some users." (*Supra*, 44 Cal.3d at 1063.) *Brown* worried that, given the unavoidable risks of "these important products," permitting such claims would undermine the public interest by deterring the development of new and improved drugs and driving up their prices. (*Id.* at 1063-65.) To read *Brown*'s footnote to dispense with the need to show a defect altogether would invite the very consequences that *Brown* sought to avoid.

2. Plaintiffs invoke *Mexicali Rose v. Superior Court* (1992) 1 Cal.4th 617. But here again, they do not (and cannot) claim that it supports the specific duty they propose. *Mexicali Rose* holds that a restaurant must exercise due care in preparing the food a patron eats—by, for example, making sure it does not contain unintended bones that could cause injury. (*Id.* at 633.) That is about exercising care in the preparation of the allegedly injurious product, not about a restaurant's obligation to offer the patron a "choice" of some other product—much less to research and develop a chicken without bones—to avoid the injury. *Mexicali Rose* offers no support for Plaintiffs here because they

disavow any claim that Gilead breached any duty with regard to the TDF medicines they used.

III. Foreseeability And Public Policy Factors Counsel Against Recognizing Plaintiffs' Proposed Duty, Whether As A New Duty Or As An Exception Under *Rowland*.

As previously noted (GSB49-51), courts consider the same questions of foreseeability and public policy whether they are considering a new duty or an exception under *Rowland*. Those factors weigh heavily against recognizing a duty here.

A. If *Rowland* applies, this Court should address its factors.

Plaintiffs' Supplemental Brief gives this Court all the reasons it needs to conclude that it should address the *Rowland* factors, if they apply. At every stage of this litigation, Gilead has made arguments addressing just about every *Rowland* factor, in substance. That includes at summary judgment. (1App.133-34; 10App.3147-48.) In its writ petition. (Pet. 49-52; Reply 18, 23-24, 40-45; see also Reply 39-40 n.4.) At oral argument before this Court. (Tr.7:17-8:5; Tr.10:15-12:2; Tr.56:17-65:20.) And in its Supplemental Brief. (GSB51-65.) At each turn, Plaintiffs noted that "a *Rowland* analysis … is precisely what [Gilead] seeks to do." (E.g., Ret. 46.) Plaintiffs now repeat the point: "This *is* a *Rowland* argument." (PSB9.)

Gilead has also presented multiple other reasons why this Court should reach the issue. (GSB50-51.) Gilead previewed them in oral argument. (Tr.21:22-23:2.) And Plaintiffs' Supplemental Brief did not refute a single one. Most notably, this is an issue of

law, which calls for a categorical—"'not case specific'"—legal assessment of exempted duties. (*Kuciemba*, *supra*,14 Cal. 5th at 1021; see GSB50-51.) The parties have fully addressed this legal question in their supplemental briefing, and Plaintiffs have had multiple opportunities to respond. Plaintiffs have not pointed to any factor where this Court might lack the record necessary for its analysis. Nor do they claim that they would suffer any prejudice if the Court did so. After 11 briefs by the parties, including many iterations of the same policy arguments discussed here, and full briefing on the *Rowland* question, judicial efficiency and fairness call for a resolution on the merits.

B. The *Rowland* factors require an exception.

As with the decision whether to recognize a new duty, Gilead has offered the Court two choices on how to frame the exception: (1) a broader exception for all decisions not to develop a new product; or (2) a narrow one for the category of cases, like this, where a drug manufacturer has not even begun Phase III clinical trials—when the candidate's safety, efficacy, and comparative advantage over a non-defective medicine on the market cannot be known. (GSB39.)

Plaintiffs address neither—instead aiming at two exceptions that are, respectively, far broader and far narrower. On the broader side, Plaintiffs challenge a strawman: "a categorical exception that would alleviate the pharmaceutical industry from the duty of reasonable care for all conduct, except claims for defective products." (PSB39.) That argument addresses only whether there can be any duty for a manufacturer for its

products besides producing a defect-free product. It does not defend Plaintiffs' proposed duty to develop, or to continue developing, other products. And thus it is not responsive to either of the exceptions Gilead has proposed.

Plaintiffs focus mostly on the much narrower argument that there should be no carve-out under the precise facts of this case—or rather, the facts as told by Plaintiffs. (See PSB43.) That analysis is wrong. Courts do not ask whether the *Rowland* factors "'support an exception to the general duty of reasonable care on the facts of the particular case before [them], but whether carving out an *entire category of cases* from that general duty rule is justified by clear considerations of policy.'" (*Kuciemba*, *supra*, 14 Cal.5th at 1021.) Plaintiffs refuse to address either category of cases that Gilead's proposed exceptions would cover.

Plaintiffs frame their *Rowland* analysis around a drug manufacturer that intentionally withholds a safer product it had "already developed," where all the questions about safety, effectiveness, and other side effects "had *already* been answered." (PSB45-46; see also PSB42-43.) But as explained above (*ante* 38), the applicable category of cases is not where all clinical testing has been completed and the drug has received or is awaiting FDA approval. Rather, it involves manufacturers in early drug development who have some basis to hypothesize that a drug candidate might be safer and as effective as an existing, non-defective medicine but have not even begun, much less completed, pivotal comparative studies and Phase III testing that could prove the drug candidate's actual and comparative safety

and efficacy. That category is not limited to manufacturers with actual knowledge, since a negligence claim sweeps in constructive knowledge from data in early drug-development stages, which would allow a jury to say that the manufacturer "should have known" the developmental candidate would be safer than the existing product. (*Ante* 27.) Even if there could be a duty to develop new products, decisions so early in the drug-development cycle should be exempted from that duty under *Rowland*.

1. The foreseeability factors favor an exception.

Foreseeability of harm. It is not reasonably foreseeable that injury will result from failure to develop a medicine for humans whose comparative safety has not been established by tests in humans. Gilead's Supplemental Brief recounts the many variables and branching possibilities that make the benefits of choosing one development path over another too indeterminate. (GSB53-55.)

Plaintiffs do not address all that uncertainty. They merely assert that the risks are foreseeable because "[p]harmaceutical manufacturers are in the best position" to know the potential risks of their medicines. (PSB40-41, 43 [citing *T.H. v. Novartis Pharmaceuticals* (2017) 4 Cal.5th 145, 168].) What risks? This is not a case like *T.H.*, which involved a failure to disclose known side effects about a medicine *on the market* that was causing injuries. (*Supra,* 4 Cal.5th at 155.) Failing to disclose those known risks could foreseeably lead to patient injuries. (*Id.* at 166-68.) But Plaintiffs admit that Gilead informed everyone of TDF's risks. (PSB42.)

This category of cases is about a completely different set of risks. Plaintiffs' negligence claim is about the continued development of a different drug candidate that had just begun early clinical trials. Thus, the question is whether it is generally foreseeable that the drug candidate under development would avoid the side effects of a non-defective medicine on the market. (See PSB10.) Nothing about that is foreseeable. When a manufacturer has barely begun clinical testing, no one can know how safe, effective, or comparatively advantageous an experimental medicine will be. (GSB12-13, 42-43.) And no "reasonably thoughtful [person] would" rely on preclinical studies in test tubes and animals to declare they know how a medicine will act in humans. (*Kesner v. Super. Ct.* (2016) 1 Cal.5th 1132, 1145 [cited at PSB41]; see also PLAC Suppl. Br. 16, 20-21; PhRMA Suppl. Br. 2-3 [documenting evidence that efficacy and safety of early-stage medicines is highly conjectural].) This defeats Plaintiffs' claim.

For reasons already stated, Plaintiffs cannot escape these universal realities of drug development by insisting that, in *this case*, Gilead somehow knew in 2004 that TAF's "'better safety profile' would eliminate or significantly reduce" the risks of TDF. (PSB42-43.) First, the assertion is demonstrably false. (*Ante* 10-13.) Second, the analysis is not case-specific; it considers foreseeability for an entire class of cases in analyzing whether that class of cases should be exempted from the duty. (*Ante* 9 [quoting *Kuciemba*, *supra*, 14 Cal.5th at 1021].) Third, Plaintiffs' proposed duty in negligence would not be limited only to

manufacturers that know a developmental candidate is safer than the existing product, because it encompasses any manufacturer that purportedly should have known it. It is not foreseeable that developing a drug that early in the cycle will avoid any harms.

Closeness of connection between defendant's conduct and plaintiff's injury. The closeness factor is closely related to foreseeability of injury. (GSB55). And like foreseeability, it must be evaluated "based on information available during the time of the alleged negligence." (*Kuciemba*, *supra*, 14 Cal.5th at 1022.) Viewed through that temporal lens, the question is this: At the time a drug manufacturer stops the pre-Phase III development of a particular drug candidate, is there a close connection between that decision and the fact that a person experiences a side effect from a different, non-defective medicine on the market?

Again, the answer is no. The information available *at the time* of the decision to stop development will not furnish the necessary knowledge, because drug manufacturers are not clairvoyant. With only preclinical testing and limited clinical testing—and without comparative data from pivotal, Phase III studies establishing a candidate's relative safety and efficacy—the causal effect of the decision to stop its development is prospectively unknowable.

Plaintiffs' entire argument about closeness of connection ignores the applicable time frame by jumping more than a decade into the future to discuss the 2018 article addressed above (PSB43-44 [citing 9App.2849-919]). (*Ante* 25.) Plaintiffs cannot

satisfy the closeness factor with evidence that Gilead *ultimately* developed a successful medicine, more than a decade after the challenged decision. Hindsight cannot furnish the connection.

Degree of certainty of plaintiff's injury. Plaintiffs do not dwell on the degree of certainty, which is no surprise because (as Gilead's Supplemental Brief explains) it is not relevant here. (GSB55-56.)

2. The policy factors favor an exception.

The lack of foreseeability alone defeats Plaintiffs' proposed duty. (GSB52-53.) Regardless, the policy factors also mandate an exception. (GSB56-64.)

Moral blame. Gilead has explained the complexities that go into any drug-development decision, and why those complexities undercut any effort to ascribe bad faith to a decision to stop developing a drug candidate. (GSB56-60.) Plaintiffs do not engage with these real-word tradeoffs. They do not explain why it is appropriate to cast moral blame on a decision not to expend millions on any research program—but especially on a program to supplement a product that is itself reasonably safe, and where resources are then spent to advance other life-saving candidates. (GSB57.)

This last point is salient even under Plaintiffs' misplaced focus on the specific facts of this case: Plaintiffs fail to explain why it was immoral for Gilead to choose to dedicate its resources toward developing a one-pill, once-a-day treatment, including the first of its kind, which FDA lauded as a "'watershed in HIV treatment.'" (GSB20; accord GSB58.) That would seem to be the

very definition of a "'high social utility'" endeavor. (*O'Neil*, *supra*, 53 Cal.4th at 365 fn.13.)

Here, again, Plaintiffs do not try to defend a duty to develop drug candidates in the category of cases at issue: where a drug manufacturer has stopped developing a product so early that it is not possible to know that it is safer than another. Instead, Plaintiffs (again) assign moral fault based on their own characterization of the specific facts of this case, which they depict as a case where a drug manufacturer "had *already* innovated" and where all the "questions" about safety and effectiveness "had *already* been answered." (PSB45; accord, e.g., PSB49, 51-52.) That is not accurate. (*Ante* 13-15.) But more important, Plaintiffs' moral aspersions have no bearing on the *category* of cases now before the Court.

Policy of preventing future harm. Plaintiffs' proposed duty will affirmatively inflict harm on the very community they purport to protect—in terms of innovation tempered and medicines lost—for reasons discussed more under "consequences to the community," below. For now, we address the other side of the ledger, what Plaintiffs hope to achieve in return for all the mischief their proposed rule will cause.

Plaintiffs insist that their proposed duty is necessary to prevent future harm because drug manufacturers need this "oversight." (PSB53.) But beyond the invectives hurled at Gilead, Plaintiffs do not describe any problem in the drug-development process that needs to be fixed. Neither they nor their multiple amici suggest that there is some widespread practice in the

pharmaceutical industry of withholding breakthrough drugs to increase profit.

Absent evidence of a widespread practice, Plaintiffs instead offer an unrealistic hypothetical: *What if* a drug manufacturer discovers "the cure for cancer" but "withhold[s]" it to rake in more money on "chemotherapy and radiation treatments"? (PSB51-52.) That is absurd. The institution that cures cancer will reap enormous financial rewards, not to mention public recognition. And incidentally, a research program to cure cancer is a massive and expensive undertaking. A drug manufacturer with a financial disincentive to release the cure would not invest in the undertaking in the first place.

Whether for cancer, HIV treatments, or common colds, Plaintiffs have the incentives wrong. Drug manufacturers make their money by *selling* new and better drugs, not putting them on ice. "The pharmaceutical industry is … highly competitive." (*Seife v. FDA* (2d Cir. 2022) 43 F.4th 231, 242.) The moment one manufacturer has a breakthrough, every competitor is nipping at its heels trying to outperform it. If 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. (See, e.g., *Kader v. Sarepta Therapeutics, Inc.* (1st Cir. 2018) 887 F.3d 48, 52 ["In pharmaceutical markets, the 'first mover' gains a considerable advantage …."]; see also Chamber Suppl. Br. 24-26 [describing "continued innovation" and "post-launch advances" under current scheme].) So if a new medicine offers a marked improvement over existing medicines,

no rational drug manufacturer would withhold it just because it would absorb revenue from an existing product—particularly where the improvement will attract more revenue from *new* patients.

This case illustrates the point. As discussed above (at __), Gilead's development documents repeatedly confirm that Gilead hoped TAF would prove to be significantly better (or safer) than TDF and that, if TAF had met Gilead's benchmarks, it would have yielded $1 billion more in revenue in just six years. (See 7App.2314.) In contrast, the financial analysis of developing TAF as part of a franchise extension was applicable *only if* TAF was not a major improvement over TDF, such as if TAF had a "comparable … safety profile." (7App.2203-04; see 7App.2313.) It defies basic business principles to suggest that Gilead would have delayed an improved product that could have promptly made it an extra $1 billion (i.e., $1 billion on top of revenues from TDF) in pursuit of a highly speculative strategy that might or might not yield benefits 13 years later.

Plaintiffs also argue that their proposed duty is necessary because drug manufacturers have a "lucrative monopoly"—i.e., patents—protecting their medicines. (PSB44.) They suggest that a patent carries with it a special obligation to bring a drug candidate to market. (*Ibid.*) That is a version of Plaintiffs' negligent-undertaking argument, and it is wrong—and very dangerous—for the same reasons. (Reply 54-55.) Plaintiffs cite for support *T.H.*'s observation that "state common law … ensure[s] the brand-name manufacturer holds up its end of the deal."

(PSB45 [quoting *T.H.*, *supra*, 4 Cal.5th at 172].) But the "deal" there was about "the responsibility to maintain an adequate warning label" (*T.H.*, *supra*, 4 Cal.5th at 172), an age-old responsibility of any manufacturer, not an obligation to invest in developing every promising drug candidate.

Beyond that, Plaintiffs offer only a list of grievances against current legal constraints on lawsuits against drug manufacturers, without explaining why any of those grievances justifies *this particular duty*. For example, Plaintiffs note that "[p]harmaceutical companies already enjoy freedom from … strict liability" for medicines that are already on the market. (PSB52.) But Plaintiffs do not explain why that justifies creating a duty governing medicines that are not yet on the market. Regardless, the whole notion is backwards. The Supreme Court imposed that limit on liability because "[p]ublic policy favors the development and marketing of beneficial new drugs" and excessive liability threatens that social good. (*Brown*, *supra*, 44 Cal.3d at 1063.) That is an argument *against* layering on novel forms of tort liability, not for it.

Next Plaintiffs observe that "once a product is approved by the FDA, preemption is triggered and there is very little that plaintiffs can do to affect oversight via state courts." (PSB52.) They describe this as a "black hole" in state oversight of pharmaceutical companies. (PSB53.) But again they fail to explain why that legal rule—prohibiting states from interfering with federal regulation of drugs that *are* on the market—somehow justifies greater state intrusion into drugs that are *not*

on the market. Regardless, this argument misunderstands the law. Where FDA is so immersed in regulatory oversight as to trigger preemption, it is a clear sign that the pharmaceutical industry is already heavily and properly regulated—not that it lacks oversight. FDA's oversight already protects consumers, as do the prescribing physicians standing as learned intermediaries between the drug manufacturer and the patient. (GSB38-39.) And, as Plaintiffs recognize in the next breath, preemption is not a black hole at all, because it leaves plenty of room for oversight by state courts. (PSB53 [quoting *Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.* (6th Cir. 2015) 808 F.3d 281, 294].) Adding a new duty to develop drug candidates on top of all this would not be filling a gap. It would be layering on unnecessary and counter-productive liability for companies that are developing and choosing among many alternatives in parallel. (GSB60.)

Consequences to community and extent of the burden to defendant. Against the unlikely benefits of Plaintiffs' proposed duty, the Court must weigh the profound countervailing consequences. The most important of them are the harms to the community in innovation suppressed and medicines lost. Gilead and numerous amici have described two consequences. First, the duty would yield powerful incentives *against* releasing new medicines and improvements on existing ones, because those innovations would be used as a basis for liability on the existing product or for taking too long to develop the new product. Second, it would chill investigation into new medicines because any subsequent decision not to develop that product or to develop it at

the expense of another would represent a path not taken—and a class of litigants who might have benefited. (See GSB60-62; 2022 PhRMA Br. 27-34; 2022 Chamber Br. 25-27; 2022 PLAC Br. 24-25.)

Plaintiffs do not address any of this, except to dismiss it (again) with the refrain that "Gilead had *already* innovated." (PSB45.) That is no answer, both because it is false (*ante* 13-15), and because the duty will apply to every manufacturer at any stage of drug development. Plaintiffs have certainly never refuted the key point that every development path not taken yields a class of plaintiffs who would have benefitted from its hypothetical outcome, and every path the manufacturer does take yields a class of patients who can argue the manufacturer should have acted sooner. (E.g., Reply 44-45.)

Plaintiffs dismiss these natural consequences as "exaggerated hyperbole." (PSB47.) But they do not say why. Surely they do not mean that sophisticated businesses ignore the costs of liability in their decisions; that would defy an axiom of tort law. And the Supreme Court has explicitly embraced exactly the concern Gilead and its amici have described: "expansive liability for drug-related injuries could deter manufacturers from developing and marketing medical drugs to benefit society." (*Carlin v. Super. Ct.* (1996) 13 Cal.4th 1104, 1121-22 [concurrence]; *see Brown*, *supra*, 44 Cal. 3d at 1063-65.) That concern is why courts do not expand liability lightly. (See GSB61-64 [quoting *N.N.V. v. Am. Assn. of Blood Banks* (1999) 75 Cal.App.4th 1358, 1383-84; see also 2022 PhRMA Br. 27-28].)

That also answers Plaintiffs' assertion that there is "no evidence that" their proposed duty "would actually chill innovation." (PSB50.) If Plaintiffs mean empirical evidence showing how their precise novel duty impacts manufacturer behavior, that would be impossible because no jurisdiction has ever adopted anything close to this duty. Nor is it required. (See *Kuciemba*, *supra*, 14 Cal.5th at 1027-30 [crediting risk of litigation without empirical evidence].)

In any event, history and precedent provide all the evidence this Court needs. The Supreme Court said it in *Brown:* The "possibility that the cost of insurance and defending against lawsuits will diminish the availability and increase the price of pharmaceuticals is far from theoretical." (44 Cal.3d at 1064). And it supplied a host of examples of products which have greatly increased in price or have been withdrawn or withheld from the market because of the fear that their producers would be held liable for large judgments. (*Id.* at 1064-65; accord 2022 Chamber Br. 24-28.)

A legion of amici who speak on behalf of key industries have weighed in repeatedly in this case to underscore that point. Those amici include the United States and California Chambers of Commerce, the auto industry, PhRMA, the California life-sciences industry, the biotech industry, the medical-technology and -device industries, as well as thought leaders in product-liability and business litigation. They have all filed briefs explaining the consequences that they see from Plaintiffs' negligence theory and specific duty. (See 2022 PhRMA Br. 27-34;

PhRMA Supp Br. 2; 2022 Chamber Br. 24-29; PLAC Supp. Br. 21.) They all agree: Plaintiffs' proposed duty is affirmatively harmful to the public.

Plaintiffs' only other answer is that the financial consequences of their rule will not matter because the pharmaceutical "industry is not want for remuneration." (PSB47.) But saying that the top "35 pharmaceutical companies" in an industry are profitable (*ibid.*) does not prove that they are indifferent to the costs of a newly imposed legal duty. Plaintiffs' whole premise for imposing liability is that drug manufacturers do consider financial consequences of their development decisions.

In any event, Plaintiffs' rule is not limited to large pharmaceutical companies. Important medical innovations come from tiny biotech start-ups like Gilead once was. (1App.340; 6App.1993, 2003-06.)[3] Certainly companies like that do not have the resources to develop all the developmental candidates that might (or might not) mitigate side effects.

Everything discussed above is about the steps drug manufacturers will have to take to avoid both litigation and

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[3] See, e.g., Wu, *Biotech Startups Face 'Series A Cliff' as Venture Capital Stays Cautious* (Mar. 24, 2023) <https://tinyurl.com/yyy4t2t9> [chronicling funding shortage for biotech startup, who "'are running out of money'"]; Masson, *'Stunning' 4% Yearly Rise in R&D Share Has Emerging Biopharma Dominating Pipeline* (Mar. 30, 2023) <https://tinyurl.com/y9sjkdwh> [documenting that emerging biopharmas—"a term for companies with less than $200 million in R&D spending … were responsible for 67% of 2022's R&D pipeline"].

liability—not about the costs of litigation and liability alone. But those costs also count. Plaintiffs sweep them aside as a "chicken little fear." (PSB49.) But the Supreme Court does not: Where the "reach of the proposed duty" is "broad[]"—as Plaintiffs' proposed duty is—"'the pool of potential plaintiffs isn't a pool at all—it's an ocean.'" (*Kuciemba*, *supra*, 14 Cal.5th at 1029; see also *Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370, 398.)

The only other substantive response Plaintiffs offer on the subject is that "Gilead's concerns related to potential increase in liability boil down to" the "premise[] that juries would evaluate imperfect decisions of pharmaceutical companies years later with the benefit of perfect hindsight about the safety data researchers *later uncovered*." (PSB49.) Plaintiffs do not deny that juries are prone to hindsight. (*Chavez*, *supra*, 47 Cal.4th at 986-87.) In fact, as noted above, Plaintiffs themselves invite hindsight in their Supplemental Brief. (*Ante* 25.) Instead, Plaintiffs say that the inevitability of jury hindsight is a "failed premise[]" because "hindsight [is] irrelevant" where Gilead supposedly knew everything there was to know "at the time it made the decision." (PSB49.) But the duty Plaintiffs propose applies to *all* manufacturers—at every stage of development—and the false portrayal that Gilead knew certain facts both obfuscates the inquiry and (again) illustrates how easy it is for a plaintiff to turn any information about a developmental candidate into an assertion of the manufacturer's full knowledge.

Availability and cost of insurance. Plaintiffs do not address this factor, which is no surprise because it, too, weighs in

favor of recognizing an exception under *Rowland*. The availability of insurance to hedge against liability for Plaintiffs' proposed duty is questionable at best. Insurance has concrete limits, which a manufacturer can quickly exceed in the face of widespread litigation. Many manufacturers have in fact done so, leading them to the point of bankruptcy—insurance notwithstanding. (See, e.g., *In re Dow Corning Corp.* (E.D. Mich. 2000) 255 B.R. 445, 462.) Even if insurance were available, its costs would skyrocket, undermining budgets for research and development and the affordability of medicines. (See GSB64.)

IV. In Rejecting Any Claim For Negligent Design Defect, Plaintiffs Made Several Concessions Bearing On Their Negligence Claim And The Disposition Of This Appeal.

Before Plaintiffs filed their Supplemental Brief, it was hard to imagine they could get any more emphatic about their intention to reject a design-defect claim. (GSB26-27 [cataloging disavowals].) But they have now quadrupled down on the disavowal: Plaintiffs "'are not pursuing a claim for negligent design defect. Rather, their negligence theory is rooted in Gilead's conduct separate and apart from the design of the TDF-based medications.'" (PSB23 [quoting Ret. 27]; see PSB13 ["Plaintiffs are not alleging negligence in the *design* of the drug composition of TDF."]; PSB32 ["negligent design defect … is not Plaintiffs' theory of liability"].) What's more, Plaintiffs have flatly rejected the premise of this Court's invitation: Their decision to reject design defect was not based on a "different understanding of the meaning of the term 'defective.'" (Contra Question 2.) Plaintiffs

understand that a safer alternative can generally be a factor in the analysis. (PSB15, 19.) They do not suggest that this blackletter law was a new revelation or that they abandoned their design-defect claim because *Brown* removed safer alternatives as a consideration. (See GSB31-32.)

Given that Plaintiffs have (again) definitively shut down any design-defect claim, this Court probably does not need any further advocacy on the subject. Obviously, several of the sub-questions are now moot, such as Question 3, which is premised on the assumption that Plaintiffs are pressing such a claim. But there are some important ramifications to Plaintiffs' design-defect position that bear on their proposed duty and the ultimate disposition of this case.

A. Plaintiffs' position on safer feasible alternatives practically forecloses their proposed duty.

Plaintiffs agree that traditionally, the existence of a safer, feasible alternative "is but one factor to be considered in the [design-defect] analysis." (PSB15; GSB14-17.) The presence of such an alternative "is not alone dispositive" to establish that a product is defective. (PSB19.) That still leaves the question (which this Court no longer need resolve) whether *Brown* eliminated that factor in the pharmaceutical context. Either way, one thing must be clear: Safer feasible alternatives cannot play a greater role in this context. (GSB17-20.) There are two ramifications to Plaintiffs' position.

The first is what Gilead noted in oral argument: *If* the availability of a safer feasible alternatives remains a factor after

Brown, then it could help address some of the hypotheticals this Court asked involving fully developed drug candidates that are definitively proven to be safer for all patients with no countervailing side effects for any. This Court need not recognize a new duty if traditional design-defect law covers a scenario.

The second is how starkly Plaintiffs' position on reasonable alternatives conflicts with their proposed new duty. Plaintiffs' proposed duty is that Gilead should be liable for delaying (or not pursuing quickly enough) a (purportedly) safer alternative. That duty takes one concededly non-dispositive factor from the design-defect analysis and blows it up into the basis for a standalone claim. And Plaintiffs go a step further: insisting that failure to invest in developing and marketing a *potentially* safer alternative constitutes negligence.

As noted earlier (*ante* 20-22), if that were the law, there would be no reason for a plaintiff to ever pursue a design-defect claim, and no reason for any court to have spilled ink over limitations on what it means for an alternative to be safer and feasible.

B. The design-defect claim that Plaintiffs have definitively disavowed is meritless.

In assessing negligent design defect, all that should matter is that Plaintiffs have abandoned their negligent-design-defect claim; it is not for a court to override a party's considered litigation judgments. (GSB32.) But there are three reasons it seems worth addressing why, at this point, Plaintiffs could not proceed with such a claim. First, Plaintiffs suggest that they

expect this Court to override the considered judgment of their many lawyers in favor of some "newly articulated theory of negligent design." (PSB24-25.) In the unlikely event that is what this Court has in mind, it should appreciate why the claim fails under current law. Second, Plaintiffs seem to further invite the Court to override their disavowal by repeating Justice Goldman's observation that Plaintiffs have not "conceded" that TDF was not defective, but simply do not "seek to prove that it's defective." (Tr.13:19-14:2; see PSB23.) That is especially odd because, after that exchange, Plaintiffs proceeded to declare "that there is not a defect in the design that renders TDF defective." (Tr.40:20-21.) Third, as explained more fully below (*post* 60-62), the one event that occurred since the parties submitted their Supplemental Briefs is that the judge overseeing the parallel proceeding in federal court denied an omnibus summary-judgment motion on design defect. There is no reason to believe this will spur Plaintiffs to try to withdraw their disavowal in the final brief; after all, they were aware of the positions their colleagues took in that parallel case. But it may nevertheless be valuable for this Court to understand why, in this case, on this record, that option is not available.

The key is that Plaintiffs made *factual concessions* that would negate any design-defect claim, on this record, even if this Court were inclined to override their lawyers' strategic judgment. Gilead listed them in its Supplemental Brief. (GSB28-29.) To summarize, Plaintiffs:

1. do "not allege that the risks of TDF outweigh[] its benefits" (10App.3021, 3103);

2. do not claim that FDA erred in approving the TDF medicines upon finding that their benefits outweigh their risks (10App.3100-01); and
3. "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).

Plaintiffs do not address concessions (1) or (2). That alone is fatal, because, as both parties agree, a design defect in the prescription-drug context requires a finding that the product's risks outweigh its benefits. (GSB15; PSB14.) And Plaintiffs actually deepen concession (3) with the embellishment that they "do not allege that Gilead should have removed all TDF products from the market" because "for a variety of reasons, some physicians and patients prefer TDF over TAF." (PSB22; accord Tr.40:17-21.)

Plaintiffs try to mitigate concession (3) with what appears to be an argument that the contrary position would be preempted. (PSB25 [citing *Mutual Pharmaceutical Co. v. Bartlett* (2013) 570 U.S. 472, 488; *Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110, 148].) But federal law preempts state *laws*, not the views of private parties. Federal law did not force Plaintiffs to take the position that TDF should stay on the market or to build their brief around the theme that Gilead should have given Plaintiffs "the *choice*" to take *either* TDF or TAF. (E.g., PSB26). Ultimately, it also does not matter *why* Plaintiffs decided to make that concession. Gilead's point is simple: The concession that TDF should stay on the market is irreconcilable with claiming that TDF is defectively designed. (GSB29-30.)

In any event, Plaintiffs could not have based their concession on preemption. On summary judgment, they argued that Gilead should have replaced TDF with TAF: Gilead had a duty to "'design[] a reasonably safe product prior to FDA approval and, in particular [by] developing and submitting for approval drugs that contained TAF *rather than TDF*.'" (10App.3027.) That was a direct quote from the trial court's demurrer opinion holding that theory survived preemption. (1App.85-86.) And the trial court proceeded to repeat those words verbatim in reiterating, on summary judgment, that the theory was not preempted. (10App.3243.) Plaintiffs made the concession—and more broadly disclaimed a design-defect claim—*despite* the trial court's preemption rule, not because of preemption.

C. Plaintiffs cannot use their disavowed negligent-design-defect claim to advance a meritless procedural position they have already waived.

Plaintiffs suggest that their design-defect claim could somehow survive summary judgment, for procedural reasons. (PSB24.) That procedural argument is meritless and waived.

Plaintiffs base their argument on the premise that Gilead did not move for summary adjudication against their "*entire* … cause of action" for negligence. (PSB24.) That is false. Gilead moved as to both design defect and free-floating negligence. (1App.126-38 [MSJ]; 10App.3142-50 [MSJ Reply]; 10App.3202-10 [Gilead MSJ Proposed Order].) That is why the trial court addressed both in ruling on Gilead's motion. (10App.3246-50.)

Independently, this Court can rule on design defect and negligence because each is a separate claim for purposes of Code

of Civil Procedure § 437c. "[A] cause of action for purposes of a summary adjudication motion means a group of related paragraphs in the complaint reflecting a separate theory of liability." (*Silva v. See's Candy Shops, Inc.* (2016) 7 Cal.App.5th 235, 257 [quotation marks omitted], *disapproved of on other grounds by Donohue v. AMN Services, LLC* (2021) 11 Cal.5th 58.) So even where multiple claims or theories of liability appear in the same count of a complaint, the court may still grant summary adjudication with respect to one claim or theory even if it does not grant summary adjudication to all theories. (*Ibid.*) Here, because Plaintiffs' Master Longform Complaint contains groups of related paragraphs reflecting separate legal theories, this Court can address each theory. (Compare 1App.68-70 ¶¶ 136-137 [focusing on purported defects with TDF] *with* 1App.69-71 ¶¶ 144-146 [focusing on purported withholding of TAF].)

This Court can also reject Plaintiffs' procedural argument for the separate reason that Plaintiffs long ago waived it. Plaintiffs mentioned this procedural argument in their Preliminary Opposition. (See Prelim. Opp. 3, 6.) Gilead addressed the argument in detail both preemptively in its Petition (at 55-56) and in its Reply to the Preliminary Opposition (at 15-16). Plaintiffs then gave up on the argument, never raising it in their Return or at oral argument.

V. The Recent Federal Decision Does Not Support Plaintiffs' Position.

The trial court presiding over the related federal litigation recently granted in part Gilead's omnibus summary judgment

motion. (*Holley v. Gilead Sciences, Inc.* (N.D. Cal. Sept. 28, 2023 No. 18-cv-06972-JST) 2023 WL 6390598 ["*Holley*"].) The court dismissed some claims while permitting others to move on to case-specific summary judgment motions under the laws of individual states.

Before explaining this ruling, it bears note that the federal litigation differs from this case in several key respects. First, the governing laws differ. In the California litigation before this Court, the parties agreed that California law would govern for purposes of summary judgment. (1App.126 fn.3; 10App.3019 fn.6.) By contrast, in the federal litigation, the parties agreed California law would *not* govern. There are no California plaintiffs in that case, and the parties agreed for summary-judgment purposes to apply to each plaintiff the law of that plaintiff's home state. (*Holley* at *1, *3 fn.2.) Accordingly, California law was not briefed or decided. Second, the claims differ. Plaintiffs in this case narrowed their claims at the close of discovery, dismissing strict-liability, failure-to-warn, breach-of-warranty, and (on appeal) negligent-design-defect claims. In contrast, the federal plaintiffs maintained all of those claims heading into summary judgment. Finally, because of differing lineups of experts and the ability to rely on lengthy expert reports, the summary judgment record differs between the two litigations.

For those reasons and others explained below, the *Holley* decision has no impact on the issues at play in this petition—

except to support Gilead's contention that Plaintiffs' fraudulent-concealment claim is meritless.

A. *Holley* did not recognize a duty to develop a new product or to make an existing product safer—let alone the existence of a general duty to "act reasonably" as Plaintiffs urge here. Rather, given that the laws of 48 states plus the District of Columbia were at play, the court felt constrained by an "absence of briefing from the parties regarding specific duties Plaintiffs assert under each jurisdiction's negligence laws." (*Holley* at *6.) It thus declined to rule out the possibility that *some* jurisdiction may give rise to a negligence claim not rooted in design defect. (*Ibid.*) The court explained that the federal plaintiffs needed to first make "clear what duties, if any, [they] contend Gilead breached"—at which point Gilead would have the opportunity to "renew its arguments" against the existence of a duty "in case-specific summary judgment motions" under the laws of the applicable state. (*Ibid.*)

B. Though the *Holley* Court narrowed the federal plaintiffs' design-defect claims, it declined to dismiss them entirely. The parties had agreed that expert testimony was necessary to establish a design defect. (*Holley* at *4.) Gilead had also argued that it was necessary for the experts to weigh the risks and benefits and opine on the balance. (*Id.* at *5.) The court disagreed, reasoning that the factfinder could view the evidence and decide for itself considering the risks, benefits, and possible feasible alternative. (*Ibid.*)

Obviously, the situation is different here. For one thing, Plaintiffs have disavowed—for the fourth time—any design-defect claim. For another, this case does not just involve the absence of expert testimony weighing the risks and benefits of TDF medicines. Unlike the federal plaintiffs, Plaintiffs here made *factual* concessions (recited *ante* 56-57) that foreclose such a claim.

C. The *Holley* Court granted Gilead summary judgment on the plaintiffs' claims for fraud insofar as they were premised on the contention that Gilead "'decided to keep secret the positive results of [the] TAF clinical study'" and its reasons for stopping TAF development. (*Holley* at *10.) The court recognized that the 1101 Study "'showed a safety profile similar to' TDF, not that TAF was safer than TDF," and thus could not have been "material" to consumers—as a fraud claim requires. (*Ibid.* [relying on universal definition of "materiality" from the Restatement].) The court further explained that "no evidence" supported the contention that information "about a drug [TAF] that had not yet been approved by the FDA and was not available on the market[] would have caused physicians to have acted differently." (*Ibid.*) The same reasoning forecloses Plaintiffs' fraudulent-concealment claim here.

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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