No. S283862

IN THE SUPREME COURT OF CALIFORNIA

GILEAD TENOFOVIR CASES

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

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

PETITIONER'S ANSWER TO AMICUS BRIEFS ON THE MERITS

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GLOSSARY OF AMICI AND AMICUS BRIEFS

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Academics Br.	Professors of Public Health & Bioethics Jonathan Crane, Michael Horný, and Ju Zhang
AHF Br.	AIDS Healthcare Foundation
Justice Catalyst Br.	Justice Catalyst

Amicus Briefs in Support of Gilead

ALF Br.	Atlantic Legal Foundation
Civil Justice Assoc. of California Br.	Civil Justice Association of California; California Manufacturers & Technology Association; California Business Roundtable; Bay Area Council; Biocom California
DRI Br.	Defense Research Institute – Center for Law and Public Policy; Association of Defense Counsel of Northern California and Nevada; Association of Southern California Defense Counsel
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ICLE Br.	International Center for Law and Economics
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PLAC Br.	Product Liability Advisory Council
PRI Br.	Pacific Research Institute
Product Manufacturers Br.	Archer Aviation, Inc.; Bayer U.S. LLC; Becton, Dickinson and Company; Biogen Inc.; Bristol Myers Squibb Company; Corteva Agriscience LLC; Cytokinetics, Incorporated; The Dow Chemical Company; GE Healthcare Technologies, Inc.; Genentech Inc.; General Motors LLC; Glaukos Corporation; GSK LLC; Hamilton Beach Brands, Inc.; Hyundai Motor America; Incyte Corporation; Johnson & Johnson, Inc.; Kenvue Inc.; Kia America, Inc.; Organon & Co.; Medtronic, Inc.; Merck & Co, Inc.; Pfizer, Inc.; Regeneron Pharmaceuticals, Inc.; Roche Molecular Systems, Inc.; Sanofi US; Takeda Pharmaceuticals U.S.A., Inc.; Toyota Motor North America, Inc.; Vertex Pharmaceuticals Inc.; Volkswagen Group of America, Inc.; Zimmer Biomet Holdings, Inc.
Technology Companies Br.	Viasat Inc.; Textron Inc.; Uber Technologies, Inc.; VIZIO, Inc.; Lyft, Inc.
U.S. Chamber of Commerce Br.	U.S. Chamber of Commerce of America; California Chamber of Commerce; Washington Legal

Foundation; National Retail Foundation

INTRODUCTION[1]

By this stage of the litigation—following summary-judgment proceedings and multiple rounds of appellate briefing—one would expect Plaintiffs and their handful of amici to have come up with a compelling justification for the expansive new tort duty upon which their case depends. Strikingly, however, the *only* justification they can muster for the Court of Appeal's duty is the purported need to address the precise allegations asserted in this case. But the alleged facts of one case, even if true, cannot by themselves support a new or expanded duty. And, as Gilead has repeatedly demonstrated, Plaintiffs' allegations are *disproven* by the undisputed record. Apart from these debunked allegations, both Plaintiffs and their amici concede that this supposed fact-pattern occurs rarely—if it has ever occurred at all. Plaintiffs and their amici offer no evidence of manufacturers intentionally delaying safer alternatives to existing products. Indeed, Plaintiffs' amici admit the opposite: that manufacturers have every incentive to speedily release any innovative new medicine and, in fact, do so now at a faster pace than ever.

That leaves this Court with no basis on which to completely upend existing tort law. Notably, Plaintiffs' amici do not dispute that the Court of Appeal's duty constitutes an extraordinary expansion of manufacturer liability. None even attempts to reconcile that duty with the no-defect rule that has long defined a

[1] This brief cites Gilead's Opening Brief as "OB," Plaintiffs' Response Brief as "RB," and Gilead's Reply as "Reply." "____ COA Br." denotes that a brief was filed in the Court of Appeal.

manufacturer's standard of reasonable care—let alone explained why abolishing such a longstanding and venerable requirement would be desirable. Nor do Plaintiffs' amici grapple with the new duty's serious negative consequences. None addresses the deleterious impacts on innovation sure to result from premising tort liability on a non-defective product, based on a manufacturer's decision regarding the development of an entirely different product. Nor does anyone explain how juries can be expected to separate "reasonable" development decisions from "unreasonable" ones or how to stem the tide of speculative lawsuits certain to flow from such an indeterminate standard.

The inability of Plaintiffs and their amici to justify the Court of Appeal's duty is all the more glaring in light of the fact that the defense they do offer is itself artificially limited. Plaintiffs and their amici have no appetite to defend the duty *except* as applied to the exact fact-pattern of Plaintiffs' *allegations*. They defend such a duty only within the pharmaceutical industry, offering no argument to support a duty that reaches beyond this one industry. Likewise, they defend this duty only where a manufacturer has "actual" knowledge of an alternative product's superior safety profile and acts in bad faith for profit-motivated reasons, saying nothing in defense of applying the duty to the heartland of negligence claims involving constructive knowledge or good-faith decisions. That leaves *no one* willing to embrace imposing liability for vast swathes of conduct that the Court of Appeal's duty covers.

Meanwhile, the notion that a tort duty is uniquely necessary in the circumstances of this case is backwards. It is contrary to this Court's precedent to single out the pharmaceutical industry for added liability—and unnecessary given the incentives for innovation that already exist in the industry, and the additional protections for patients from the FDA approval process and learned doctors who stand between the manufacturer and the patient. Moreover, a tort duty arising in negligence cannot possibly be cabined to actual knowledge and bad faith. And Gilead has demonstrated that *no* pharmaceutical manufacturer can actually know a developmental drug is safer than an existing, non-defective medicine before Phase III and head-to-head clinical trials. Thus, at a minimum, this Court should hold that the Court of Appeal's duty cannot attach before that point in the development cycle. On this point, Plaintiffs' amici offer resounding silence.

In all events, products-liability law should not be upended to address a bogeyman of Plaintiffs' invention. This Court should reverse the Court of Appeal's decision.

ARGUMENT

I. Plaintiffs' Amici Fail To Establish That A Manufacturer's Duty Of Reasonable Care Extends Beyond The Duty To Provide A Non-Defective Product.

Plaintiffs' amici scarcely dispute that, up until the Court of Appeal's decision, California courts have uniformly held that a consumer who claims injury from a manufacturer's product must establish proof of a defect. (OB23-33; Reply 15-23.) Instead, they

echo Plaintiffs' assertion that this Court invented the defect requirement solely to limit the reach of strict liability, not negligence. (AAJCAC Br. 16; see RB20.) But these amici provide no support for Plaintiffs' position. And they outright ignore the extensive authority Gilead marshalled refuting Plaintiffs' assertion. (OB25-27.) Not a word about all the cases demonstrating that tort claims alleging injury from a manufacturer's product required proof of a defect, decades before this Court even authorized strict liability. (*Ibid.*)

In contrast, the amici supporting Gilead provide added authority for Gilead's position. They trace the history of products-liability law even further back, to its origins in Romano-British law, through the invention of modern theories of negligence, and across various waves of liability reform, to demonstrate that the defect requirement has been a fixed feature throughout. (PLAC Br. 15-30.) This comprehensive history demolishes the conclusory assertion from Plaintiffs' amici that the defect requirement is "novel." (AHF Br. 13.)

Next, Plaintiffs' amici attack a strawman: attributing to Gilead the argument that "a manufacturer of any product may never be held liable for manipulating the availability of its product … unless the product is proven to be defective." (Justice Catalyst Br. 21.) Gilead made no such argument. The only argument Gilead has advanced is that a plaintiff seeking to hold a manufacturer "liable in *tort*" for *physical injuries* caused by a product must show that "defects in their product[]" were the cause. (OB24, quoting *Soule v. General Motors Corp.* (1994) 8

Cal.4th 568, 568, fn.5, italics added and quotation marks omitted.) Obviously, manufacturers are subject to other legal duties that no one contends were violated here, including the duty not to "lie about their products or defraud their customers." (OB23.)

So Plaintiffs' amici prove nothing by featuring tobacco, opioid, and product-hop litigation in which manufacturers have been held criminally and civilly liable for "deliberately manipulat[ing] the market to maximize … profit." (AAJCAC Br. 19-21; Academics Br. 11-12; Justice Catalyst Br. 21-24.) For starters, Plaintiffs who benefited from Gilead's lifesaving medicines are in no way akin to the plaintiffs addicted to cigarettes and opioids in those cases. For another, the tobacco and opioid cases involved classic fraud and failure-to-warn theories of liability, such as "misle[a]d[ing] healthcare providers and patients about the addictive nature" of their products (AAJCAC Br. 20, quotation marks omitted), and "engag[ing] in deceptive practices, [including] downplaying the dangers of [their products] … despite overwhelming evidence of health risks." (Academics Br. 11.) Everyone agrees that those are legally cognizable theories. But those theories have no bearing here because the lower courts dismissed all the fraud and failure-to-warn claims from this case. So too with product-hopping claims: Though never asserted in this case, antitrust claims regarding the commercialization of TAF vis-à-vis TDF and supposed product-hopping were brought in another litigation and dismissed with prejudice. (See *Staley v. Gilead Sciences, Inc.*

(N.D. Cal. Jul. 29, 2020) No. 19-cv-02573, 2020 WL 5507555, at *19.)

If anything, the repeated efforts of Plaintiffs' amici to reframe this case about alleged injury from a product as a "case … about market manipulation" backfire. (AAJAC Br. 10; see also Justice Catalyst Br. 9.) On the one hand, they underscore how far afield these claims are from the roots, norms, and objectives of products-liability law. On the other, they illustrate that if Plaintiffs' true concern is illicit market manipulation, there are numerous *other* levers available to police such misconduct—making it entirely unnecessary to contort personal-injury tort law to address it. Plaintiffs have brought their claim as a products-liability claim sounding in negligence, not an antitrust or unfair competition claim. As such, they must satisfy products-liability standards.

When this case *is* properly viewed as a products-liability action, centering on the risks created by Gilead's decision to sell TDF medicines—as the Court of Appeal acknowledged it must be (see OB40, discussing Op. 26, 36)—Plaintiffs' theory of negligence is plainly not cognizable. (OB9; see also IADC Br. 20-21.) Plaintiffs' amici admit it themselves: Since there is no claim that "TDF was defective," there is "*no way for* [*plaintiffs'*] *injuries to be addressed under the defect standard*." (AAJCAC Br. 15-16.) It is precisely because, as Plaintiffs' amici concede, Gilead cannot be held liable for injuries arising from TDF "under the defect standard" (*id.* at 16, italics omitted) that Plaintiffs have sought to

circumvent it with a novel duty to develop and sell a completely different product. (OB35-36.)

Tellingly, Plaintiffs' amici do not dispute that the TDF medicines have been extraordinarily beneficial for people living with HIV (see Patient Advocacy Groups Br. 15-19; OB11-13), that the adverse bone and kidney function side effects of TDF are extremely rare (OB12), and that those risks were fully disclosed (OB12). That would be enough in any products-liability case to hold for the manufacturer. That Plaintiffs' amici argue otherwise here only confirms that they are using the wrong lens to examine Gilead's conduct.

In shifting the legal rubric, Plaintiffs' amici also dramatically misjudge just how fundamentally this new duty changes the law. It is simply not true that "the proposed duty does no harm to the defect standard." (AAJCAC Br. 13.) In reality, this duty is a road map for finding liability that would otherwise be impossible under the defect standard. (See generally IADC Br. 30-33 [explaining that the Court of Appeal effectively allowed claims against Gilead for negligent design defect without a finding of defect].) A manufacturer will no longer fulfill its duty of care by marketing a reasonably safe product. (OB34-37; Reply 24.) And negligent design-defect claims will effectively be written out of the law. After all, who would go through the trouble of proving a defect if a consumer may recover for injuries by establishing corporate "negligence" alone? (OB30-31.) Plaintiffs' amici do not even attempt to square these irreconcilable standards.

The complete abnegation of products liability is starkest in amici's position that the body of common law defining a manufacturer's standard of reasonable care simply does not matter. In their view, Civil Code § 1714 supersedes any and all common-law limitations on liability. (AHF Br. 12-13; AAJCAC Br. 15; see generally Reply 26-28 [refuting Plaintiffs' same argument].) Plaintiffs' amici claim that a defect requirement cannot cabin § 1714 unless and until the "California Legislature has … decreed that liability for harm caused by a product *is limited to defective products*." (AAJCAC Br. 17.) On this view, this Court has no power at all to define the metes and bounds of "ordinary care" under § 1714. (See generally Reply 27-29 [refuting Plaintiffs' theory of § 1714].)

That cannot be right. Section 1714 does not "impose a presumptive duty of care to guard against any conceivable harm that a negligent act might cause," and this Court's imposition of "meaningful limits" is necessary to "safeguard the efficacy of tort law." (*S. Cal. Gas Leak Cases* (2019) 7 Cal.5th 391, 399, 401.) This Court should reaffirm both the defect requirement and its own authority to determine what ordinary or reasonable care requires.

II. Plaintiffs' Amici Confirm That A Radically Expanded Duty To Develop Safer Alternative Products Is Unnecessary.

Plaintiffs' amici fail to fill one of the most glaring voids in Plaintiffs' briefing: the absence of any justification for the seismic shift they advocate.

To review, Plaintiffs' argument in favor of the Court of Appeal's duty derives chiefly from their *allegation* that Gilead knew TAF was safer than TDF in 2004 and suspended development of TAF anyway to reap greater profits from its patents over TDF. (RB8-9, 32; see RB14.) The trouble is that the undisputed record disproves those allegations, so the allegations cannot survive summary judgment. (Reply 9-14; IADC Br. 40-42; *post* 27-28.) That leaves a gaping hole. Without the disproven allegations of this case, Plaintiffs have no support for their assertion that Congress misaligned patent incentives so severely that manufacturers routinely (or ever) choose to "delay[] the commercialization of a[] [safer] alternative product to maximize the patent protection of … existing product[s]." (RB41.)

Instead of filling in the missing support, the amicus submissions only reinforce that there is no need for the Court of Appeal's duty. Amici on both sides now confirm that drug manufacturers have powerful incentives to bring better and safer drugs to market. Plaintiffs' amici even concede that "this constellation of facts"—that is, the factual narrative *alleged* by Plaintiffs—"does not regularly occur," if it occurs ever. (AAJCAC Br. 21.) And they emphasize that the pace of developing and releasing beneficial new medicines has never been faster, spurred by regulatory and products-liability regimes that ensure safety and accessibility while incentivizing innovation. (Justice Catalyst Br. 17-19.)

A. Pharmaceutical manufacturers have strong incentives to release safer alternative medicines and constantly innovate on existing, non-defective medicines.

The Court of Appeal posited that its proposed duty would yield "speedier delivery of improved medications." (Op. 49.) Imposing a duty to achieve this end might make logical sense if, as one of Plaintiffs' amici argues, a pharmaceutical company otherwise has "no incentive to … market safer versions of its drugs" because "doing so might cut into profits." (AAJCAC Br. 16.) But pharmaceutical manufacturers are already driven to release safer new medicines as quicky as possible—as amicus briefs supporting both parties show. The Court of Appeal has "create[d] a new duty … to fix a problem that does not exist." (PhRMA Br. 31.)

To start, even Plaintiffs and their amici recognize that "manufacturers have *ample* incentive to release safer products into the marketplace." (RB45; Justice Catalyst Br. 17-19.) By way of illustration, Plaintiffs never dispute that had TAF proven to be safer than TDF in that early Phase I/II study (Study 1101), Gilead projected that it would earn an *additional billion dollars* of near-term profit from proceeding with immediate development and marketing of TAF. (OB18-19, 54; Reply 37-38; see 7App.2314.) That undisputed evidence reflects the reality across the pharmaceutical industry. As amici document, competition in this sector is relentless, as is the pace of technological improvement. Constant improvement is an imperative for any pharmaceutical manufacturer, to avoid getting lapped—or

entirely superseded—by a competitor who releases a better or safer drug. The faster a pharmaceutical company can release an improved medicine, the more likely it is to retain and expand its market share and defend it against rivals who are also improving their medicines. (PhRMA Br. 31; see PRI Br. 32-33, 39-40.)

Plaintiffs' amici defy all these market dynamics and common sense by positing that a manufacturer will delay releasing an improved medicine to avoid "cut[ting] into [the] profits" of an existing medicine. (AAJCAC Br. 16.) That hypothesis misses a basic point: When a pharmaceutical company releases an improved version of its own medicine, it does not lose its current customers and revenues; it retains the old customers by shifting some or all of them to the new medicine and *expands* its customer base by attracting new patients to a superior product. (See, e.g., OB18-19; PRI Br. 35.)

Here, again, the record in this case confirms that dynamic in two ways. First, that is precisely what Gilead predicted would happen if TAF had proven to be superior to TDF in 2004: Gilead forecasted that a full development strategy for a superior TAF at that time would *increase* revenue, even as TAF would "cannibalize" part of TDF's market share. (OB18-19; see 7App.2314-15.) Second, when Gilead repeatedly innovated on its TDF-based medicines to benefit different populations of patients living with HIV, it immediately went to market with those improvements—notwithstanding any impact it had on the market share of its predecessors. Gilead released its first TDF medicine, Viread®, in 2001. It followed that up, at a rapid clip,

with Truvada® in 2004, Atripla® in 2006, Complera® in 2011, and Stribild® in 2012, each of which cut into the market share of those before it, but also expanded Gilead's overall customer base. (See PRI Br. 35; OB11-12; 1App.201.)

The notion that a theoretically "safer," alternative medicine would completely replace the market share of an existing, non-defective one—therefore reducing a manufacturer's incentive to release it—also misunderstands the dynamics of patient care. Whether one medicine is "safer" than another is a highly patient-specific question. (PhRMA Br. 27-28.) So even as the Court of Appeal considered TAF "safer" than TDF for the purposes of this litigation, many doctors continue to prescribe TDF because its portfolio of benefits and drawbacks better meets the needs of their patients. (See PRI Br. 41-44; Pls.' Supp. COA Br. 22 [disavowing any allegation that TDF should be removed from the market because "for a variety of reasons, some physicians and patients prefer TDF over TAF"].) This is one reason why Gilead's TDF medicines continued to have strong sales even after TAF entered the market. (PRI Br. 37.) In other words, TAF and TDF are marketed to distinct but overlapping patient populations because they have different profiles that appeal to different patients; one does not replace the other for all patients.

Plaintiffs have vaguely asserted that the "patent system" somehow undermines these market dynamics by motivating pharmaceutical companies to delay the release of safer alternative medicines. (RB46; see AAJCAC Br. 14.) But Plaintiffs' own amici provide evidence refuting that point. As one of the

articles they cite explains, "because patent protection for drugs is relatively short, pharmaceutical companies … feel … pressure to introduce drugs to the market quickly." (Ausness, *Corporate Misconduct in the Pharmaceutical Industry* (2021) 71 DePaul L. Rev. 1, 40, cited by Justice Catalyst Br. 19; see also Reply 37-38.) That pressure applies with full force to new medicines that may benefit members of a manufacturer's existing patient populations. Manufacturers are incentivized to seek patent protection for an alternative medicine quickly, lest a rival discover the invention, patent it first, and market it in competition with the existing medicine.

The incentives do not change just because a patent on an alternative medicine might extend beyond the manufacturer's patents on the existing medicine. On the one hand, when making development decisions about a drug candidate, the manufacturer can never be sure whether the candidate will succeed, whether it actually will extend the manufacturer's overall patent franchise, and, if so, by how much. (See Reply 37.) On the other hand, the manufacturer still has the same incentive to get that improvement to market as soon as possible to maximize the relatively short patent monopoly period. Because patent terms run from the date of the application, the manufacturer risks losing patent exclusivity—and revenue—for every day it delays marketing an FDA-approved drug. (See Ausness, *supra*, at 40; Ho, *A Dangerous Concoction: Pharmaceutical Marketing, Cognitive Biases, and First Amendment Overprotection* (2019) 94 Ind. L.J. 773, 795 ["[D]rugs are oftentimes patented but with a

relatively short window for companies to recoup profits."]; Justice Catalyst Br. 11 [explaining that the Hatch-Waxman Act sought to "induc[e] pioneering development of pharmaceutical formulations"].) Having filed a patent application on TAF in *2001*, Gilead would have had every incentive to bring TAF to market quickly had it realized that it was safer for some patients, in order to maximize the commercial potential of TAF. (See U.S. Patent No. 7,390,791 B2 [approving application filed on July 20, 2001].)

Plaintiffs and their amici have no response. They have collectively filed 13 briefs between this Court and the Court of Appeal. Not a single one has explained how the patent system would ever incentivize a pharmaceutical manufacturer to delay marketing a medicine it knows to be safer. They broadly assert that a pharmaceutical manufacturer has a (time-limited) monopoly on *its own* medicine. But no one has a monopoly on treating an entire disease. (PhRMA Br. 30-31; PRI Br. 35, 39-40.) Patent protection over TDF never provided Gilead with "a monopoly [over] treating … HIV or Hepatitis" (PRI Br. 35); other manufacturers developed rival medicines that competed with Gilead's. (Reply 40.) All pharmaceutical manufacturers, including Gilead, always have to worry about superior drugs from rivals. To this day, Plaintiffs have never explained what patent benefit Gilead obtained (or might have hoped to gain) by delaying the development of TAF, nor why that benefit, which could not even theoretically have materialized for at least 13 years, would have

been worth sacrificing the immediate billion dollars from marketing an improved medicine.

Instead, Plaintiffs and their amici discuss perverse incentives that have materialized in an entirely different context that has nothing to do with bringing an improved medicine to market: where the pharmaceutical manufacturer tries to fend off competition from generics after a patent expires. (See Justice Catalyst Br. 12, 20-24; RB46.) Plaintiffs' amici give the inapposite example of a branded pharmaceutical company paying a generic manufacturer to delay the release of a generic mimic of the *same exact drug*. (Justice Catalyst Br. 20.) They also discuss at length a practice called "product hopping" (Justice Catalyst Br. 21-24), which entails shifting demand from a brand-name medicine facing imminent generic competition to another version of the same medicine (see generally PRI Br. 32-33). They argue that such a practice is problematic where the purportedly new medicine is "*functionally identical*" to the old one (and therefore to the generic), but the manufacturer tries to trick patients, doctors, and insurance companies into believing that the new version is different from the generic in order to maintain market dominance. (Justice Catalyst Br. 22, italics added; PRI Br. 32-33.)

There are already remedies for such practices—as Plaintiffs' amici detail. (Justice Catalyst Br. 20-24.) As mentioned (*ante* 15-16), that further confirms that this Court need not unsettle the entire tort system to address them. But for present purposes, the important point is that all these practices entail manipulating markets through developing or fending off

competition from *identical medicines* that do *not improve safety, efficacy, or patient outcomes in any way*. None of these practices relate to the topic at hand: whether a manufacturer has an incentive to delay release of a superior new product for which it stands to make *additional* revenue from immediate marketing.

On that topic, Plaintiffs and Plaintiffs' amici have no evidence of a perverse incentive structure. Gilead, by contrast, demonstrated that delay is a profit-losing strategy—sacrificing significant short- and medium-term profits for much smaller and highly speculative revenue many years later. (Reply 37-38.) To the extent Plaintiffs' amici address this matter at all, it is only to confirm that the current regulatory regime properly incentivizes pharmaceutical manufacturers to swiftly research and develop beneficial new medicines: Pharmaceutical manufacturers are not only introducing more new medicines than ever before, but doing so more *quickly* than ever, and investing a greater proportion of their budgets into research and development than ever. (Justice Catalyst Br. 17-18.) Much of that investment goes into improving on medicines that have already received FDA approval. (PhRMA Br. 38-40.)

In sum, everyone agrees the pharmaceutical industry is "more innovative than ever." (Justice Catalyst Br. 17.) And everyone agrees that this is the direct result of a patent system that "balance[s]" policy interests in "inducing pioneering development" of improved new medicines while facilitating access to "low-cost, generic copies" as well; FDA regulations that "protect patients" from hazardous products and corporate

misconduct; and anticompetition laws that prevent the manipulation of patents. (See Justice Catalyst Br. 11, 19-24.) There is no reason to risk undermining a regime that even Plaintiffs' amici concede is working so well—especially because the problem the new duty purports to address (manufacturers delaying commercialization of improved new medicines) does not exist.

B. Consumer safety in the context of pharmaceuticals is already well-protected by the defect requirement, learned intermediaries, and intense regulatory supervision.

Plaintiffs' amici also fail to address all the ways in which current law, common law protections, and the regulatory framework keep consumers—particularly patients—safe.

1. To start, Plaintiffs' amici nowhere address the merits of the defect requirement or explain why it should be displaced. Plaintiffs' amici have no answer to Gilead's arguments about how the defect requirement carefully balances safety and accessibility, already includes consideration of feasible, safer alternatives, and provides clear guidance to manufacturers, courts, and juries—among other benefits. (OB27-31, 34-35; Reply 17-18.) Plaintiffs' amici do not address the reasonable limits the defect rule places on manufacturer liability—limits that will be erased by the Court of Appeal's novel duty. (OB35; Reply 24.)

Here, again, Plaintiffs' amici resort only to echoing Plaintiffs' position that any arguments in favor of the defect requirement are "graphically refute[d]" by the alleged "facts of this case." (AAJCAC Br. 13; accord *id.* at 15-16 [arguing that

"this case is the poster child" for why this Court should "reject" the defect requirement]; see Reply 19.) And again, that will not do because *allegations* in a single case cannot justify displacing a well-reasoned limitation on manufacturer liability this Court has recognized for decades, particularly where the voluminous record flatly contradicts the allegations. (Reply 9-14; see OB43 [must look at "entire 'category of negligent conduct,'" not a "narrowly defined set of circumstances"], quoting *Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 774.)

2. Some of Plaintiffs' amici suggest that even if the defect requirement properly ensures consumer safety generally, something more is required in the context of the pharmaceutical industry. (Academics Br. 5-6 ["Patients … are not mere consumers."].) They advocate an "affirmative duty" on pharmaceutical companies to act in the "best interests" of the patient-consumers of their medicines, analogizing to the physician-patient relationship. (*Id.* at 5-10.) But the analogy breaks down in light of crucial differences between the physician and the pharmaceutical manufacturer. A physician tailors treatment to the individual patient, based on "the patient's particular needs and risk factors." (*Himes v. Somatics, LLC* (2024) 16 Cal.5th 209, 222; see PhRMA Br. 27-28.) A pharmaceutical manufacturer, however, never knows whether a given treatment regimen will be "safer and equally effective for any specific individual patient." (PhRMA Br. 27.) Rather, pharmaceutical companies train their eyes on entire *patient populations* and ensure that the medicines they market are

reasonably safe overall and accompanied with adequate warnings, leaving decisions about whether a medicine is right for a specific patient to the doctor. (*Ibid.*)

Attempting to transplant the physician's "individual-patient-centric" standard of care to the "entire-patient-populations" context of pharmaceutical manufacturers would therefore not only be ill-advised but effectively impossible. A pharmaceutical manufacturer who acts in the "best interests" of one patient (Academics Br. 10) sacrifices the "best interests" of another one. (See PRI Br. 41-42 [explaining that the notion of a "[m]ore safe, less dangerous" drug "misstates the underlying medical realities"]; see also OB52, 55, 57-58; Reply 38 [every drug development decision creates a class of potential plaintiffs aggrieved by the "path not taken"].) And prioritizing the interests of outlier patients who suffer rare side effects might come at the expense of a path that is *more* beneficial to patient populations in general—as would have been the case if Gilead had focused on developing TAF in 2004 rather than the watershed once-a-day combination TDF medicines. (OB52, 55; see OB13-14; *post* 43.) Plaintiffs' amici, however, advocate a duty that distorts the relevant analysis by focusing solely on whether a pharmaceutical manufacturer could have acted otherwise to prevent harm to the *particular* plaintiff at issue. (OB35, 38, citing Op. 42.)

At the same time, the arguments of Plaintiffs' amici highlight yet another reason a heightened standard of care for pharmaceutical manufacturers is unnecessary: Numerous layers of protection already mediate patient care. FDA regulations

require pharmaceutical manufacturers to undertake "scientifically rigorous clinical trials" before "certifying drug safety and effectiveness." (Justice Catalyst Br. 19-20.) These regulations, among other FDA efforts, ensure that "consumers of prescription drugs are afforded *greater* protection against defects than consumers of other medicines." (*Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1069 fn.12, italics added.) Furthermore, physicians act as "learned intermediar[ies] between the manufacturer and patient," bearing responsibility for assessing a medicine's "relative advantages and disadvantages" and explaining those benefits and risks to lay patients who lack medical training. (*Himes*, *supra*, 16 Cal.5th at 222.)

Gilead recognizes that patients of pharmaceutical medicines are not ordinary consumers. The fact that patient-consumers depend on beneficial, lifesaving medicines—despite the inherent and unavoidable risks of treatment—does not justify the duty that Plaintiffs propose. Rather, as this Court has previously determined, such considerations require special *limitations* on common-law liability. (See OB30, 37-38, 52-53.) As discussed at length below, the lifesaving benefits of prescription medicines make the duty's vastly negative consequences that much more unacceptable, because diminishing innovation in this industry threatens public health. (See *post* 31-33, 36-37; see generally *Brown*, *supra*, 44 Cal. 3d at 1063-65; AHF Br. 15 [acknowledging "how prescription drugs have made vast differences in people's lives" and how important it is to maintain "the incentives of pharmaceutical makers to develop new

medicines and treatments" and "not to impede the development of better medicines and treatments"].)

III. Plaintiffs' Amici Fail To Address The Duty's Overwhelmingly Harmful Effects.

As a veritable chorus of amici supporting Gilead explain—from blue-chip Fortune 500 companies to emerging biomedical companies to patient advocacy groups to one of the country's preeminent tort scholars—Plaintiffs' proposed duty will devastate manufacturers and patients alike. Plaintiffs' amici fail to dispel those concerns.

A. The duty imposes a vague liability standard driven by hindsight, which will necessarily skew development priorities for the worse and yield crushing litigation.

A wide array of amici agree that this duty will change manufacturers' behavior in ways that redound to the detriment of the public. Because of the vague, unpredictable liability standard the duty creates—one inevitably distorted by hindsight bias—manufacturers will be forced to shift their research and development priorities for the worse. And regardless of the changes in manufacturers' behavior, the duty will usher in a tidal wave of litigation—reducing the resources available to manufacturers to invest in innovation and imposing massive costs on companies of all stripes.

The duty will skew product development priorities for the worse. As amici from all corners of the corporate, legal, academic, and patient advocacy communities attest, there is little doubt this duty will meaningfully alter manufacturers' behavior

and stifle innovation, to the detriment of patients and consumers. (See, e.g., Technology Companies Br. 9-12; Product Manufacturers Br. 14-24; Patient Advocacy Groups Br. 21-27; U.S. Chamber of Commerce Br. 22-25; PhRMA Br. 36-40.) The perverse incentives that the duty creates will affect manufacturer decision-making in several ways.

First, rather than allowing companies to prioritize bringing their most innovative and impactful new products to market, this duty will force manufacturers to instead focus on immediately commercializing any product they discover that might improve the safety—at least for some consumers—of a non-defective product they already sell. (See, e.g., Technology Companies Br. 9-11; Patient Advocacy Groups Br. 24; Product Manufacturers Br. 21-22.) At best, potentially lifesaving or lifechanging products will be delayed while manufacturers instead push to market marginally safer alternatives to already-safe existing products; at worst, potentially game-changing innovations will be nixed entirely, falling victim to finite financial, temporal, and human resources. (See, e.g., Patient Advocacy Groups Br. 24-25; Product Manufacturers Br. 21; Technology Companies Br. 10-11; ICLE Br. 23-24.)

Second, companies will be incentivized to abandon research prematurely, lest they go too far down the path of development and cross the (nebulous) line into "knowing" a product is safer for at least a subset of consumers. (See, e.g., Product Manufacturers Br. 15; Patient Advocacy Groups Br. 25; Technology Companies Br. 11-12; PhRMA Br. 38.) None of this benefits consumers. To

the contrary, it harms them by reducing the development of innovative products, including highly beneficial new medicines. (E.g., Patient Advocacy Groups Br. 21-26; PhRMA Br. 36-40; ICLE Br. 21-23.)

Plaintiffs' amici nowhere address the concrete examples of how the Court of Appeal's duty will distort a manufacturer's product development decisions. They do not dispute that manufacturers respond to threats of liability; nor could they since the very purpose of tort law is to "induce behavioral changes" in potential defendants to avoid liability. (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1026.) Nor do they suggest that the manufacturer reactions discussed above would be irrational.

Instead of engaging on the substance, Plaintiffs' amici merely accuse Gilead and its amici of crying wolf in the past. For example, Justice Catalyst argues that pharmaceutical companies have previously cited "innovation" to resist "regulation" and that no harmful consequences have materialized. (Justice Catalyst Br. 9-20.) But their brief largely focuses on industry responses to incremental *FDA regulations and federal laws*. (See *id.* at 9-12, 19-20.) The most these examples show is that policymakers and the expert regulatory agency charged with ensuring the safety of medicines have successfully balanced patient protection with burdens on manufacturers to avoid the worst impacts. The duty the Court of Appeal recognized is in a different realm entirely. (IADC Br. 22-23; OB24-25; Reply Br. 22-23.) There is nothing incremental about this unprecedented and unbounded tort

liability. And no expert agency or elected legislative body crafted—much less carefully limited—the duty. So this Court can draw no comfort from the assertion that past policy changes did not devastate the industry.

Justice Catalyst also cites a few cases they analogize to this one, most notably *Wyeth v. Levine* (2009) 555 U.S. 555 and its progeny. (Justice Catalyst Br. 13, citing *Wyeth* and *Merck Sharp & Dohme Corp. v. Albrecht* (2019) 587 U.S. 299.) But in *Wyeth*, the U.S. Supreme Court sided with the longstanding and near-unanimous view of lower courts in holding that federal law does not categorically preempt state-law failure-to-warn suits. (See *Levine v. Wyeth* (Vt. 2006) 944 A.2d 179, 186 ["courts have been nearly unanimous in holding that state failure-to-warn tort claims do not conflict with federal law"].) That is not instructive here, because this duty is entirely novel—no court, anywhere in the country, has ever before allowed tort liability against manufacturers for personal injuries caused by non-defective products. (IADC Br. 22-23; OB24-25; Reply Br. 22-23.)

Plaintiffs' amici make a similar observation about the various lawsuits that address market manipulation of the sort discussed above, such as lawsuits to protect generic competition. Plaintiffs' amici assert that those suits have not stymied innovation. (Justice Catalyst Br. 17-20.) But they ignore that (as discussed *ante* 25-26) those lawsuits target activities that entail no innovation at all—such as, in the case of product hopping, the release of alternative products that offer *no* benefits over existing, non-defective products. (Justice Catalyst Br. 22.)

Unlike all of those past refinements or reforms, this case directly targets innovation in a way that no duty ever has. Quite literally. This duty *threatens* liability "once a pharmaceutical company makes the decision to innovate." (Academics Br. 15.) This is the only cause of action in American history where the decision to bring a safer or more effective product to market automatically creates a plaintiff class of people who could have benefited from an earlier release, and the only one where a manufacturer can be sued because it learned too much about a possible alternative to an already safe, non-defective product. The duty, and its follow-on effects, are sui generis.

In any event, Plaintiffs' amici are wrong that expanded tort liability is consequence-free. The number of pharmaceutical products-liability suits continues to rapidly rise. For example, in 2023, nearly 38,000 pharmaceutical and healthcare products-liability suits were filed in federal courts alone—a staggering 132% increase over the previous year, to say nothing of state courts where the overwhelming majority of products-liability cases are brought. (See Admin. Office of the U.S. Courts, *Table C-2A: U.S. District Courts—Civil Cases Commenced, by Nature of Suit, During the 12-Month Periods Ending September 30, 2019 through 2023*, https://tinyurl.com/3p5ht5vv.) That follows a longer trend of increased products-liability litigation. Since 2015, there has been a 90% increase in products-liability cases filed in federal court, the most common of which are against pharmaceutical companies and medical device manufacturers—and that figure does not even include the tens of thousands of

cases filed in multidistrict litigations. (See Lex Machina (2023) *Product Liability Litigation Report*; see also Field, *Product Liability Claims Rose Over 5 Years, Report Says*, Law360 (Sept. 13, 2023) https://tinyurl.com/2tzfnjv2.)

As this Court has known for decades, expanded liability against pharmaceutical companies comes at a cost: medicines "withdrawn or withheld from the market because of the fear that their producers would be held liable for large judgments," and medicines "greatly increased in price" to offset the costs of litigation. (*Brown*, *supra*, 44 Cal.3d at 1064.)

Brown discussed in detail the prescient tale of Benedictin, the only antinausea drug available for pregnant women. The price of Benedictin skyrocketed over 300% because of litigation, leading the manufacturer to withdraw the medicine from sale because the cost of insurance almost equaled the entire income from sale of the drug. (*Ibid.*) *Brown* also detailed the example of a different manufacturer that was unable to bring a new medicine for vision problems to market because it could not obtain liability insurance at a reasonable cost. (*Id.* at 1065.) The U.S. Supreme Court recognized a similar situation in *Bruesewitz v. Wyeth* (2011) 562 U.S. 223, explaining that before Congress passed the National Childhood Vaccine Injury Act, a "massive increase in vaccine-related tort litigation" caused all but one manufacturer of the DTP vaccine to withdraw from the market, while potential tort liability for the sole remaining manufacturer exceeded its annual sales by a factor of 200. (*Id.* at 226-28.)

That pattern has only continued in the decades since *Brown*. For example, a vaccine for Lyme disease—which infects around 300,000 people every year in the U.S.—was pulled from the market in 2002 after the threat of litigation outweighed the relatively low demand. (Flaherty, *Can a New Lyme Disease Vaccine Overcome a History of Distrust and Failure?* STAT News (Aug. 22. 2019), https://tinyurl.com/37rx3v4f.) The impact of tort liability on reproductive health has been particularly devastating, with some arguing that the "threat of liability is the primary reason for private sector abandonment of the field of contraceptive research and development." (Lindenfeld, *The Unintended Pregnancy Crisis: A No-Fault Fix* (2016) 17 Marq. Benefits & Soc. Welfare L. Rev. 285, 291 [collecting authorities].) This Court should not accelerate these "unfortunate consequences" (*Brown*, *supra*, 44 Cal.3d at 1065) by approving this duty.

This duty is unworkable. The amici supporting Gilead powerfully reinforce the concern that the Court of Appeal's duty gives juries and courts no workable standard by which to weigh the numerous and multifaceted considerations that influence product development decisions. (See OB46; Reply 32-33; see generally U.S. Chamber Br. 13-19.) A standard no more defined than "due care" and "reasonableness" will result in nothing but chaos. It leaves all manufacturers guessing, condemned to try to avoid running afoul of an "inscrutable balancing of an unknown set of factors" that are "impossible" for them to discern. (Nat'l Assoc. of Manufacturers Br. 17-18; U.S. Chamber Br. 18-19

[explaining that "[b]usinesses cannot operate under such uncertainty"]; see DRI Br. 19-20.) Worse still, while juries equipped with the benefit of hindsight may find it easy to see where a manufacturer went wrong, manufacturers making product development decisions in real time face paralyzing uncertainty. (U.S. Chamber Br. 18-19.) Whatever purported benefit the duty is meant to achieve, it cannot be furthered when manufacturers have no idea what it means to conform—or any practical ability to do so.

The point here is not that boardroom decisions are immune from judicial scrutiny, but rather that standardless, retroactive scrutiny provides no guidance and yields arbitrary results. The fact that courts have assessed other sorts of corporate decisions under clearer standards—as Plaintiffs' amici point out—therefore proves nothing at all. (Justice Catalyst Br. 24-26; AAJCAC Br. 19-21; Academics Br. 11-12.) Plaintiffs' amici again cite civil and criminal cases involving lying and willful market manipulation—such as inapposite tobacco and opioid litigation and product-hop cases arising under antitrust law discussed above. (See *ante* 15-16.) None of these cases depend on a negligence standard assessing the "reasonableness" of a defendant's corporate decision-making; every single one requires specific intent to cause harm and measurable standards to guide both corporate defendants and courts.

Take, for example, the product-hopping cases arising under antitrust law that Plaintiffs' amici describe as an "instructive analog." (Justice Catalyst Br. 24.) Unlike the Court of Appeal's

duty, antitrust law does not subject the reasonableness of every boardroom decision to scrutiny. (Contra *id.* at 24-25.) It prohibits one particular decision intentionally taken with a specific anticompetitive motive. So the command is straightforward: Do not intentionally develop and market effectively indistinguishable products and lie to patients and doctors about their benefits with the specific intent to "coerce[] consumers and impede[] competition." (*New York ex rel. Schneiderman v. Actavis PLC* (2d Cir. 2015) 787 F.3d 638, 652, 651 [discussing specific intent requirement].) Moreover, much as courts in California have developed a robust body of law guiding determinations of what constitutes a defect, courts have also devised a "helpful framework" for determining when the release of an alternative product design violates antitrust law. (*Id.* at 652.) The fact that antitrust law also implicates manufacturers' boardroom decision-making and resource allocations does not justify empaneling juries to second-guess the "reasonableness" of every development decision anytime a consumer of their products suffers harm, especially when the allegedly injury-causing product is not defective. (Contra Justice Catalyst Br. 25-26.)

Simply put, it is fairly obvious to a manufacturer how to avoid liability when it comes to fraud, racketeering, and antitrust laws. And proving to courts and juries that those rules have been violated is also relatively straightforward. It is nearly impossible to prove one of these claims without a paper trail establishing that the manufacturer was intentionally misleading consumers. (See generally U.S. Dep't of Justice, *Justice Department*

Announces Global Resolution of Criminal and Civil Investigations with Opioid Manufacturer Purdue Pharma and Civil Settlement with Members of the Sackler Family (Oct. 21, 2020) https://tinyurl.com/k7aa2njj, cited by AAJCAC Br. 20 fn.5.) But there are no such brightline rules to guide juries confronting the Court of Appeal's duty here. When is it unreasonable to weigh the interests of different patient populations, consider expected profits, or shelve a once-promising new technology that has been technically "invented" but remains years and an immense investment of resources away from the uncertain prospect of commercialization in favor of other development priorities that potentially benefit a larger patient population? (See OB46.) Plaintiffs' amici have no answers—or even meaningful guideposts.

The duty will bury manufacturers in a wave of litigation. Plaintiffs' amici do not seriously contest that the duty will lead to a wave of litigation. Instead, they minimize the consequences with a false syllogism: They posit that widespread liability will not materialize unless development decisions that unreasonably value profits over patients are "pervasive"; if, however, those sorts of decisions "do[] not regularly occur," the "parade of horribles" will never materialize. (AAJAC Br. 21-22.) Of course, that syllogism depends on the massive leap of faith that lawyers will bring cases only when meritorious, and that juries will be able to correctly apply a duty that is incapable of principled application, without the benefit of any meaningful standards or even expert testimony. (See, e.g., OB45-47; Reply

32-33.) But even were that so, Plaintiffs' amici's argument is flawed on its own terms because it ignores the deadweight cost of litigation necessary to separate meritorious tort claims from meritless allegations. (See, e.g., Product Manufacturers Br. 22-23; U.S. Chamber Br. 19-21; Nat'l Assoc. of Manufacturers Br. 15; PRI Br. 13-14.)

Lawsuits—even if ultimately resolved in favor of the manufacturer—are costly, destabilizing, and destructive. This case demonstrates the unnerving ease with which enterprising plaintiffs' lawyers can allege that a company "knew" an alternative product was safer, and make it past summary judgment despite overwhelming evidence that the manufacturer did not have such knowledge and could not have had such knowledge. (See Reply Br. 9-11, 26, 39; IADC Br. 40-42.) And that means that any such litigation will be expensive—as well as unpredictable.

The cost of litigating all these cases all the way through trial will be crushing even for established companies; for startups or low-margin manufacturers, it may prove fatal. (See, e.g., Product Manufacturers Br. 22-23; U.S. Chamber Br. 21; Nat'l Assoc. of Manufacturers Br. 15; PRI Br. 13-14.) Every decision a manufacturer has made about its research-and-development priorities will suddenly become ripe for "expensive fishing expedition[s]." (Nat'l Assoc. of Manufacturers Br. 15.) For many companies—no matter how reasonably they acted and no matter how meritless the claims against them—the pressure of such suits may be so overwhelming that they have no choice but to

settle. (PRI Br. 13-14; U.S. Chamber Br. 21; Nat'l Assoc. of Manufacturers Br. 15.)

The expense will start long before any litigation begins. As numerous amici explain, "[b]ecause of the risk of exposure, companies will likely need to involve lawyers at every stage of their product-development decisions, adding further expense and delay to the research-and-development process." (Product Manufacturers Br. 22; see also Technology Companies Br. 12; PRI Br. 46.) Opening up a manufacturer's entire range of research-and-development decisions to litigation will mean distracting key personnel, who will be forced to sit for depositions and dig for decades-old documents rather than performing their *actual* jobs of finding new and improved products for the benefit of consumers and patients. (Nat'l Assoc. of Manufacturers Br. 15; Product Manufacturers Br. 23.)

Even with the best legal advice, no manufacturer can be confident that a jury will correctly assess reasonableness in this context. So the potential liability will necessarily affect corporate decisions in ways that disserve the public interest. All of these costs will ultimately be borne by the consumer in the form of higher prices and products not developed. (See, e.g., IADC Br. 65-66; Nat'l Assoc. of Manufacturers Br. 12; U.S. Chamber Br. 19-25.)

Moreover, because such lawsuits will be entirely retrospective and hindsight-driven about decisions that allegedly should have been made differently years or even decades earlier (see *ante* 37-38), there will be no benefit to consumers in terms of

safer products. Unlike a design-defect action, where the product can be changed or retrofitted later, manufacturers cannot go back in time and make a different development decision.

B. The most credible patient advocates and advocacy groups confirm that the new duty will harm patients.

Patients are the ones who will suffer the worst consequences of this duty—in the form of fewer groundbreaking medications, fewer improvements to existing medications, fewer resources invested in research and development, and higher prices to offset the costs of litigation. (Patient Advocacy Groups Br. 20-27; see also U.S. Chamber Br. 19-24; Nat'l Assoc. of Manufacturers Br. 12, 20-22; PhRMA Br. 36-40; Product Manufacturers Br. 14-24.) Patients will gain nothing in exchange. (Patient Advocacy Groups Br. 27.)

That is why patient advocates and advocacy groups have sided with Gilead. (See generally Patient Advocacy Groups Br.) These amici include advocates and organizations who have been on the front lines of the fight against HIV/AIDS for decades. (*Id.* at 6-15.) They have witnessed the transformation of HIV from a fatal disease with no effective treatment options into a treatable and even largely preventable chronic illness. (*Id.* at 15-19.) That remarkable evolution came about because of pharmaceutical companies' innovations in the field—including Gilead's invention of the watershed single-pill breakthrough and Gilead's recent development of a twice-yearly preventative injection. (*Id.* at 18; OB11-12.)

But lifesaving innovations like these are possible only under a tort system that gives manufacturers clear guidance about their obligations and avoids the disincentives that Plaintiffs' proposed duty would create. (Patient Advocacy Groups Br. 20; see also, e.g., OB27-28, 45-47.) It is doubtful that these revolutions in HIV's mortality, morbidity, and transmissibility would have happened if the Court of Appeal's duty had been in effect 40 years ago—because as explained, this duty will chill the development of groundbreaking new medicines and incremental improvements alike. (*Ante* 32-33.) It will chill revolutionary new medicines—like Gilead's new twice-yearly preventative injection for HIV—because manufacturers will be forced to spend their resources on urgently commercializing any in-development drug they discover that might prove to be an even-safer alternative to an existing drug, rather than on developing truly pathbreaking products. And it will chill improvements, because companies will feel pressure to stop early research into potential alternatives to existing medicines, so as to avoid acquiring "knowledge" that a developmental drug is a safer alternative and therefore *must* be fully developed and commercialized, regardless of the costs or countervailing considerations.

Against the voices of these patient advocates stands one group, the AIDS Healthcare Foundation (AHF), which contends that Plaintiffs' proposed new duty is necessary to protect patients. But AHF is far from a disinterested party: AHF lawyers are counsel of record for plaintiffs in cases that are part of this JCCP currently before this Court. (See Petersen, *Patients Sue*

Gilead, Saying Drug Company Intentionally Delayed Safer HIV Medicine, L.A. Times (May 9, 2018), https://tinyurl.com/2vyevff8; Complaint, *Lujano v. Gilead Sciences, Inc.* (May 8, 2018) No. BC702302.) One of the attorneys listed as counsel on the cover of AHF's amicus brief—Thomas Myers—is also counsel for two plaintiffs from the *Lujano* matter, which was one of the earliest cases in the JCCP. (See Register of Actions, *Lujano v. Gilead Sciences, Inc.*, No. BC702302.) Another lawyer for the *Lujano* plaintiffs, Liza Brereton, is listed in this Court's docket as a lawyer at AHF.

AHF cannot mask its role as an advocate in this litigation by (intermittently) listing their counsel's affiliation on the JCCP docket as "HIV Litigation Attorneys," which represents hundreds of plaintiffs in the JCCP. HIV Litigation Attorneys is a spinoff of AHF, composed of attorneys who were—and continue to be—officers and employees of AHF. HIV Litigation Attorneys stated in filings below that they are "in-house counsel to the AIDS Healthcare Foundation." (Declaration of Arti L. Bhimani in Support of Plaintiffs' Motion to Amend Case Management Order No. 1 at ¶ 18(a) (Oct. 23, 2019) *Gilead Tenofovir Cases*, No. CJC-19-005043.) Myers, for example, represented to the *Lujano* court in July 2019 that he was affiliated with HIV Litigation Attorneys—but he signed AHF's amicus brief as in-house counsel and has an AHF biography that says that he has been an employee of AHF since 1998. (See Register of Actions, *Lujano v. Gilead Sciences, Inc.* (July 30, 2019) No. BC702302; AIDS Healthcare Foundation, *Tom Myers*, https://tinyurl.com/4by68esr

[as of Jan. 27, 2025].) An archived version of the website for HIV Litigation Attorneys explains that "TDF litigation against Gilead brought by HIV Litigation Attorneys is funded by AIDS Healthcare Foundation (AHF)[.]" (Wayback Machine, *About AIDS Healthcare Foundation (AHF)*, (May 10, 2021), HIV Litigation Attorneys, https://tinyurl.com/2f5w88v6.)

AHF admits that even apart from its alter ego firm, it has directly funded some of the lawsuits that are in this JCCP. (AHF Br. 9-10.) AHF adds the carefully worded statement that *AHF* has not made "any request for … monetary recovery"—so far. (*Id.* at 10.) But it has studiously avoided representing that neither AHF nor its affiliate will take a share of any recovery should Plaintiffs in these cases prevail. Regardless, AHF is far from an uninvolved friend of the court; it is an active participant in this litigation.

Given AHF's deep connection and prospective financial stake in this case, it is particularly galling that AHF argues its views deserve greater weight than those of other patient advocates and advocacy groups that filed a brief supporting Gilead. (AHF Br. 16 & fn.3.) Those patient advocacy amici include six groups with more than 100 years combined of commitment to advocating for the HIV/AIDS community. (See generally Patient Advocacy Group Br. 6-14.) By way of example, Community Education Group was founded in 1992 to provide community-level strategies—including patient care and public policy advocacy—to empower women, people of color, and other disenfranchised communities vulnerable to HIV/AIDS. (*Id.* at 6;

see Community Education Group, *About Us*, https://tinyurl.com/3m4ekf4s [as of Jan. 27, 2025].) Also among amici are world-renowned public health experts and HIV/AIDS advocates like Dr. Eugene McCray, who served as the Director of CDC's Division of HIV/AIDS Prevention and the first-ever Director of CDC's Global AIDS Program; Phill Wilson, who founded the Black AIDS Institute, cofounded numerous other esteemed AIDS service organizations, and served in several AIDS-focused public health positions; and C. Virginia Fields, who led the National Black Leadership Commission on Health for nearly two decades. (Patient Advocacy Groups Br. 11-14.) The positions they take in their amicus brief—about historic seismic developments in HIV treatment, the need for further revolutionary advances, and the dangers of discouraging innovation in this area—are based on decades of experience and consistent with their long-held positions.

In a halfhearted attempt to discredit the views of these experts—who have spent their careers spearheading major public health initiatives and advocating on behalf of the HIV/AIDS community—AHF claims that they should be disregarded simply because they do not provide direct patient care. (AHF Br. 16 fn.3.) To begin, AHF's assertion is incorrect: Some of the patient advocacy amici, like the Community Education Group, *do* provide patient care. (Patient Advocacy Groups Br. 6.) In any event, to disregard the views of internationally recognized HIV/AIDS experts and advocates just because they do not provide direct health services is absurd. Public health experts like Dr. McCray

(who led multiple federal HIV/AIDS programs) and advocates like Phill Wilson (who founded and cofounded numerous HIV/AIDS advocacy organizations) are intimately familiar with the HIV/AIDS community and its needs, and their decades of experience fully equips them to understand the disastrous consequences of this duty on that community.

Equally specious is AHF's assertion that "all" of the patient advocacy organization amici are "funded by drug companies." (AHF Br. 16 fn.3.) This repeats Plaintiffs' earlier attempt to impugn the integrity of these amici, which Gilead previously addressed. (Gilead Response to Plaintiffs' Letter Regarding Amicus Support Review, Mar. 22, 2024, at 1.) Specifically, the patient advocacy amici that do receive modest charitable support from donors in the industry are all "independent organizations" who "do not act at the direction of their donors." (Patient Advocacy Groups Br. 6.) And it is hardly remarkable that companies devoted to the treatment of patients would give charitable contributions to groups focusing on that same goal. Moreover, AHF does not even attempt to make the same allegation as to the individual patient advocate amici. (See AHF Br. 16 fn.3.) In any event, AHF's direct interest in this litigation is far more suspect than any charitable contributions to certain patient advocacy groups.

IV. Plaintiffs' Amici Fail To Defend The Duty's Full Scope Or Address Gilead's Proposed Limitations.

While the arguments of Plaintiffs' amici fail on their own terms, it bears emphasis that Plaintiffs' amici—like Plaintiffs—

do not even begin to address and defend the full policy consequences of the Court of Appeal's duty. That is because, like Plaintiffs (see Reply 6-7, 24-26), Plaintiffs' amici limit their defense of that duty to a narrow and extreme scenario that even they concede is rare, if it ever happens at all—cases where a *pharmaceutical* manufacturer *actually knows* that a *fully developed* alternative medicine is safer than an existing, non-defective medicine and *unreasonably chooses to withhold* that medicine from the market for *immoral, profit-motivated* reasons. (See, e.g., AAJCAC Br. 12, Academics Br. 13; see also AHF Br. 15-16 [arguing that drug manufacturers may not be insulated from liability for such "blatantly immoral actions"]; Justice Catalyst Br. 21 [arguing that Gilead may be held liable for "manipulating the availability of [its] product"].) Yet nothing constrains the Court of Appeal's duty to this stylized (and false, *ante* 19, 27-28) fact pattern—a point Gilead made in its briefing (Reply 24-26, 31), and to which Plaintiffs' amici provide no answer. This Court should not adopt a duty of care that sweeps so far beyond what *any* party or amicus is willing to defend.

Type of manufacturer. Plaintiffs' amici adopt Plaintiffs' boundless view of § 1714, and insist that, despite longstanding common-law limitations on manufacturer liability, there is a supplementary "duty on a drug manufacturer to be responsible for an injury caused by its want of ordinary care in its business operations." (AAJCAC Br. 13; see also OB28; Reply 26-29.) Yet Plaintiffs' amici do not address how an expansive understanding of "negligence liability" that extends to "*every* … person and

entity" (AAJCAC Br. 15, italics added) will be limited to the pharmaceutical industry. (*Id.* at 13 [this duty purportedly applies to "drug manufacturer[s] … *just like every other business*"]; see generally Reply 24-25.) Plaintiffs' amici entirely neglect to address the impacts of a duty that will expose just about every product development decision to second-guessing. (OB36-37.)

Indeed, as is demonstrated by the chorus of products-manufacturer amici writing in support of Gilead—ranging from car makers to medical device companies to software designers—the Court of Appeal's duty places just about every industry at risk of potentially speculative lawsuits. (Nat'l Assoc. of Manufacturers Br. 13-14; see generally Product Manufacturers Br.; Technology Companies Br.) Indeed, any industry that "rel[ies] on research and development to bring innovative products to market" may find itself in the new duty's crosshairs. (Technology Companies Br. 5.)

For these manufacturers, just as for Gilead, the clarity and assurance of the defect requirement will be cast aside in favor of a standardless "reasonableness" rule that provides no guidance whatsoever. (Nat'l Assoc. of Manufacturers Br. 15-20; Product Manufacturers Br. 24-26.) And distorted incentive structures will come to drive product development across numerous and varied industries. Amici provide examples of real tradeoffs: For example, "Textron could be forced to finance minor adjustments to aircraft that already meet stringent FAA certification requirements instead of investing in groundbreaking research in other areas that affect safety or sustainable power generation." (Technology

Companies Br. 10.) Meanwhile, expanded liability will necessarily drive up prices—making the beneficial new products that do manage to hit the market more costly and less accessible. (Nat'l Assoc. of Manufacturers Br. 20-23; Product Manufacturers Br. 31.)

Motive and scienter. Critical to every one of the justifications for the duty advanced by Plaintiffs' amici is the defendant's purportedly nefarious motive for delaying the sale of a safer, alternative product. (AAJCAC Br. 14; Academics Br. 13; AHF Br. 15-16; Justice Catalyst Br. 21, 24-25.) Indeed, Plaintiffs' amici repeatedly liken the Court of Appeal's duty to other legal mechanisms used to hold manufacturers accountable when they make "conscious decision[s]" to prioritize profits over consumer welfare. (Academics Br. 11-12; see also AAJCAC Br. 20-21.) Yet Plaintiffs' amici—like Plaintiffs—do not explain how a claim arising in *negligence* could be limited to cases involving intentional misconduct. (See Reply 31.)

As this Court has always understood it, "[w]illfulness and negligence are contradictory terms." (*Donnelly v. S. Pac. Co.* (1941) 18 Cal.2d 863, 869.) Unlike a "person guilty of willful misconduct," a "negligent person has no desire to cause the harm that results from his carelessness." (*Ibid.*) And negligence explicitly focuses on the "*act*" not the "*motive.*" (*Davis v. Hearst* (1911) 160 Cal. 143, 162.) (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"].)

Plaintiffs' amici thus cannot justify the duty here by focusing on the bogeyman of a bad-faith manufacturer. This Court's evaluation of duty must address the "entire category of negligent conduct" at issue, not the case-specific reasons a defendant created a risk of harm. (*Cabral*, *supra*, 51 Cal.4th at 774 [duty question does not turn on the facts of the "particular parties in a narrowly defined set of circumstances"; "bas[ing] a duty ruling on the detailed facts of a case risks usurping the jury's proper function," which is deciding whether there has been a breach].)

If anything, amici's relentless focus on actual knowledge supports Gilead's argument that, at a minimum, the Court of Appeal's duty must be limited with a heightened scienter standard. (Reply 39; see OB43.) If, as Plaintiffs' amici insist, it is an "essential" element of this case that Gilead "knew" injuries would be inflicted by delaying TAF development (AAJCAC Br. 15; see Academics Br. 13 [advocating for a duty "[w]here a pharmaceutical company has actual knowledge of the … safety of the withheld alternative"]), then, this Court should reject a duty premised on constructive knowledge (Reply 30-31). Manufacturers should not have to struggle with the significant "precautionary obligation" imposed by a duty that presumptively extends to cases hinging on what a manufacturer purportedly should have known. (*Cabral*, *supra*, 51 Cal.4th at 773 fn.3; see OB43.)

Stage of drug development. Even if Plaintiffs' amici could guarantee that certain "essential … elements" will limit the

scope of the Court of Appeal's duty (AAJCAC Br. 14-15), Plaintiffs' amici cannot explain how those elements could possibly be satisfied in a case—like this one—where a decision to stop development of an alternative medicine occurs before Phase III and head-to-head clinical trials.

To start, Plaintiffs' amici do not address how it is even *possible* for a pharmaceutical manufacturer to know that it "possess[es]" a "safer alternative" to an existing non-defective medicine when an experimental drug candidate remains years of testing and tens of millions of dollars away from regulatory approval. (Contra AHF Br. 12-13.) As several amici vividly illustrate, Plaintiffs' notion that the Court of Appeal imposed no duty to develop (RB11) betrays a misunderstanding of the drug development process. (PhRMA Br. 22-26 [discussing limited conclusions that may be drawn from preclinical and Phase I-II studies and substantial resources necessary for Phase III trials]; ALF Br. 12-14; PRI Br. 44-45; see generally Reply 25-26.)

Plaintiffs' amici also do not dispute that a manufacturer cannot generally "know" a promising drug candidate is "safer" than an existing, non-defective medicine before Phase III and similarly largescale head-to-head clinical comparisons. (OB60-62; Reply 41-42.) Indeed, as the amici supporting Gilead point out, scientific "knowledge" of this sort is rarely straightforward. (ALF Br. 10-11; ICLE Br. 10.) Rather, conclusions may be drawn only from the results of iteratively "postulating, testing, and disproving hypotheses" in progressive experiments of "adequate sample size[]" and "appropriate control[s]." (ALF Br. 11.)

Plaintiffs' amici themselves recognize that in the pharmaceutical context, only the "scientifically rigorous [clinical] trials" that FDA regulations require enable drug manufacturers to "certify[] drug safety and effectiveness." (Justice Catalyst Br. 19-20; see also ICLE Br. 10; PhRMA Br. 40.) And as Plaintiffs' own experts repeatedly acknowledged, certifying the *relative* safety of TAF over TDF could not be based on the limited information Gilead had at the time and would have instead required—at a minimum—Phase III and head-to-head trials. (OB61.)

That is consistent with the amici supporting Gilead, who explain, in no uncertain terms, that "there is no juncture prior to the completion of large Phase III trials and FDA approval" at which a drug manufacturer "can be expected to reasonably 'know'" that a medicine is safe and effective. (PhRMA Br. 26.) Amici ground this contention in statistics and concrete examples, detailing that:

- preclinical and clinical testing *cannot* establish the safety profile of an experimental drug, and instead provides only a "ticket to entry" into much more extensive Phase III testing;
- early promise in Phase I and Phase II trials *regularly* fails to materialize in the form of an FDA-approved new medicine; and
- even Phase III clinical trials may only provide evidence of "non-inferiority"—not *superiority*—over an existing medicine.

(PhRMA Br. 22-36.)

Given the realities of drug development, the Court of Appeal's duty at the very least should not attach before a drug manufacturer even begins Phase III trials. (OB60-64.) The Court of Appeal declined to reach the issue, disclaiming any ability to make "generalizations" about "what can reasonably be known after Phase II trials as compared to Phase III trials" on the existing record. (Op.56.) But the undisputed facts, figures, and regulations that Gilead cites—and that multiple amici now confirm—plainly demonstrate that a manufacturer *cannot* generally know the relative safety profile of an experimental drug before Phase III trials. (OB61-63; see, e.g., PhRMA Br. 22-36; ALF Br. 12-14; PRI Br. 44-45.) Despite multiple opportunities, Plaintiffs have never challenged any of that evidence. Plaintiffs assert, with no evidence, that it is *conceivable* a manufacturer could obtain the necessary knowledge sooner in some outlier case, without so much as an explanation of how that can happen and no suggestion that it is generally true, as would be necessary to justify a duty never before recognized. (OB64; Reply 41.) And Plaintiffs' amici are now resoundingly silent on this key issue as well. No further record evidence is needed to prove what *no one* disputes.

CONCLUSION

This Court should reverse.

January 27, 2025

Respectfully submitted,

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This brief is proportionally spaced and contains 10,822 words, according to the word processing program used to prepare it.

Dated: January 27, 2025

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

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

>> on the parties to this proceeding as follows:

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

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

Executed on January 27, 2025 at New York, New York

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