No. S283862

IN THE SUPREME COURT OF CALIFORNIA

GILEAD TENOFOVIR CASES

GILEAD SCIENCES, INC.,
Petitioner,

v.

SUPERIOR COURT OF THE STATE OF CALIFORNIA, 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

APPLICATION AND PROPOSED *AMICI CURIAE* BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE CALIFORNIA CHAMBER OF COMMERCE, WASHINGTON LEGAL FOUNDATION, AND THE NATIONAL RETAIL FEDERATION

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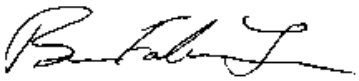
CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

Except for the parties and any entities or persons already identified by the parties, counsel for *Amici Curiae* know of no entity or person that must be listed in this Certificate under Rule 8.208(e) of the California Rules of Court.

Dated: November 4, 2024 DLA PIPER LLP (US)

By: 

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Application to File *Amici Curiae* Brief

Pursuant to California Rules of Court, rule 8.520(f), the Chamber of Commerce of the United States of America, the California Chamber of Commerce, Washington Legal Foundation, and the National Retail Federation (collectively, "*Amici Curiae*") respectfully request leave to file the attached *amici curiae* brief in support of Petitioner Gilead Sciences, Inc. ("Gilead" or "Petitioner").

The Chamber of Commerce of the United States of America ("U.S. Chamber") is the world's largest business federation. It represents around 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country—including throughout the State of California. An important function of the U.S. Chamber is to represent the interests of its members in matters before federal and state courts, Congress, and the Executive Branch. To that end, the U.S. Chamber regularly files *amicus curiae* briefs in cases, like this one, that raise issues of concern to the business community. The U.S. Chamber also routinely files *amicus curiae* briefs in cases pending before California courts, including cases involving pharmaceutical and labor and employment matters.

The California Chamber of Commerce ("CalChamber") has more than 13,000 members, both individual and corporate, representing virtually every economic interest in the State. While CalChamber represents several of the largest corporations in California, seventy-five percent of its members have 100 or fewer

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employees. CalChamber acts on behalf of the business community to improve the State's economic and employment climate by representing business on a broad range of legislative, regulatory, and legal issues.

Washington Legal Foundation ("WLF") is a nonprofit, public-interest law firm and policy center with supporters nationwide, including many in California. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as *amicus curiae* to oppose novel state-law tort duties that second-guess the safety of federally regulated products. (*See*, *e.g.*, *Burningham v. Wright Med. Tech., Inc*. (Utah 2019) 448 P.3d 1283; *McNair v. Johnson & Johnson* (W. Va. 2018) 818 S.E.2d 852.) Such suits undermine the very goals of public health and safety that tort law is intended to further. WLF's Legal Studies division also regularly publishes articles by outside experts on state-law approaches to product liability. (*See*, *e.g.*, John J. Park, Jr., Law Rejecting "Innovator Liability" Theory Restores Civil Justice Sanity to Alabama, WLF Legal Opinion Letter (June 19, 2015).)

Established in 1911, the National Retail Federation ("NRF") is the world's largest retail trade association and the voice of retail worldwide. Retail is the largest private-sector employer in the United States. The NRF's membership includes retailers of all sizes, formats, and channels of distribution, spanning all industries that sell goods and services to consumers. The NRF frequently provides courts with the perspective of the retail

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industry on important legal issues impacting its members by filing *amicus curiae* briefs.

The aim of this brief is to help the Court understand why it should reverse the Court of Appeal's grossly improper ruling imposing a duty on product manufacturers to market alternative products. *Amici Curiae* agree with Petitioner that no such duty exists under California law. The proposed brief does not repeat Petitioner's compelling legal arguments why this Court should vacate the Court of Appeal's decision creating a new duty. Rather, *Amici Curiae* highlight how the Court of Appeal unjustifiably departed from settled tort law and announced a new duty rule that will disrupt the careful balance struck by California tort law and place product manufacturers in the untenable position of being answerable in tort whenever one product is brought to market before another. Because *Amici Curiae* believe their brief would help the Court understand the adverse consequences of the Court of Appeal's departure from settled California tort law, *Amici Curiae* respectfully request this Court's permission to file it.

No party, attorney for a party, or judicial member drafted this brief or participated in *Amici Curiae*'s decision to file it. Other than *Amici Curiae* and their members, no person or entity, including any party or party's counsel, made a monetary contribution intended to fund the preparation or submission of this brief.

Petitioner's Reply Brief on the Merits was filed on October 3, 2024. This application has been timely filed by the deadline for

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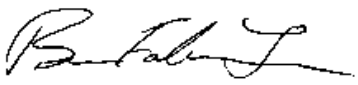
filing amicus briefs in this appeal. (See Cal. Rules of Court, rule 8.520(f)(2).)

November 4, 2024 Respectfully submitted,

DLA PIPER LLP (US)

By: 

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INTRODUCTION

For all its protestations that its holding is narrow and unremarkable, the Court of Appeal has issued an opinion that, if allowed to stand, would reshape California products-liability law in a deeply unfair and unsustainable fashion. Until now, a manufacturer satisfied its duty to consumers by producing safe and non-defective products. No more. For the first time ever, a California appellate court has held that a consumer may sue the manufacturer of a non-defective product on the theory that the manufacturer should have developed and then sold that consumer a different product.

The creation of this new duty to develop and sell alternative products to benefit certain consumers is untenable. Every decision to sell a product benefits some consumers. But given limited resources, that choice has costs, including forgoing development of other products that could benefit different consumers. The decision to develop and sell a product should be guided by considerations of product safety and practicality. The predictable outcome of a duty to develop as quickly as possible or not at all is fewer safe products, more litigation, and higher costs for consumers. While the Court of Appeal's newly created duty will adversely impact all sectors of our economy and society, it will particularly stifle the development of new medicines, given the extraordinary cost, time, and uncertainty required to research, test, and obtain regulatory approval of new drugs.

Manufacturers rely on established California tort law to order their affairs, and especially to invest in research and

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development. For decades, that law has imposed liability only when plaintiffs can show that they were injured by a defective product. The lack of any precedent to support a new duty to sell alternative products underscores the Court of Appeal's departure from the framework of California tort law and its costly disruption to industry.

California tort law has powerful influences on U.S. manufacturing practices, given California's position as the largest economy in the country. The Court of Appeal's opinion steers the law in the wrong direction—one that is untenable, unprecedented, and unsustainable. This Court should reverse the Court of Appeal's decision.

ARGUMENT

I. Creating a New Duty to Commercialize Alternative Products Imposes Liability for Nonfeasance and Defies Logic.

In this case, Plaintiffs seek to recover for injuries caused by the known, rare side effects of Gilead's lifesaving tenofovir disoproxil fumarate ("TDF") medications, not because the medications were defective, but based on a novel theory that they were "deprived of the *choice*" to benefit (theoretically) from a still-in-development alternative. (*See Gilead Tenofovir Cases* (2024) 98 Cal App.5th 911, 918 ("Op.").) Plaintiffs do not claim that Gilead failed to warn Plaintiffs of the side effects of TDF or that TDF was defective, and those two facts alone should have foreclosed their negligence claim against Gilead. (*Id.* at 919; *see also Himes v. Somatics, LLC* (2024) 16 Cal.5th 209, 221 ["[T]he manufacturer cannot be held liable if it has provided appropriate warnings."].)

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Because tort law does not permit a plaintiff to recover for the known side effects of a non-defective and lifesaving medication accompanied by adequate warnings, Plaintiffs have no claim against Gilead under established California law. The decades-old framework governing a claim that a product caused injury has always required a plaintiff to "prove that a defect caused injury." (*Merrill v. Navgar, Inc.* (2001) 26 Cal.4th 465, 479.) A plaintiff must also prove that the defect occurred because the manufacturer failed to "use reasonable care to so design his product as to make it not accident-proof, but safe for the use for which it was intended." (*Pike v. Frank G. Hough Co.* (1970) 2 Cal.3d 465, 470.)

The Court of Appeal undermined this framework by allowing Plaintiffs' claims to proceed, notwithstanding the lack of any allegation (let alone proof) that TDF is defective. The court did so by imposing a distinct and unprecedented duty on manufacturers to develop, commercialize, and sell products *other* than the one that Plaintiffs consumed and that allegedly caused injury. It reasoned that Gilead can be held liable because the side effects from using TDF might have been reduced if Gilead had prioritized continued development and commercialization of a different medication—tenofovir alafenamide ("TAF")—more quickly. (Op. at 918.)

This new duty is untethered from any limiting principle and would entitle any subset of consumers (however small) to claim a different product would have been safer for them, and so long as that alternative product is within the manufacturer's power to develop and market, the number of potential claims is endless. A

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plaintiff could assert a viable negligence claim against a manufacturer who did not produce enough units of a product, who downsized an existing product line, or even who stopped manufacturing parts for older models that had been replaced on the market.

This is fundamentally inconsistent with California law, which requires a manufacturer to ensure that its products perform as safely as could reasonably be expected when used by an ordinary consumer, or that the benefit of a chosen design outweighs its risks. (*Barker v. Lull Eng'g Co.* (1978) 20 Cal.3d 413, 427.) That standard of care can be objectively known by a manufacturer and applied by a court. The new "duty" instead requires a manufacturer to prioritize its research and development projects to benefit (at least potentially) an undefined subset of consumers. Yet in doing so, it is exposed to liability to a different subset of consumers who would have (at least potentially) benefited from a different prioritization of research and development projects.

Taking the simplest of matrices, where a manufacturer has a legal, non-defective, reasonably safe product 1, and, with its finite revenues can either develop a different delivery system, product 2, that will benefit a broader population than will benefit from product 1 or can develop product 3 as an alternative to product 1, which will benefit a subset of existing consumers from product 1. The decision of the Court of Appeal would allow potential candidates for product 3 to sue if the manufacturer pursued product 2—and could in the right circumstances allow

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potential candidates for product 2 to sue if the manufacturer pursued product 3. That manufacturer would be liable even though there is no defective product: liability is premised on the prioritization between two beneficial choices.

This new duty is ungrounded, unadministrable and counter-productive in every sense of the word. California law does not obligate a manufacturer to improve on non-defective products, as the Court of Appeal itself acknowledged. (Op. at 921.) Imposing such an "endless obligation to pursue ever-better new products or improvements to existing products would be unworkable and unwarranted." (*Id.*) "Manufacturers are not insurers of their products; they are liable in tort only when 'defects' in their products cause injury." (*Soule v. Gen. Motors. Corp*. (1994) 8 Cal.4th 548, 568.) In other words, California products-liability law protects a manufacturer that satisfies its duty to produce safe products and that chooses not to improve or iterate on the product. Thus, Plaintiffs must concede that if no company had ever developed TAF, there would be no liability because consumers would have received a safe and non-defective medication in TDF. Said differently, Gilead had satisfied its duty to Plaintiffs by ensuring that in taking TDF, they were taking a non-defective drug. (Op. at 918.)

Yet, paradoxically, the Court of Appeal held that once Gilead investigated and supposedly "developed" an alternative product—an undefined point in the process that is somewhere between conception and marketing—Gilead now had an additional duty to commercialize that alternative product without delay and could be

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liable to Plaintiffs for failing to do so quickly enough. How do consumers suddenly have a viable claim that Gilead had a duty not to "deprive" them of an improved product when no manufacturer had a duty to conceive or develop the product at all? Until this case, no such claim could survive.

The Court of Appeal's theory thus boils down to imposing liability on Gilead based on *nonfeasance*, where the law is "reluctan[t] to impose liability." (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 214.) Indeed, under the Restatement (Second) of Torts, § 314, even if an actor "realizes or should realize that action on his part is necessary for another's aid or protection," something more is required before there is a duty to act. In this case, Gilead was manufacturing a non-defective drug, so there was no necessity to act, much less knowledge of that necessity.

To be sure, if Gilead acted and the action created an unreasonable risk of physical harm, or if the action caused such harm that a person was "helpless and in danger of further harm," Restatement (Second) of Torts, §§ 321, 322, then a duty could arise. But the development of new, marginally safer medications does not increase the risk of injury, much less cause injury, from existing medications. Thus, the time taken to develop the new medication cannot be the basis for liability. (*See City of Santee v. County of San Diego* (1989) 211 Cal.App.3d 1006, 1015 [dismissing where "the failure to report the light outage did not increase the risk posed by an inoperative light; instead, the risk posed by the inoperative light remained unaltered"].) Nor could the time Gilead took to bring the drug to market "increase the risk of harm." (*Paz*

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v. State (2000) 22 Cal.4th 550, 558-59); *see also Williams v. State* (1983) 34 Cal.3d 18, 23 [citing Restatement (Second) of Torts § 323].) And Plaintiffs are not suing for Gilead's investigation and development of TAF medicines. Plaintiffs claim that Gilead is liable for failing to develop and market TAF medicines more quickly—to get them to the market in 2006 rather than 2015. That is a classic nonfeasance argument based on not taking action.

The Court of Appeal notes that nonfeasance typically involves harm from a third party, while here the alleged harm stems from TDF sold by Gilead. But this is an empty distinction because TDF is not defective, and the sale of TDF is not a "wrongful act." (*USA Taekwondo,* 11 Cal.5th at 214.) Gilead falls within the general rule that no duty exists "to protect [] from harm not created by any *wrongful act* of the defendant." (*Id*., italics added.) Plaintiffs already concede that the TDF medicines are not defective—which means Gilead undertook no "wrongful act" by marketing and selling them. So there can be no claim for Gilead failing to take an additional action to avoid or prevent an injury caused by those non-defective medicines, and certainly no duty to do so by continuing to develop and to commercialize an entirely different medicine that Plaintiffs could take instead, such as TAF.

If the Court of Appeal's reasoning is adopted, then it would impose a duty to innovate on the manufacturer of the existing product, holding it liable for the normal side effect of an existing medication simply because it attempted to innovate a safer alternative. Yet under that same reasoning, another manufacturer would have no such duty, even if it were better positioned to

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innovate, simply because it did not sell the original non-defective product. The fact that no one contends the second manufacturer has a duty based on a nebulous "positioning" is a powerful reason to conclude that the first has no such duty either. No company had a duty to innovate TAF. Gilead satisfied its duty by ensuring that TDF was not defective.

II. Creating a New Duty to Commercialize Alternative Products Would Be Unworkable for Business and Courts.

A duty to commercialize products would create significant uncertainty for businesses in California and would be unadministrable for courts and businesses alike. The Court of Appeal breezily suggested that a new duty to market products would be straightforward because it "does not require the pursuit of commercialization at all costs." (Op. at 944.) Contrary to this simplistic notion, it is nearly impossible for manufacturers to determine the reasonable "cost" of commercialization, let alone for courts or juries to do so armed with the benefit of hindsight.

The "costs" of commercializing a product are multi-faceted and go beyond the direct expenses of manufacturing and marketing. "Real costs are opportunity or alternative cost." (Robert H. Bork, *The Antitrust Paradox: A Policy at War With Itself* at 392 (1993 ed.).) Every expenditure by a business comes with tradeoffs, and "foregone alternatives are only partly known and are constantly shifting in value." (*Id.* at 392.) Money spent commercializing an improved iterative product could have been used to develop and commercialize an entirely different product,

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benefiting a different set of consumers. It could have been used to lower the cost of existing products. Or it could have been used to buy new machinery or hire new scientists so that it will be better able to bring other products to market over a longer period of time.

By focusing on what could be a single consumer plaintiff who claims that he or she was "deprived" of an alternative product, the Court of Appeal conducted an overly narrow analysis untethered from the traditional, holistic analysis businesses must undertake—one that weighs short-term against long-term and weighs feasibility against foreseen benefits. The Court of Appeal's question is not about what strategy is prudent or wise or admirable for a business to pursue, nor whether consumers prefer incremental safety over higher prices, nor what would benefit the greatest number of consumers. Rather, it asks whether an individual consumer (or small subset of consumers) would prefer an improved product despite the "cost of commercialization" for the business to produce it. That standard would be unworkable.

Financial cost is one factor among several in California's risk-benefit test for a strict liability design defect claim. (*See Barker*, *supra*, 20 Cal.3d at 431-32.) But the focus of the risk-benefit test is the product itself and whether that product is defective and whether the alleged defect caused the plaintiff's injury. The costs the jury looks at are the costs to make a product safer and whether consumers would still value a "safer" product. In other words, the question is would the product remain effective for all its uses? Under that test, a jury is tasked with evaluating whether an alternative design could have reduced foreseeable

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risks without significantly impacting the product's usefulness or cost. Because the Court of Appeal eschewed the need to show any defect here, the jury's focus will shift from evaluating the product to scrutinizing how the firm has chosen to allocate resources and invest in product development across the business as a whole. This new approach introduces a retroactive element, as it holds manufacturers liable not for specific design flaws at the time of manufacture, but for their abilities to forecast and implement resource allocation that would satisfy a jury operating with the hindsight perspective of a small group of injured consumers.

The Court of Appeal's new duty means that businesses could always be found liable, regardless of the actual safety or quality of their products.[1] Liability would be based on a jury's view of resource allocation and associated costs from the perspective of the plaintiff's claim. Contrary to the Court of Appeal's empty assurance, it is hard to imagine that plaintiffs would "face a difficult road" to convince a jury that the "cost" was not too high for the business when the only potential benefit is measured by that particular plaintiff.

Even if a company were to demonstrate and quantify the relative value produced by pursuing one course before another, it remains unclear how any jury could effectively assess the full universe of resource allocations underlying a company's decisions. These decisions include whether to develop or commercialize a

[1] There is reason to fear that expanding non-feasance to the consequences of a strategy not chosen would be applied not just to manufacturers but to any point along a product or service delivery continuum.

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particular product, or to refrain from doing so. Allowing juries to impose liability by declaring such decisions "unreasonable" would effectively allow juries to establish business policy. This will lead to outcomes that are random, unpredictable, and unprincipled.

The new duty to commercialize alternative products also disregards realities of product manufacturing. The Court of Appeal assured manufacturers that they need not improve existing, non-defective products but need only to commercialize and sell alternative products that have already been "developed" (a distinction that ties in with the Court of Appeal's view on "nonfeasance," discussed above.) (Op. at 944.) Yet no manufacturer can precisely determine when a product is sufficiently "developed" to trigger this duty. Take TAF: It hadn't received FDA approval in 2004 (*id.* at 916), which shows that Gilead never withheld a "developed" product. The Court of Appeal's assertion that "TAF was already developed" because it went through a single Phase I/II trial makes no sense. Completion of such an early-stage trial did not permit Gilead to sell TAF (or even apply to FDA for approval)—not even close. And even after early-stage trials had been completed, there would remain considerable cost, research, and uncertainty lying between the initial phases of product conception and FDA approval—with no guarantee that the product would pass all three stages of clinical trials and obtain all regulatory approvals necessary to sell TAF. Indeed, in 2004, Gilead would have needed to expend tens of millions of dollars in further research and development over four more years before it could even seek FDA approval for TAF—an

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outcome itself riddled with uncertainties. (Petitioner's Opening Br. at 17.)

Even the Court of Appeal recognized the inherent vagueness of the new duty that it was creating, acknowledging that "the meaning of 'develop' in the pharmaceutical context is ambiguous." (Op. at 921 n.3.) But its proposal to substitute "developed" with "invented" does nothing to resolve the ambiguity. "Invented" is no clearer to manufacturers, courts, or juries than "developed."

Determining when a product is "developed" or "invented" outside the pharmaceutical context is equally unclear. For instance, when does a car manufacturer "develop" or "invent" a new, safer airbag and become liable for withholding it? Is it at the production stage, the prototype stage, or merely when the engineer first sketches the concept out on a drawing board? Does a car manufacturer have a duty to commercialize and sell individual component parts of a car as soon as the safety of a particular part, or a combination of parts, is marginally improved? Could a car maker be held liable for not selling innovative lane assist technology as a standalone product, and instead waiting to include it as part of its new car model? The Court of Appeal's novel and unprecedented duty has led manufacturers in various industries to begin asking similar questions, but the Court of Appeal's opinion provides no answer. (*See* Lemann, *supra*, 12 J. TORT. L. 157, 159 (2019) [explaining that "products liability has frequently declined to impose liability on manufacturers for their failure to include cutting edge safety technology"].)

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Nor can manufacturers avoid the new tort liability by rushing products to market. Indeed, plaintiffs often sue manufacturers and complain about a supposed "rush" to market without ensuring complete safety. (*See, e.g.*, *Romer v. Toyota Motor Corp.* (S.D. Fla. 2013) 916 F. Supp. 2d 1301, 1308 ["Toyota needed to rush their product to market . . . and did not want to subject the model to delays resulting from additional testing and redesign."]; *Tuchman v. DSC Commn's Corp.* (N.D. Tex. 1993) 818 F. Supp. 971, 975 [alleging manufacturer "sacrificed manufacturing quality . . . because of its overriding desire to 'rush to market.'"].)

The Court of Appeal's new duty thus imposes an unrealistic, completely unpredictable "Goldilocks" standard on manufacturers. They are expected to release products at just the right time—neither too early nor too late. Too early in development, and they risk launching an unsafe product without adequate testing. Too late, and they now risk liability for withholding a "developed" product. This dichotomy is unworkable when based on such a vague and flimsy guidepost as when a product is sufficiently "developed" or "invented." And the consequences of it would be immediate and significant. Rather than focusing on ensuring products are safe and defect-free—as tort law requires—manufacturers will have to weigh the risks of enormous, incalculable liabilities *before* they even decide to invest in research and development.

A duty to commercialize an alternative product is nebulous and imprecise, leaving manufacturers guessing and juries second-

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guessing. Businesses cannot operate under such uncertainty. (*See First Nat'l Maint. Corp. v. NLRB* (1981) 452 U.S. 666, 679 [observing that to be a "profitable business," a company "must have some degree of certainty beforehand as to when it may proceed to reach decisions without fear of later evaluations labeling its conduct" as unlawful].) The Court of Appeal's expectation for manufacturers to get the timing "just right" ignores the complex reality of product development. Its demand that manufacturers determine the reasonable "cost" of commercialization ignores that answering the question requires weighing incommensurable considerations—as well the hindsight bias that will inevitably impact a jury's review of whether the development process was a "reasonable" one. In short, the Court of Appeal's decision puts manufacturers in a legal quagmire that makes it impossible for them to predictably avoid liability for making routine, reasonable investment decisions.

III. Creating a New Duty to Commercialize Alternative Products Would Gratuitously Expand Tort Liability and Harm Consumers and Businesses.

Creating a new duty to commercialize alternative products would threaten serious negative consequences for consumers as well, because it would necessarily increase costs and stifle development of improved and innovative products. Litigation and liability costs are not free. Excessive liability is inversely related to investment in research and development. (*See* Michael J. Moore & W. Kip Viscusi, *Product Liability Entering the Twenty-first Century: The U.S. Perspective* 25, 27 (2001) [collecting studies].) "Making it easier to bring lawsuits has meant that a

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manufacturer, whether in the right or not, has had to spend more of its resources, including those that would have been devoted to innovation, in defending itself, even if a case is settled." (*See* Nat'l Academy of Engineering, *Product Liability and Innovation: Managing Risk in an Uncertain Environment* (1994) ("*Product Liability and Innovation*" at 6.) "The risk of litigation can discourage the development and sale of new products and can slow innovation." (*See* U.S. Chamber of Commerce Institute for Legal Reform, *Tort Costs in America: An Empirical Analysis of the Costs and Compensation of the U.S. Tort System* at 6 (Nov. 2022).)

As this Court acknowledged in *Brown v. Superior Court*, it is the strong public policy of the State to foster the development and commercialization of new and improved pharmaceutical products. ((1988) 44 Cal.3d 1054, 1063-65.) *Brown* cautioned that the over-extension of tort liability on drug manufacturers has the potential to "substantially impair[]" the public's interest in such innovation. (*Id.* at 1067.) That is because of "the possibility that the cost of insurance and of defending against lawsuits will diminish the availability and increase the price of pharmaceuticals." (*Id.* at 1064.) Indeed, as this Court has recognized, "discourag[ing] the development and availability of life-sustaining and lifesaving drugs" has the effect of "defeating a strong public interest." (*Carlin v. Superior Ct.* (1996) 13 Cal.4th 1104, 1126-27.)

The Court of Appeal dismissed these concerns by asserting that the threat was "overstate[d]" and that "most plaintiffs would likely face a difficult road in establishing a breach of the duty of

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reasonable care." (Op. at 943.) This unsubstantiated claim is flawed for at least three reasons.

First, it disregards this Court's admonition that these adverse consequences are "far from theoretical" (*Brown*, 44 Cal.3d at 1064), as reflected by 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 [discussing examples]).

Second, it ignores the reality that "since 90 to 95 percent of all civil cases are settled, it is likely that a considerable portion of a company's resources expended in product liability litigation are not related to jury awards." (*See Product Liability and Innovation*, *supra*, at 6 n.3 [internal quotation omitted].) And even if companies ultimately prevail before a jury, they often must spend vast sums to litigate these claims all the way to trial. For smaller and emerging companies, "the economic costs of defending a lawsuit could throw a business operating on a narrow profit margin into bankruptcy." (*See Campbell v. Superior Ct.* (1996) 44 Cal.App.4th 1308, 1321.)

Third, and most importantly, it overlooks the minimal justification for creating a new duty that holds manufacturers liable for the rare injuries from safe, non-defective products. Consumers of TDF are already protected by established California products liability law, which would hold Gilead liable for any defect in TDF. If Plaintiffs cannot prove that TDF was defective (and they concede they cannot), then they have no basis to sue

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Gilead on the novel theory that Gilead owed them a duty to sell a different product (TAF) that Gilead had no duty to develop.

Moreover, far from incentivizing safe innovation, the most obvious and predictable result of the Court of Appeal's creation of this illogical duty to sell alternative products is an incentive for manufacturers to *avoid* innovation. Such a drive toward stagnation is not good for anyone. "Safe products and innovation are desirable goals that are in the public interest. The product liability system must ensure that they are not mutually exclusive." (*Product Liability and Innovation*, *supra*, at 18.) A manufacturer, however, will be deterred from innovating if its decisions in prioritizing research and development subject it to the claim that consumers were "deprived" of a product by delays in its commercialization. (Gideon Parchomovsky & Alex Stein, *Torts and Innovation*, 107 MICH. L. REV. 285, 289 (2008) ["An innovator will consider carrying out her idea when her expected profit is greater than the costs of R&D. The anticipated payout to tort plaintiffs, however, always adds to the innovator's costs, thereby eroding her incentive to innovate. In some cases, this erosion may forestall the innovation completely. In others, it induces the innovator to develop and patent the innovation but stop short of commercializing it because of increased tort liability."].)

The consequences of the Court of Appeal's new duty would be immediate and significant. Rather than focusing on ensuring products are safe and defect-free—as tort law requires—manufacturers will have to weigh the risks of enormous, incalculable liabilities before they decide to begin researching and

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developing new alternative products. Many will decide the risks outweigh the benefits. And few will have any incentive to expend considerable resources to explore the feasibility and safety of conceptualized improvements or alternatives for existing non-defective products if any allocation of resources will give rise to a negligence claim urging that a different allocation would have been to someone's advantage. The result of the Court of Appeal's ruling, then, is to invert the traditional tort-law incentives to improve on existing products.

This is particularly troubling in the pharmaceutical context, where many products are improved incrementally over time. (*See* Joanna Shepherd, *Deterring Innovation:* New York v. Actavis *and the Duty to Subsidize Competitors' Market Entry* (2016) 17 MINN. J.L. SCI. & TECH. 663, 703-04 ["According to analysis of FDA data, two-thirds of new drug approvals are for incremental innovations. . . . And according to the World Health Organization, over sixty percent of drugs deemed necessary for combating prevalent diseases are the result of incremental innovations."].) It is equally true in other, non-pharmaceutical manufacturing contexts as well. (*See* Alexander B. Lemann, *Autonomous Vehicles, Technological Progress, and the Scope Problem in Products Liability*, 12 J. TORT. L. 157 (2019) [explaining that "the history of automobile safety has been one of incremental improvements that have led to exponential increases in the safety of motor vehicle travel" and how "incremental improvements . . . have cumulatively revolutionized automobile safety in the past half century"].)

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As this Court recognized in *Brown*, 44 Cal.3d at 1063-65, over-extension of tort liability can "substantially impair" the public's interest in innovation, especially in pharmaceuticals. For this reason, *Brown* concluded that imposing novel forms of liability on pharmaceutical manufacturers "would not further the public interest in the development and availability of these important products." (*Id*. at 1064-65.) That is especially true here. Liability that attaches early in the development of an alternative product is a powerful disincentive to develop at all. (*See Torts and Innovation*, *supra*, at 307 ["When R&D costs are moderate or low, innovators may elect to complete the development stage, and when possible, even patent their inventions, because they expect no tort liability at these early stages. Many innovators, however, will stop short of commercializing their inventions because commercialization may lead to liability in torts. This dynamic will leave society with a list of unimplemented inventions—both patented and unpatented."]; Am. Med. Ass'n, Report of the Board of Trustees, *Impact of Product Liability on the Development of New Medical Technologies* (1988) ["Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance."].)

The Court of Appeal missed this point. It claims that the new duty will not alter incentives because manufacturers are economically motivated to avoid delaying the release of developed products. (Op. at 943.) But that assumes that all costs have been expended, and all risk absorbed, except for placing the product on the market itself. That was not true here, and it will not be true

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for the development of any pharmaceutical products until the end of the FDA approval process. In other words, while manufacturers have existing incentives to capitalize on fully developed products, the creation of the new duty discourages manufacturers from engaging in any iterative innovation that invites unpredictable tort liability.

The costs of California's tort system already exceed $60 billion—nearly $4,600 per household (fifth highest in the nation) and 2 percent of the State's entire GDP. (*See* U.S. Chamber Institute for Legal Reform, *Tort Costs in America: An Empirical Analysis of Costs and Compensation of the U.S. Tort System* at 17, 20 (Nov. 2022).) "[L]itigation causes not just financial loss, but also substantial emotional hardship, and often changes the tone of the business." (*See* Klemm Analysis Group for Small Bus. Admin. Off. of Advocacy, *Impact of Litigation on Small Business* (Oct. 2005) p. ii (as of Jan. 23, 2023).) There is very little reason to add gratuitous tort liability—and plenty of reasons to reject the Court of Appeal's novel holding and newly created duty here.

CONCLUSION

For all these reasons, *Amici Curiae* respectfully urge this Court to grant the relief requested in Gilead's petition.

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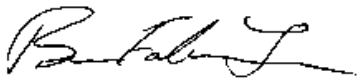
November 4, 2024 Respectfully submitted,

DLA PIPER LLP (US)

By: 

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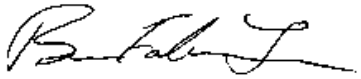
CERTIFICATE OF COMPLIANCE

This Amicus Curiae Brief complies with the type limitations of the California Rules of Court, Rules 8.204(b)-(c). This brief contains 13-point font, in Century Schoolbook typeface, and, together with the accompanying Application for leave to file it, contains 5,113 words, not including the Tables of Contents and Authorities, the caption page, signature blocks, Certificate of Interested Parties, and this Word Count Certificate.

November 4, 2024 By: 

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PROOF OF SERVICE

I am a citizen of the United States, over 18 years of age, and not a party to the within action. I am employed by the law firm of DLA Piper LLP (US). My business address is 555 Mission, Street, Suite 2400, San Francisco, CA 94105.

On November 4, 2024, I served the within **APPLICATION AND PROPOSED AMICI CURIAE BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE CALIFORNIA CHAMBER OF COMMERCE, WASHINGTON LEGAL FOUNDATION, AND THE NATIONAL RETAIL FEDERATION** on the parties interested in this proceeding, as addressed below, by causing true copies thereof to be distributed as follows:

All Counsel—As listed on TrueFiling Servicing Notifications List (Via TrueFile)

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

Executed November 4, 2024 at San Francisco, California.

/s/ Travis Jensen

Travis Jensen

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