S283862

IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

GILEAD LIFE SCIENCES, INC.,
Defendant and Petitioner,

v.

SUPERIOR COURT OF THE CITY AND COUNTY OF SAN FRANCISCO,
Plaintiff and Respondent,

PLAINTIFFS IN JCCP NO. 5043,
Real Parties in Interest.

AFTER A DECISION BY THE CALIFORNIA COURT OF APPEAL
FIRST APPELLATE DISTRICT, CASE NO. A16558
HON. ANDREW Y.S. CHENG, TRIAL JUDGE
SAN FRANCISCO SUPERIOR COURT CASE NO. CJC-19-005043

APPLICATION TO SUBMIT AMICUS BRIEF AND AMICUS CURIAE BRIEF OF THE INTERNATIONAL CENTER FOR LAW AND ECONOMICS IN SUPPORT OF PETITIONER GILEAD SCIENCES, INC.

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APPLICATION FOR LEAVE TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF PETITIONER

Pursuant to rule 8.520(f) the International Center for Law & Economics (ICLE) respectfully requests leave to file the attached amicus curiae brief in support of Petitioner.

ICLE is a nonprofit, non-partisan global research and policy center aimed at building the intellectual foundations for sensible, economically grounded policy. ICLE promotes the use of law and economics methodologies and economic learning to inform policy debates. It also has longstanding expertise in evaluating law and policy relating to innovation and the legal environment facing commercial activity.

ICLE has no interest in or connection to either party in this case. No party or party's counsel authorized the attached amicus curiae brief in whole or in part. No party outside of ICLE made a monetary contribution intended to fund the preparation or submission of this brief.

ICLE seeks leave to file the accompanying brief because it has longstanding expertise in evaluating law and policy relating to innovation and the legal environment facing commercial activity. In particular, ICLE wishes to elucidate some of the crucial considerations concerning the effect on innovation incentives that we believe would arise from the Court of Appeal's ruling in this case.

Because ICLE believes the accompanying brief would assist the Court it in its resolution of this important issue, it respectfully requests this Court's leave to file the amicus brief.

Dated: 11/4/2024

/s/ *Ian Adams*

_____

Ian Adams
Attorney for Amicus Curiae
ICLE

I.
INTRODUCTION

This case presents a pivotal question that could fundamentally reshape product liability law and significantly impact product innovation. At its core, this case asks whether a pharmaceutical company should be held liable for purported injuries resulting from a FDA-approved medication, not because the medication itself was defective, but because the company allegedly failed to develop and market a potentially safer alternative drug sooner.

The Court of Appeal's decision to recognize such a duty represents a dramatic departure from established principles of product liability law. It effectively creates a new form of liability that does not require proof of a product defect - a cornerstone of product liability jurisprudence for nearly a century. The central legal question before this Court is whether pharmaceutical companies should bear a duty to develop and bring to market a purportedly safer drug sooner, even when their existing product is not defective and complies with all regulatory requirements.

The importance of this case extends far beyond the immediate parties and industry involved. It has profound implications for innovation, legal precedent, and the fundamental structure of product liability law. If upheld, the Court of Appeal's decision could chill innovation in the pharmaceutical industry (and beyond) by exposing companies to potentially unlimited liability for their research and development decisions. It would allow juries to second-guess complex scientific and business judgments made in the face of significant uncertainty, potentially deterring companies from investing in the development of new products.

Moreover, this case challenges the long-standing requirement that plaintiffs in product liability cases must prove a defect in the product that caused a cognizable harm. Eliminating this requirement would not only upend decades of legal precedent but also remove a crucial safeguard that balances consumer protection with the need to promote innovation and ensure the availability of beneficial products.

We urge the Court to consider carefully the potentially drastic consequences of expanding liability in this manner against the established principles of product liability law and the broader public interest in promoting pharmaceutical innovation and access to life-saving medications.

II.
LEGAL DISCUSSION

This Court should reject the Court of Appeal's unprecedented expansion of tort liability for two fundamental reasons. First, the ruling dramatically departs from established product liability principles by eliminating the crucial requirement that plaintiffs prove a product defect—a cornerstone of product liability law for nearly a century. Second, the ruling rests on a fundamental misunderstanding of pharmaceutical development, incorrectly assuming that manufacturers can "know" a drug candidate is superior before completing the extensive FDA approval process. This flawed reasoning would create perverse incentives that would ultimately harm the very patients the tort system aims to protect by deterring innovation and delaying access to beneficial treatments. Such an outcome would run contrary to the public interest of the citizens of California.

A. THE COURT OF APPEAL'S RULE IMPOSES UNLIMITED LIABILITY

The Court of Appeal's ruling represents a significant and troubling departure from traditional products-liability law. In *Brown v. Superior Court*, (44 Cal.3d 1049 (1988)), this Court recognized the unique challenges and public health implications of pharmaceutical development. This Court explicitly rejected a standard that would hold drug manufacturers liable for failing to develop an alternative, purportedly safer product. (*Id.*) This decision was rooted in the understanding that such liability could discourage the development and distribution of beneficial drugs, ultimately harming public health.

Expanding liability to products *never even sold* is an unprecedented, unprincipled, and dangerous approach to product liability. California Civil Code § 1714 does not impose liability for "fail[ing] to take positive steps to benefit others," (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 215), and Respondents abandoned any theory that the medicine they received was defective. Respondents also abandoned any theory that the TDF medicines were not accompanied by adequate warnings under federal or state law. Thus, Respondents' case—as accepted by the Court of Appeal—is that they consumed a product authorized by the FDA, that they were fully aware of its potential side effects, but *maybe* they would have experienced fewer side effects had Petitioner made the decision to accelerate (against some indefinite baseline) the development of an alternative medicine. To call this a speculative harm is an understatement, and to dismiss Petitioner's conduct as unreasonable because allegedly motivated by profit, (Op. 32), not only flatly misrepresents the record but also elides the complex nature of product-development decisions in which profit is *always* a factor.

Practically speaking, there are two fundamental problems with this approach to products liability law: it does not require a "defective" product, and it fundamentally misunderstands the empirical realities of creating innovative pharmaceutical products.

1. Products Liability Law Requires a "Defective" Product

For nearly a century, California courts have adhered to a fundamental principle: a plaintiff alleging injury from a product must prove a defect in that product. (*Kalash v. Los Angeles Ladder Co.* (1934) 1 Cal.2d 229, 233). This requirement is, logically, a critical component in a products liability case. After all, how can one bring a suit for a defective product that is not actually "defective"?

This Court has repeatedly affirmed this principle, stating that manufacturers "are liable in tort only when 'defects' in their products cause injury" (*Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 568 fn.5). The defect requirement serves as a crucial limitation on manufacturer liability, ensuring that companies are not held responsible for injuries unless their products fall below an acceptable standard of safety.

Even Respondents do not maintain that the risks of TDF outweigh its risks, and indeed admit that it has been a hugely beneficial drug that should not be removed from the market. The safety and efficacy of highly regulated pharmaceuticals are determined in large part by the FDA in a process that takes many years, if not decades, and is more than sufficiently protective of patient safety. (*See* Gail A. Van Norman, *Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs, (2016), 1* JACC: BASIC TO TRANSLATIONAL SCIENCE *3* , *https://doi.org/10.1016/j.jacbts.2016.03.002).* After a comprehensive set of testing phases, and a thorough review of relevant scientific results related to the pharmaceutical, the FDA approves a new drug application. (*See* Peter Grossi & Daphne O'Connor, *FDA Preemption of Conflicting State Drug Regulation and the Looming Battle Over Abortion Medications*, J. L. & BIOSCIENCES, *10*(1), https://doi.org/10.1093/jlb/lsad005 at 5 *(2023)*). Even

after this review period, the FDA requires drug manufacturers to perform post-approval testing to ensure that the product is in fact safe and effective. (*Id*.) "The depth and breadth of this regulatory regime make clear that FDA's control over pharmaceuticals is not a one-time, binary choice between approval or prohibition, but rather requires the Agency to impose nuanced regulation, which is revised on a continual basis to take account of new data." (*Id.* at 6.) This last point is particularly relevant here, as the record is clear that FDA has never sought to reverse the approval of any of the TDF medicines, nor have the TDF medicines been recalled.

The pharmaceutical industry is characterized by inherent uncertainty. Drug development is a complex, time-consuming process where the ultimate safety and efficacy of a compound cannot be reasonably known until extensive clinical trials are completed. This uncertainty is a fundamental aspect of the scientific process, not a flaw to be penalized. The FDA's rigorous approval process is designed to navigate this uncertainty. It involves multiple phases of clinical trials, each building upon the last to establish safety and efficacy. This process can take years and cost billions of dollars, with no guarantee of success. The FDA's role is to evaluate the totality of evidence and make informed decisions about the benefits and risks of new drugs. A product that passes through the regulatory overview of the FDA is thoroughly tested to reasonably ensure it is not "defective." To require more is to impose an impossible standard. By contrast, the decision below is predicated on a standard that would second-guess the FDA's careful process, designed to navigate uncertainty, with the hindsight process of jury evaluation, which is necessarily biased by the certainty of events that have actually come to pass.

Respondents conceded that they are not claiming that TDF is defective. But, practically speaking, Respondents' framing of their claim as one of negligent timing in bringing TAF to market rather than as a defect in

TDF is an attempt to circumvent the fundamental defect requirement in products liability law through alternative pleading. While Respondents expressly disclaim any allegation that TDF was defective, their argument necessarily implies that the TDF medicines are insufficiently safe. By contending that TAF is less harmful compared to TDF, Plaintiffs inherently suggest that TDF's risk-benefit profile was suboptimal—in other words, that it was "defective" relative to TAF.

This argument goes directly to TDF's core characteristics: its particular combination of efficacy and side effects. Even while acknowledging that "the benefits of TDF use for hundreds of thousands of HIV/AIDS sufferers have vastly exceeded the harm from its side effects" (Op. 32), the Court of Appeal and Respondents essentially argue that TDF was deficient because Petitioner might have provided patients with a better alternative had they accelerated TAF's development. This is merely a recharacterization of a traditional products liability claim, attempting to achieve the same result while avoiding the required showing of defect.

Respondents' effort to subvert the defect requirement by recharacterizing their claim should not be countenanced by this Court. The defect requirement is a key, longstanding element of products liability law that properly balances burdens on manufacturers with protections for patients. Accordingly, California courts have consistently required proof of defect across the spectrum of product liability cases. (*See, e.g.*, *Merrill v. Navegar, Inc*. (2001) 26 Cal.4th 465; *Jiminez v. Superior Court* (2002) 29 Cal.4th 473, 478; *Cronin v. J.B.E. Olson Corp*. (1972) 8 Cal.3d 121, 133; *Garrett v. Howmedica Osteonics Corp.* (2013) 214 Cal.App.4th 173, 182; *Artiglio v. Superior Court* (1994) 22 Cal.App.4th 1388, 1393.) This requirement reflects courts' implicit understanding that when a plaintiff sues a pharmaceutical manufacturer over injuries allegedly caused by its product, the claim fundamentally reduces to an assertion that the

manufacturer, either negligently or otherwise, produced a defective drug. Allowing Respondents to bypass this requirement through creative pleading would undermine this carefully developed body of law.

Removing the defect requirement would destabilize tort law and the pharmaceutical market in profound ways. It would expose manufacturers to potentially unlimited liability for products that are reasonably safe and defect-free. This shift would create unprecedented uncertainty in the legal landscape, making it difficult for companies to predict their liability exposure and plan their operations accordingly.

Moreover, the defect requirement is essential to striking a balance between consumer protection and innovation. It provides a clear, objective criterion for assessing product safety while allowing manufacturers the flexibility to innovate and improve their products.

2. The Opinion Below is Out of Phase with the Empirical Realities of Creating Innovative Pharmaceutical Products

Respondents and the Court of Appeal placed great weight on the allegation that Petitioner's profit motive distorted its interests in bringing innovative pharmaceuticals to market. (Op. at 2, 28). But a focus on the narrow question of profits for a particular drug misunderstands the inordinate complexity of pharmaceutical development and risks seriously impeding the rate of drug development overall. A pharmaceutical medicine is priced not only to recoup the substantial costs of its particular development, but also to account for the numerous failures and mediocre successes that make up the company's drug development portfolio overall. (*See, e.g.*, F. M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 113 (1993)).

Drug companies invest massive amounts of money into research, and most of these attempts fail. What makes this huge investment worthwhile is the rare success story when they discover a drug that works better than what is currently available. When they do find such a breakthrough drug, companies are eager to get it to market as quickly as possible. Profit incentives play a large role in moving this process along.

Indeed, Respondents' claim on this ground is essentially self-refuting. If the "superior" product they claim was withheld for "profit" reasons was indeed superior, then Petitioner could have expected to make a superior return on that product. (See ARMEN A. ALCHIAN & WILLIAM R. ALLEN, EXCHANGE & PRODUCTION: COMPETITION, COORDINATION, & CONTROL (1983), at 292) (Noting that companies will adopt superior technologies in order to recoup greater profit opportunities). Thus, Respondents claim they were allegedly "harmed" by not having access to a product that was still many years and many millions of dollars away from commercialization, even though Petitioner had every incentive to release a potentially successful alternative as soon as possible, subject to a complex host of scientific and business considerations affecting the timing of that decision. Indeed, Petitioner explicitly considered releasing TAF if it proved to be superior to TDF because, in such a case, it expected to realize over $1 billion in additional revenue. (Petitioner's Opening Brief at 18). That is to say, Petitioner would have had much greater gain from releasing TAF earlier if it believed it was likely to be more effective and safer and likely to make it through FDA review. Sitting on TAF, had Petitioner truly believed it to be safer and more effective, would have inexplicably left a tremendous amount of profit on the table.

Relatedly, the Court of Appeal's decision rests on the unfounded assumption that Petitioner "knew" TAF was safer than TDF after completing a limited Phase I and Phase II trial. This ignores the realities of

the drug development process and the inherent uncertainty of obtaining FDA approval, even after promising early results. Passing Phase I trials, which typically involve a small number of healthy volunteers, is a far cry from having a marketable drug. According to the Biotechnology Innovation Organization, only 7.9% of drugs that enter Phase I trials ultimately obtain FDA approval.[1] (Biotechnology Innovation Organization, *Clinical Development Success Rates and Contributing Factors 2011-2020,* Fig. 8b (2021), *available at* https://perma.cc/D7EY-P22Q.) Even after Phase II trials, which assess efficacy and side effects in a larger patient population, the success rate is only about 15.1%. (*Id*.) Thus, at the time Petitioner decided to pause TAF development, it faced significant uncertainty about whether TAF would ever reach the market, let alone ultimately prove safer than TDF.

Moreover, the clock on Petitioner's patent exclusivity for TAF was ticking throughout the development process. Patent protection for new drugs officially lasts 20 years from the filing date (FDA, *Patents and Exclusivity*, (May 2015), FDA/CDER SBIA CHRONICLES, https://www.fda.gov/media/92548/download) but, due to the lengthy development process and other regulatory factors, pharmaceutical companies typically enjoy only about 12 years of actual market exclusivity. (*See* Aaron S. Kesselheim, *Determinants of Market Exclusivity for Prescription Drugs in the United States*, The Commonwealth Fund, https://www.commonwealthfund.org/publications/journal-article/2017/sep/determinants-market-exclusivity-prescription-drugs-united; *see also* Dean G. Brown, et al., *Clinical Development Times for Innovative Drugs*, 21(11) NAT REV DRUG DISCOV. 793, 794 (2022), https://pmc.ncbi.nlm.nih.gov/articles/PMC9869766/ (Noting that the pre-

[1] It is important to note that this number varies with the kind of medicine involved, but across all categories of medicines there is a high likelihood of failure subsequent to Phase I trials.

release period of a pharmaceutical averages 10 years, about half the life of the statutory patent term)). Exactly how much market exclusivity a manufacturer has for a given drug will depend in large part on how quickly it successfully navigates the regulatory process. Had Petitioner "known" that TAF was a safer and more effective drug, it would have had every incentive to bring it to market as soon as possible to maximize the period of patent protection and the potential to recoup its investment. The fact that Petitioner instead chose to focus on TDF strongly suggests that it did not have the level of certainty the Court of Appeal attributed to it.

Notwithstanding popular (mis)perception, economists generally dispute that companies have an incentive to unilaterally suppress innovation for economic gain, because "it is rare to uncover cases where a worthwhile technology has been suppressed altogether." (John J. Flynn, *Antitrust Policy, Innovation Efficiencies, and the Suppression of Technology*, 66 ANTITRUST L.J. 487, 490 (1998)).

Calling such claims "folklore," the economists Armen Alchian and William Allen note that, "if such a [technology] did exist, it could be made and sold at a price reflecting the value of [the new technology], a net profit to the owner." (ALCHIAN & ALLEN, *supra*, at 292). Indeed, "even a monopolist typically will have an incentive to adopt an unambiguously superior technology." (Joel M. Cohen and Arthur J. Burke, *An Overview of the Antitrust Analysis of Suppression of Technology*, 66 ANTITRUST L.J. 421, 429 n. 28 (1998)). While nominal suppression of technology can occur for a multitude of commercial and technological reasons, there is scant evidence that doing so coincides with harm to consumers, except where doing so affirmatively interferes with market competition under the antitrust laws—a claim not advanced here.

One reason the tort system is inapt for second-guessing commercial development and marketing decisions is that those decisions may be made

for myriad reasons that do not map onto the specific safety concern of a products-liability action. For example, in the 1930s, AT&T abandoned the commercial development of magnetic recording "for ideological reasons. . . . Management feared that availability of recording devices would make customers less willing to use the telephone system and so undermine the concept of universal service." (Mark Clark, *Suppressing Innovation: Bell Laboratories and Magnetic Recording*, 34 TECH. & CULTURE 516, 520-24 (1993)). One could easily imagine arguments that coupling telephones and recording devices would promote safety. For instance, a domestic abuse victim could claim that she would have had sufficient evidence to seek a restraining order against her abuser had she been able to produce recordings of harassing phone calls. And a failure of AT&T to bring to market technology it knew could be used for such beneficial purposes represented a negligent failure to market (or innovate) in line with the Court of Appeal's holding. But the determination of whether safety or universal service (and the avoidance of privacy invasion) was a "better" basis for deciding whether to pursue the innovation is not within the ambit of tort law (nor the capability of a products-liability jury). And yet, it would necessarily become so if the Court of Appeal's decision were to stand.

B. PUBLIC POLICY CONSIDERATIONS

Even if California law did not clearly require proof of a product defect to advance the suit in question, the weight of public policy considerations is strongly against the holding below. As this Court has observed, "[F]oreseeability alone is not sufficient to create an independent tort duty. '" . . . [The] existence [of a duty] depends upon the foreseeability of the risk and a weighing of policy considerations for and against imposition of liability."'" (*Erlich v. Menezes* (1999) 21 Cal.4th 543, 552.) It is appropriate, therefore, to avoid assigning liability where the

undesirable consequences of assigning liability outweigh the perceived benefits. (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 781; *see also Merrill, supra*, 26 Cal.4th at 502.) Even if this Court were inclined to accept Respondents' arguments on whether a manufacturer may be held liable for injury from a non-defective product, the downstream chilling effects on innovation of finding liability here would be disastrous to pharmaceutical development in particular, and product development in general.

Although our purpose here is not to engage in a full discussion of the *Rowland* factors for analyzing a duty of care under Civil Code section 1714, (*Rowland v. Christian* (1968) 69 Cal.2d 108, 113-16), here, three of the factors directly bear on a main argument of this amicus brief: public policy strongly cautions against extending a capacious duty of care to pharmaceutical manufacturers contemplating alternative drug development. In particular, the aim of preventing future harm, the extent of burden to the defendant, and the consequences of the decision to the community. (*Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1145).

The Court of Appeal notes that "a duty that placed manufacturers 'under an endless obligation to pursue ever-better new products or improvements to existing products' would be unworkable and unwarranted," (Op. 10), yet avers that "plaintiffs are not asking us to recognize such a duty" because "their negligence claim is premised on Gilead's *possession* of such an alternative in TAF; they complain of Gilead's knowing and intentionally *withholding* such a treatment…." (*Id*).

From an economic standpoint, this is a distinction without a difference.

Both a "duty to invent" and a "duty to market" what is already invented would increase the cost of bringing any innovative product to market by saddling the developer with an expected additional (and

unavoidable) obligation as a function of introducing the initial product. In both cases, it disincentives investigations into developing products.[2]

This Court in *Brown v. Superior Court*, (44 Cal. 3d 1049 (1988)), worried explicitly about the "[p]ublic policy" implications of excessive liability rules for the provision of lifesaving drugs. (*Id.* at 1063-65). As the Court in *Brown* explained, drug manufacturers "might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments." (*Id.* at 1063). The Court of Appeal agreed, noting that "the court's decision [in *Brown*] was grounded in public policy concerns. Subjecting prescription drug manufacturers to strict liability for design defects, the court worried, might discourage drug development or inflate the cost of otherwise affordable drugs." (Op. 29).

In rejecting the relevance of the argument here, however, the Court of Appeal (very briefly) argued a) that *Brown* espoused only a policy against burdening pharmaceutical companies with a duty stemming from *unforeseeable* harms, (Op. 49-50), and b) that the relevant cost here might be "some failed or wasted efforts," but not a reduction in safety. (Op. 51). Related, the Court of Appeal also makes the mistaken justification that the new duty will be unlikely to have negative effects, because it will be difficult to establish breach. (Op. at 52-3).

All of these claims are erroneous.

[2] To the extent the concern is with disclosure of information regarding a potentially better product, that is properly a function of the patent system, which requires public disclosure of new ideas in exchange for the receipt of a patent. (See *Brenner v. Manson*, 383 U.S. 519, 533 (1966) **(**"one of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions.")). Of course, the patent system preserves innovation incentives despite the mandatory disclosure of information by conferring an exclusive right to the inventor to use the new knowledge. By contrast, using the tort system as an information-forcing device in this context would impose risks and costs on innovation without commensurate benefit, ensuring less, rather than more, innovation.

On the first, the legalistic distinction between foreseeable and unforeseeable harm was not, in fact, the determinative distinction in *Brown*. Rather, that distinction was relevant only because it maps onto the issue of incentives. In the face of unforeseeable, and thus unavoidable, harms, the risk of liability would be so great that pharmaceutical companies would have severely diminished incentives to develop and market beneficial new drugs. For that reason, *Brown* disapproved of imposing strict liability for injuries arising from prescription medicines. As for foreseeable harms, the Court in *Brown* determined that incentives to innovate would be best furthered by constraining liability for pharmaceutical manufacturers to (1) negligent design defect claims; (2) manufacturing defect claims; and (3) failure to warn claims. (*Brown*, 44 Cal.3d at 1069 fn.12.) To be sure, the Court wanted to ensure that the beneficial, risk-reduction effects of the tort system were not entirely removed from pharmaceutical companies. But the Court in *Brown* made clear that the pharmaceutical industry presents significant countervailing considerations that warranted a more limited scope of liability:

"Perhaps a drug might be made safer if it was withheld from the market until scientific skill and knowledge advanced to the point at which additional dangerous side effects would be revealed. But in most cases such a delay in marketing new drugs -- added to the delay required to obtain approval for release of the product from the Food and Drug Administration -- would not serve the public welfare. Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering." (*Id.* at 1063).

That same calculus applies here, and it is this consideration, not a superficial question of foreseeability, that animated the Court in *Brown*.

On the second, the Court of Appeal inexplicably fails to acknowledge that the true cost of the imposition of excessive liability risk from a "duty to market" (or "duty to innovate") is not limited to the expenditure of wasted resources, but the *non*-expenditure of *any* resources. The court's contention appears to contemplate that such a duty would not remove a firm's incentive to innovate entirely, although it might deter it slightly by increasing its expected cost. But economic incentives operate *at the margin*. Even if there remains *some* profit incentive to continue to innovate, the imposition of liability risk simply for the act of doing so would necessarily reduce the amount of innovation (in some cases, and especially for some smaller companies less able to bear the additional cost, to the point of deterring innovation entirely). But even this reduction in incentive is a harm. The fact that some innovation may still occur despite the imposition of considerable liability risk is not a defense of the imposition of that risk; rather, it is a reason to question its desirability, exactly as this Court did in *Brown*.

This fact is particularly relevant in light of the public policy of California to not extend a duty of care where the costs of imposing a duty outstrip the benefits and where the consequences to the community would be detrimental. (*Cabral, supra*, 51 Cal.4th at p. 781-82). In considering this point the Court of Appeal assumed away the impacts of judicial second guessing on the incentives to innovate in the pharmaceutical industry, in part by crediting Respondents' argument that drug makers have an incentive to forego larger profits on potential blockbuster drugs by extending the patent term on inferior medicines. (Op. 49-50). But, as noted above, there is no serious evidence that suggests that firms forego greater profit opportunities when a superior product is available. (ALCHIAN & ALLEN, *supra*, at 292). Because there is no harm to be mitigated by the new

duty, all it does is disincentivize innovation, resulting in net negative policy consequences

1. The Court of Appeal's Decision Would Create Perverse Incentives that Stifle Pharmaceutical Innovation

Innovation is a long-term, iterative process fraught with uncertainty. During the research and development process, it is impossible to know whether a potential new drug will ultimately prove superior to existing drugs. Most attempts at innovation fail to yield a marketable product, let alone one that is safer or more effective than its predecessors. Deciding whether to pursue a particular line of research depends on weighing myriad factors, including the anticipated benefits of the new drug, the time and expense required to develop it, and its financial viability relative to existing products. Sometimes, potentially promising drug candidates are not pursued fully, even if theoretically "better" than existing drugs to some degree, because the expected benefits are not sufficient to justify the substantial costs and risks of development and commercialization. And all of this occurs against the backdrop of the clock running down on the length of available patent protection.

If left to stand, the Court of Appeal's decision would mean that whenever this stage of development is reached for a drug that may offer *any* safety improvement, the manufacturer will face potential liability for failing to bring that drug to market, regardless of the costs and risks involved in its development or the extent of the potential benefit. Such a rule would have severe unintended consequences that would stifle innovation.

First, by exposing manufacturers to liability on the basis of early-stage research that has not yet established a drug candidate's safety and efficacy, the Court of Appeal's rule would deter manufacturers from

pursuing innovations in the first place. Drug research involves constant iteration, with most efforts failing and the potential benefits of success highly uncertain until late in the process. If any improvement, no matter how small or tentative, could trigger liability for failing to develop the new drug, manufacturers will be deterred from trying to innovate at all.

Second, such a rule would force manufacturers to direct scarce resources to developing and commercializing drugs that offer only small or incremental benefits because failing to do so would invite litigation. This would necessarily divert funds away from research into other potential drugs that could yield greater advancements. Further, as each small improvement is made, it reduces the relative potential benefit from, and therefore the incentive to undertake, further improvements. Rather than promoting innovation, the Court of Appeal's decision would create incentives that favor small, incremental changes over larger, riskier leaps with the greatest potential to significantly advance patient welfare.

Third, and conversely, the Court of Appeal's decision would set an unrealistic and dangerous standard of perfection for drug development. Requiring pharmaceutical companies to market only the theoretically "safest" version of a drug would create an impossible standard, as it would force them to exhaustively test every potential alternative compound before release. This would not only drastically delay patient access to effective treatments, but it also ignores the reality that drug safety varies from person to person. Instead, companies should be permitted to market drugs that meet established safety thresholds, even if safer versions might hypothetically be developed in the future.

Fourth, the threat of liability would lead to inefficient and costly distortions in how businesses organize their research and development efforts. To minimize the risk of liability, manufacturers may avoid integrating ongoing research into existing product lines, instead keeping the

processes separate unless and until a potential new technology is developed that offers benefits so substantial as to clearly warrant the costs and liability exposure of its development in the context of an existing drug line. Such an incentive would prevent potentially beneficial innovations from being pursued and would increase the costs of drug development.

Finally, the ruling would create perverse incentives that could actually discourage drug companies from developing and introducing safer alternative drugs. If bringing a safer drug to market later could be used as evidence that the first-generation drug was not safe enough, companies may choose not to invest in developing improved versions at all in order to avoid exposing themselves to liability. This would, of course, directly undermine the goal of increasing drug safety overall.

2. The Court of Appeal's Decision Would Delay Initial Drug Releases

The Court of Appeal's ruling would create an additional, potentially deadly consequence: delaying the initial release of life-saving medications. Pharmaceutical companies often discover multiple promising formulations simultaneously during drug development. Under the Court of Appeal's new liability framework, when a company identifies multiple potential formulations, it would face strong incentives to delay releasing any formulation until all variants complete FDA trials. This is because once a company has knowledge of multiple formulations, it could face liability for releasing anything but the safest version—even if that "safest" version is years away from FDA approval.

The HIV treatment context illustrates the potentially devastating human cost of such delays. When Petitioner initially brought TDF to market, it had already identified TAF as another promising formulation. Under the Court of Appeal's ruling, Petitioner would have faced pressure to

delay releasing TDF until TAF completed FDA trials to avoid potential liability. This would have meant years of delay before any effective HIV treatment reached patients.

The empirical evidence suggests such delays would have had devastating consequences. Before TDF's introduction, HIV mortality rates were significantly higher. For example, World Health Organization data shows the U.S. HIV mortality rate standing at 5.38 per 100,000 people in 2000, the year before TDF was introduced. In 2021, that rate had fallen to 1.51 per 100,000. (*Death rate from HIV/AIDS*, Our World In Data, *available a*t https://ourworldindata.org/grapher/death-rate-from-hivaids-who?tab=table (*last visited* Nov. 4, 2024)). A 2017 report detailed the importance of the introduction to TDF in combatting AIDS, noting that it "showed superior viral load suppression and tolerability as compared to [other ART regimens]." (Tegene Legese Dadi, et al., *Efficacy and Tolerability of Tenofovir Disoproxil Fumarate Based Regimen as Compared to Zidovudine Based Regimens: A Systematic Review and Meta-Analysis*, AIDS Research and Treatment (2017), https://doi.org/10.1155/2017/5792925).

By bringing TDF to market when it did, rather than waiting for TAF's development, Petitioner provided earlier access to life-saving treatment for HIV patients. The Court of Appeal's ruling would create incentives that work against such prompt deployment of beneficial treatments. For patients suffering from life-threatening conditions, such delays could prove fatal. This Court should not adopt a rule that would incentivize pharmaceutical companies to withhold beneficial treatments while pursuing perfect ones.

3. The Court of Appeal Assumed a Very Superficial Level of Evidence Was Required for a Manufacturer to "Know" that a Drug Candidate is Superior

The Court of Appeal gave insufficient consideration to these severe policy consequences of the duty it recognized. Indeed, the Court of Appeal came very close to understanding these public policy arguments but ultimately missed them when it noted that "[b]ecause plaintiffs assert that Gilead knew TAF was safer than TDF, we also conduct the *Rowland* analysis under the assumption that the drug manufacturer *knows* that the alternative drug is safer than (and at least as effective as) the current drug." (Op. 39.) (emphasis added). One more step of analysis reveals how unworkable this superficially reasonable statement becomes. What does it mean to "know" that a drug is at least as effective and has less side effects than a current medicine that has been through rigorous testing and FDA approval and is actually a known quantity? When looking at its drug development pipeline, the most that could be said is that Petitioner *hoped* that TAF would ultimately be a more successful drug, but that given TAF's equivocal early testing results, the long approval process, and the need for much more extensive testing there was no way it could *know* such information.

The Court of Appeal merely glosses over this epistemic uncertainty and asserts there would not be net harm to the community because the duty it created "does not apply generally to "improved" products, but only to products that the manufacturer *knows* will avoid significant side effects of a manufacturer's existing product." (Op. 52) (emphasis added). Again, the Court of Appeal assumes away the fact that demonstrating what a manufacturer knows with a relatively undeveloped product in comparison to one that is ready to market is an extremely complicated question. Every

alternative drug of any promise will be able to form the basis of expensive litigation that distracts drug makers away from the task of discovering, testing, and marketing pharmaceuticals. This is why the extensive process the FDA oversees is so critical in this context. In an imperfect world of uncertainty, it gives us a pathway upon which to depend that pharmaceuticals will be net beneficial. The notion that a *jury* without *any* expert training and operating with hindsight bias could determine that a manufacturer knew (or even "should have known") that a developmental drug was safer than an existing one is absurd. Second guessing that process will only chill incentives for research and development.

Indeed, as Petitioner notes in its brief, the undisputed facts around drug development demonstrate that "knowing" a drug is safer and more effective is extraordinarily difficult to determine, particularly early on in the process. (Petitioner's Opening Brief at 60-61) (Noting the exorbitant cost of developing drugs, the high failure rate of drug candidates overall, and the high failure rate of drugs that make it to Phase III clinical trials). In short, in a legal and economic sense, to "know" something about the efficacy and safety of a drug candidate is only possible once the regulatory process is all-but-completed before the FDA—and potentially not until after FDA approval, once there have been large-scale head-to-head comparative studies. The Court of Appeal's position on Petitioner's "knowing" that TAF was safer or more effective puts drug developers in a bind. On the one hand the Court of Appeal wants the law to presume some hidden knowledge with which to create a binding obligation on drug developers. But on the other, the FDA itself treats claims about safety and efficacy of unapproved drugs as false or misleading advertisements. (21 U.S.C. §§ 331, 352; 21 C.F.R. § 202.1(e)(6)(i)-(ii), (xvi)). Petitioner is eminently reasonable in pointing to the necessity of completing Phase III and head-to-head clinical trials before we can say there is anything approaching "knowing" that a drug is superior.

And this is the very core of problem: The Court of Appeal believes that courts and attorneys can more readily second guess the expensive and uncertain drug R&D process. The Court of Appeal expects that this second-guessing will not end up with pharmaceutical firms becoming much more conservative in exactly how much they put into researching new treatments. This completely misunderstands the drug development process. In short, a manufacturer's decision when to bring a potentially safer and more effective drug to market involves complex trade-offs that courts and juries are ill-equipped to second-guess—particularly in the limited context of a products liability determination.

III.
CONCLUSION

The Court of Appeal's novel duty to develop and market any potentially less-harmful alternative to an existing non-defective product would deter innovation to the detriment of consumers. The Court of Appeal failed to adequately consider how its decision would distort incentives in a way that harms the very patients the tort system is meant to protect. This Court should reverse the Court of Appeal's decision to prevent this unprecedented expansion of tort liability from distorting manufacturers' incentives to develop new and better products

Dated: 11/4/2024

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CERTIFICATE OF WORD COUNT

This brief contains 8133 words per a computer-generated word count.

s/ Ian Adams

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PROOF OF SERVICE

I am employed in the County of Multnomah, State of Oregon. I am over the age of 18 and not a party to the within action; my business address is 2117 NE Oregon Street #501, Portland, OR 97232.

On the date set forth below, I served the foregoing document(s) described as follows: **AMICUS BRIEF IN SUPPORT OF PETITIONER, GILEAD SCIENCES, INC.**, on the interested parties in this action by placing the original/a true copy thereof enclosed in a sealed envelope(s) addressed as follows:

SEE ATTACHED SERVICE LIST

☒ BY ELECTRONIC SERVICE VIA TRUEFILING Based on a court order, I caused the above-entitled document(s) to be served through TrueFiling at https://www.truefiling.com addressed to all parties appearing on the electronic service list for the above-entitled case. The service transmission was reported as complete and a copy of the TrueFiling Filing Receipt Page/Confirmation will be filed, deposited, or maintained with the original document(s) in this office.

☒ STATE I declare under penalty of perjury that the foregoing is true and correct.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this declaration was executed November 4, 2024 at Portland, Oregon.

s/ Ian Adams
Ian Adams

SERVICE LIST

Gilead Sciences, Inc. v. The Superior Court of California, County of San Francisco (S283862)

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