S283862

CALIFORNIA SUPREME COURT

GILEAD SCIENCES, INC.,

Defendant and Petitioner

vs.

SUPERIOR COURT OF THE CITY AND COUNTY OF SAN FRANCISCO

Respondent

- -

GILEAD TENOFOVIR CASES,

Plaintiffs and Real Parties in Interest.

After a Decision by the California Court of Appeal,
First Appellate District, Division Four, Case No. A16558
San Francisco Superior Court, Case No. CJC19005043
The Hon. Andrew Y.S. Cheng, Judge Presiding

APPLICATION TO FILE AMICUS BRIEF AND AMICUS BRIEF OF AMERICAN ASSOCIATION FOR JUSTICE AND CONSUMER ATTORNEYS OF CALIFORNIA IN SUPPORT OF REAL PARTIES IN INTEREST

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Attorneys for *Amicus Curiae* American Association for Justice and Consumer Attorneys of California

CERTIFICATE OF INTERESTED PARTIES

Pursuant to California Rule of Court 8.208, each amicus certifies that:

The American Association for Justice and the Consumer Attorneys of California are non-profit organizations that have no shareholders. Each amicus and their counsel certify that each amicus and their counsel know of no other person or entity that has a financial or other interest in the outcome of the proceeding that each amicus and their counsel reasonably believe the Justices of this Court should consider in determining whether to disqualify themselves under canon 3E of the Code of Judicial Ethics.

Dated: November 4, 2024

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Attorney for American Association for Justice

Sharon J. Arkin
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APPLICATION TO SUBMIT AMICUS BRIEF IN SUPPORT OF PLAINTIFFS AND REAL PARTIES IN INTEREST

The American Association for Justice ("AAJ") and the Consumer Attorneys of California ("CAOC") hereby apply for an order permitting the filing of their attached joint amicus brief in support of plaintiffs and real parties in interest.

STATEMENT OF INTEREST OF THE AMICI

The American Association for Justice ("AAJ") is a national, voluntary bar association established in 1946 to strengthen the civil justice system, preserve the right to trial by jury, and protect access to the courts for those who have been wrongfully injured. With members in the United States, Canada, and abroad, AAJ is the world's largest plaintiff trial bar. AAJ members primarily represent plaintiffs in personal injury actions, employment rights cases, consumer cases, and other civil actions, including pharmaceutical product liability cases. For more than 78 years, AAJ has served as a leading advocate for the right of all Americans to seek legal recourse for wrongful injury.

Consumer Attorneys of California ("CAOC") is a voluntary membership organization representing approximately 6,000 associated attorneys practicing throughout California. The organization was founded in 1962. Its membership consists

primarily of attorneys who represent individuals subjected in a variety of ways to personal injury, employment discrimination, and other harmful business and governmental practices. CAOC has taken a leading role in advancing and protecting the rights of injured Californians in both the courts and the Legislature. As an organization representative of the plaintiff trial bar throughout California, CAOC has a strong interest in the significant issues related to the determination of whether a duty was owed in this case.

ISSUES TO BE ADDRESSED IN THE *AMICUS* BRIEF

Amici believe their brief can offer this Court useful insights with regard to the issues presented. The brief addresses a limited number of issues that have not been otherwise fully discussed in the parties' briefing.

Because these issues are so important to consumers throughout both California and the United States, the amici respectfully request that their attached brief be accepted for filing.

CERTIFICATION

Pursuant to California Rules of Court, Rule 8.200(c)(3)(A), no party authored the proposed amicus brief in whole or in part and no party made a monetary contribution intended to fund the preparation or submission of the brief.

Dated: November 4, 2024

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AMICUS BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE AND THE CONSUMER ATTORNEYS OF CALIFORNIA IN SUPPORT OF REAL PARTIES IN INTEREST

INTRODUCTION

"The sky is falling, the sky is falling!."[1] Or so petitioner would have this Court believe. Histrionics and angry vehemence aside, this case is not about either punishing or impairing the prescription drug industry's ability to innovate. It is about market manipulation.[2] But unlike the manipulation of financial markets, which "only" steal money from investors, the manipulation of the prescription drug market inflicts actual, physical injury, medical care costs and pain on people who are already suffering from devastating diseases.

Gilead stridently asserts that the evidence in the trial court does not support plaintiffs' claims and reversal is warranted on

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[1] Henny-Penny: The Sky is Falling, *English Fairy Tales*, retold by Flora Annie Steel (1922).

[2] "Market manipulation is a type of market abuse where there is a deliberate attempt to interfere with the free and fair operation of the market; the most blatant of cases involve creating false or misleading appearances with respect to the price of, or market for, a product, security or commodity." (See *Market Manipulation*, Wikipedia, https://en.wikipedia.org/wiki/Market_manipulation (last visited Nov. 1, 2024).)

that basis alone. (See, e.g., Reply Brief on the Merits [RBM], pp. 9-11.) Interestingly, in seeking review from this Court, Gilead nowhere argued that the appellate court should have reversed on the basis of disputed issues of fact. Thus, to make that argument in its reply brief is pointless.

That argument is also irrelevant. In its thorough and compelling analysis, the Court of Appeal addressed the fundamental issue, i.e., "[d]oes a drug manufacturer have a duty of reasonable care to users of a drug it is currently selling, which is not alleged to be defective, when making decisions about the commercialization of an allegedly safer, and at least equally effective, alternative drug?"

This Court's statement of the issue is similar: "Does a drug manufacturer have a duty of reasonable care to users of a drug it is currently selling, which is not alleged to be defective, when making decisions about the commercialization of an allegedly safer, and at least equally effective, alternative drug?"

Duty is a legal question. (*Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1142.) Disputes in the evidence are simply beside the point at this stage. Assuming a duty is found, the facts only come into play to establish whether that duty was *breached*. (*Kesner, supra*, 1 Cal.5th at p. 1144.)

That distinction highlights the fundamental flaw in Gilead's entire analysis.

For example, Gilead asserts that "[t]he upshot of Plaintiffs' argument is clear: All manufacturers *would have a duty to*

develop and sell, without delay, alternatives to existing reasonably safe products. That duty would apply to any phase of product development, and whether the manufacturer knows or, in hindsight, merely should have known the alternative product is safer. But Plaintiffs shirk any responsibility to defend the duty's full scope. They defend only a duty tailored to the specific industry and scenario they allege here. Yet they do not explain how any court could adopt their ad hoc limits going forward." (RBM, p. 7.)

That overblown proclamation includes factual predicates that may, or may not, exist and ignores the *actual* issue, i.e., whether the duty arises, as this Court expressed it, "when making decisions about the commercialization of an allegedly *safer, and at least equally effective, alternative drug*."

Thus, the *predicate* for the existence of the duty is that *the alternative drug is safer and equally effective*.

The question then becomes: If, but only if, the alternative drug is safer and equally effective, but the manufacturer *chooses* to withhold the safer drug from the market in order to maximize its profit from the original drug, should it be liable for the avoidable injuries caused by that decision?

That is precisely where California's negligence law fills the gap. When a person or entity makes a decision in its own self-interest that will foreseeably injure others, Civil Code section 1714, subdivision (a) steps in to protect the casualties of that decision.

Thus, the parameters drawn by this Court's identification of the issue are very narrow. And Gilead's extravagant rhetoric in no way changes the narrow limitations on the question of duty to be decided here.

Finally, all of Gilead's arguments are predicated on a misleading focus, i.e., that "the defect standard [is] a court *requirement*" for manufacturer liability. (RBM, p. 15.) Gilead claims that the defect standard for product liability is quite sufficient to protect product users and the proposed duty is therefore unnecessary. But the facts of this case graphically refute that assertion. Without a finding of duty in here, Gilead and others will be incentivized to seek ways to increase their profits without any consideration of the harm they may cause in the process.

Even though this case does not relate to a defective product, the proposed duty does no harm to the defect standard; rather, imposition of a duty under the parameters articulated by this Court in stating the issue only imposes a duty on a drug manufacturer to be responsible for an injury caused by its want of ordinary care in its business operations—*just like every other business*. (Civ. Code, §1714, subd. (a).)

LEGAL ARGUMENT

1.
THE NEGLIGENCE PLED BY REAL PARTIES IS GROUNDED IN STANDARD TORT PRINCIPLES THAT PETITIONER SIMPLY INGORES

The appellate court expertly sifted the wheat from the chaff in Gilead's arguments and hysterical foretelling of doom if a duty is found to exist by this Court. The appellate court also dispelled Gilead's misdirection that the negligence pled in this case must arise out of a product defect rather than Gilead's *business decisions* in knowingly withholding a safer product *in order to maximize its own profits* at the sacrifice of its customers' safety.

What Gilead ignores are the actual allegations framed by this Court's identification of the issue here. For purposes of this Court's decision, Gilead: (1) had the exclusive right to develop tenofovir-based drugs; (2) knew that tenofovir alafenamide fumarate ("TAF") would work; (3) knew that TAF was safer than its existing drug, tenofovir disoproxil fumarate ("TDF"); (4) actually made the decision to eventually develop and market TAF; but (5) deliberately chose to delay getting FDA approval for TAF until the patent on TDF expired and the resulting generic market rendered TDF far less profitable.

It is undisputed that Gilead had no competitors because it had the exclusive right to develop drugs based on the tenofovir

molecule. And as alleged, Gilead always intended to get approval for and to market TAF, but delayed doing so only to allow it to maximize its return on TDF, irrespective of the injuries it knew would be inflicted on the patients who continued to be prescribed TDF.

Those elements are essential to the analyses in this case, and none of the arguments, case law or public policy analyses proffered by Gilead address a situation even remotely similar to this one.

The focus in this case is not whether TDF was defective; it is presumed that it was not. But the plaintiffs' injuries arose because the patients were forced to use TDF, when it was more probable than not that, at the very least, TAF would have caused less severe injuries from its side effects.

California's general liability law, Civil Code section 1714, subdivision (a), applies to Gilead's alleged conduct in this case.

Gilead is subject to the very same foundational principles of negligence liability under California law that apply to every other person and entity: "Everyone is responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person." (Civ. Code, § 1714, subd. (a).)

Gilead asserts that the defect requirement in product liability law is more than sufficient to protect consumers. AAJ and CAOC categorically reject that contention—and this case is

the poster child for why that is so.

There is no dispute that TDF users suffered severe side effects from its use, including damage to their bones and kidneys. Assuming the plaintiffs' allegations that TAF would have resulted in substantially fewer and less severe side effects, *there is no way for those injuries to be addressed under the defect standard.*

Without the availability of a claim for negligence, pharmaceutical companies like Gilead have no incentive to bring to market safer versions of its drugs—particularly where, as here, doing so might cut into its profits. And especially so where *the drug company already knows that it has a safer version of the drug*.

That there is a distinction between defect claims and negligence claims is illustrated by the fact that the legislative bodies of some other states, like Utah and New Jersey, have enacted "tort reform" measures that *narrow* a product supplier's liability to defect claims.[3] Such legislation would be unnecessary if there was no negligence basis for every product claim in every context.

And despite the decades of development of California's

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[3] *E.g.*, *Brown v. Sears, Roebuck Co.* (10th Cir. 2004) 328 F.3d 1274, 1283; *see also*, *Sinclair v. Merck & Co.* (2008) 195 N.J. 51, 54, 948 A.2d 587, 588–589 ["We hold that the definition of harm under our Products Liability Act (PLA), 589 *N.J.S.A.* 2A:58C–1 to –11 . . . is the sole source of remedy for plaintiffs' defective product claim."].

product liability law in the courts, the California Legislature has not decreed that liability for harm caused by a product *is limited to defective products*.[4]

Defendants who want the blessing of a categorical exception to that principle must make their case to the Legislature, like those who sought "a broad statutory immunity against civil liability for social hosts who furnish alcoholic beverages." (*Bass v. Pratt* (1986) 177 Cal.App.3d 129, 132.) Similarly, Civil Code section 43.5, subdivision (c) provides, "No cause of action arises for . . . Seduction." (*Barbara A. v. John G.* (1983) 145 Cal.App.3d 369, 376.)

If Gilead wants immunity from the same responsibility to use due care imposed on everyone else under California law, it must go to the Legislature to achieve that aim – it cannot ask this Court to legislate that protection for it.

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[4] To the contrary, in partially overturning the Supreme Court's holding in *Aas v. Superior Court* (2000) 24 Cal.4th 629, which limited the recoverable damages for defective construction, the Legislature enacted Civil Code sections 895, et seq., providing a cause of action allowing additional damages in those cases.

2.

NO PUBLIC POLICY WARRANTS LIMITATION OF PHARMACEUTICAL COMPANIES' LIABILITY FOR INJURIES ONLY WHERE THERE IS A DEFECT

In addressing section 1714, subdivision (a), this Court has steadfastly maintained that "in the absence of [a] statutory provision declaring an exception . . . no such exception should be made unless clearly supported by public policy." (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 217, quoting *Rowland v. Christian* (1968) 69 Cal.2d 108.)

Not only has Gilead failed to establish any statutory basis for an exemption from section 1714(a) in this case, it has also failed to provide any public policy basis for immunizing it from the same negligence principles that apply to every other California business.

Instead, Gilead relies on this Court's prior decision in *Brown v. Superior Court* (1988) 44 Cal.3d 1049 to vehemently and repeatedly argue that public policy precludes imposition of liability on the pharmaceutical industry in the absence of a defect:

> This Court has emphasized that, because prescription medications "save lives and reduce pain and suffering," "[p]ublic policy favors the development and marketing of beneficial new drugs, even though [they present] some risks, perhaps serious ones." (*Brown*, *supra*, 44 Cal.3d at 1063.) The Court pointed specifically to the danger that excessive liability could make manufacturers "reluctant to undertake research

> programs to develop" new medicines or drive "the cost of medication[s] beyond the reach of those who need [them] most." (*Ibid.*) Meanwhile, the need for regulation through the tort system is diminished because prescription medicines go through an "onerous" regulatory process that ensures the safety of a drug's design and the adequacy of its warnings. (*Mutual Pharmaceutical Co. v. Bartlett* (2013) 570 U.S. 472, 476.)

(Gilead Opening Brief on the Merits (OBM), p. 30.)

In other words, Gilead claims that a pharmaceutical company—*unlike every other for-profit business organization in the state*—can be and must be immunized from liability for its *business decisions*. Instead, Gilead asserts, its liability *must* be limited only to harm from its scientific decisions in assessing and warning of potential side effects and risks of the drugs it manufactures.

But like every other for-profit industry, pharmaceutical companies can, and should, be held accountable when their *unreasonable* business decisions result in harm.

While the business of the for-profit pharmaceutical industry is important, it is not sacred.

The importance of the public policy interest in protecting against the effect of unreasonable *business* decisions by pharmaceutical companies is illustrated by the criminal and civil actions brought against opioid manufacturers. As the California Department of Justice explains:

> The opioid crisis is a public health crisis stemming from an increase in prescription opioids and the illegal

> practices of opioid manufacturers and others who misled healthcare providers and patients about the addictive nature of opioids. This flooded the market with an over-supply of opioids, helping create the crisis the country faces today. Through ongoing litigation and investigative efforts, the California Department of Justice (DOJ) seeks to hold accountable the opioid manufacturers, distributors, retail pharmacies, and consulting and other firms that advised the pharmaceutical companies, all of which are alleged to have fueled the crisis, and to bring funding and relief to affected communities nationwide.

(*Opioids Litigation*, Cal. Dep't of Just., https://oag.ca.gov/fentanyl/opioidslitigation (last visited Nov. 1, 2024).[5]

The civil and criminal liability imposed on the pharmaceutical companies that overpromoted opioids had nothing to do with scientific decisions about any defects in their opioid drugs and everything to do with the *business decisions* taken to increase their profits.

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[5] *See also* Press Release, U.S. Dep't of Just., 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://www.justice.gov/opa/pr/justice-department-announces-global-resolution-criminal-and-civil-investigations-opioid (regarding the resolution of civil and criminal cases against Purdue Pharma LP for its actions in promoting the use of prescription opioids); *Opioids Investigations, Litigation, and Settlements*, Nat'l Assoc. of Attys. Gen., https://www.naag.org/issues/opioids (last visited Nov. 1, 2024) (reporting on the settlement of actions against Johnson & Johnson stemming from actions that fueled the opioid crisis).

The opioid litigation confirms that no public policy supports immunity from accountability for a corporation granted a monopoly on the marketing of its pharmaceutical product where it deliberately manipulated the market to maximize its profit with no regard to the harm it inflicted upon its own customers in the process.

CONCLUSION

Because the circumstances here are unique to the drug industry, Gilead's overblown fear mongering not only fails to overcome California's own duty mandate it also fails to acknowledge that this constellation of facts does not regularly occur; at least it can only be hoped that they do not. And imposing negligence liability in the context of these facts can assure the public that such strategic and injurious self-interest will be discouraged—which is, after all, the fundamental purpose of California's tort system. (*J'Aire Corp. v. Gregory* (1979) 24 Cal.3d 799, 804 ["the policy of preventing future harm" is a factor in determining the existence of a duty].)

Thus, holding Gilead to a negligence duty under these particular circumstances will not result in the parade of horribles articulated by Gilead. But if, in fact, the conduct here is so pervasive that stopping it causes the drug industry to fear for its very existence, such a level of corruption is a much larger problem than ever suspected. That, in turn, further justifies

imposition of liability on drug manufacturers who engage in such misconduct.

Dated: November 4, 2024

Jeffrey R. White	*Sharon J. Arkin*
JEFFREY R. WHITE	SHARON J. ARKIN
Attorney for American Association for Justice	Attorney for Consumer Attorneys of California

CERTIFICATE OF LENGTH OF BRIEF

I, Sharon J. Arkin, declare under penalty of perjury under the laws of the State of California that the word count for this Brief, excluding Tables of Contents, Tables of Authority, Proof of Service and this Certification is 3768 words as calculated utilizing the word count feature of the Word:Mac software used to create this document.

Dated: November 4, 2024

Sharon J. Arkin
SHARON J. ARKIN

PROOF OF SERVICE

I am over the age of 18 and not a party to the within action; my business address is 1720 Winchuck River Road, Brookings, OR 97415.

On **November 4, 2024**, I served the within document described as:

APPLICATION TO FILE AMICUS BRIEF AND AMICUS BRIEF OF AMERICAN ASSOCIATION FOR JUSTICE AND CONSUMER ATTORNEYS OF CALIFORNIA IN SUPPORT OF REAL PARTIES IN INTEREST

on the interested parties in this action by placing true copies thereof enclosed in sealed envelopes addressed as set forth below by depositing the envelopes with the U.S. Postal Service on this day, with postage thereon fully prepaid, at Brookings, OR.

San Francisco Superior Court
400 McAllister Street
San Francisco, CA 94102

California Court of Appeal
First Appellate District, Div. 4
350 McAllister St.
San Francisco, CA 94102

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

Executed on November 4, 2024, at Brookings, Oregon.

Sharon J. Arkin
SHARON J. ARKIN