A165558

COURT OF APPEAL OF THE STATE OF CALIFORNIA
FIRST APPELLATE DISTRICT, DIVISION FOUR

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.

Petition after an Order Denying Summary Judgment
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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CERTIFICATE OF INTERESTED PARTIES

Pursuant to California Rule of Court 8.208, amici certify that:

The American Association for Justice and the Consumer Attorneys of California are non-profit organizations that have no shareholders. Amici and their counsel certify that amici and their counsel know of no other person or entity that has a financial or other interest in the outcome of the proceeding that the amici 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: September 28, 2022

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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 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. For more than 75 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. Consumer Attorneys 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, Consumer Attorneys has a strong interest in the significant issues related to the determination of the duty owed in this case.

ISSUES TO BE ADDRESSED IN THE *AMICUS* BRIEF

Amici believe that 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 and focuses on issues raised in the amicus letters supporting the petitioner.

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: September 28, 2022

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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 and its amici would have this Court believe. Histrionics 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 a devastating disease.

The Superior Court's decision was based on the actual evidence in this case; Petitioner and its amici, however, entirely ignore that evidence in making their arguments. But that

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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, https://en.wikipedia.org/ wiki/Market_manipulation.

evidence demonstrates that Gilead Sciences, Inc. ("Gilead") embarked on a deliberate campaign to squeeze every possible cent out of selling a drug it knew had dangerous side effects while deliberately choosing to hold back a new drug that it knew worked as well, but which had substantially fewer side effects. Contrary to Gilead's arguments to this Court, the evidence in the lower court is compelling in demonstrating that Gilead deliberately, knowingly and intentionally withheld the development of the safer drug for the very purpose of maximizing its profits from its earlier, less safe, drug.

As a matter of law, logic and public policy, this is not corporate conduct that can, or should, be condoned. The trial court's denial of summary judgment was correct and the issues should be presented to a jury.

LEGAL ARGUMENT

1.
THE NEGLIGENCE PLED BY REAL PARTIES IS NOT "FREE-FLOATING;" IT IS GROUNDED IN STANDARD TORT PRINCIPLES THAT PETITIONER AND ITS AMICI SIMPLY INGORE

Real Parties' Return expertly sifts the wheat from the chaff in Gilead's arguments and hysterical foretelling of doom if this case is permitted to go forward. The Return also dispels Gilead's claims that the negligence pled in this case arises out of ***any*** product defect, but rather arises from Gilead's business decisions – not its scientific evaluation and assessment – in knowingly withholding a safer product *in order to maximize its own profits* at the sacrifice of its customer's safety.

Gilead's amici similarly fail to distinguish strict liability law from simple negligence law. Magician-like, they attempt to divert this Court's attention from what Gilead really did, so they can argue the "error" of the trial court's decision.

What they all ignore is the evidence that 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; (5) but, 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.

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

For example, the U.S. and California Chambers of Commerce ("the Chambers") rely on *Brown v. Sears, Roebuck Co.* (10th Cir. 2004) 328 F.3d 1274, 1283. (Chambers letter, 7/7/22, p. 5.) In *Brown,* a parent sued when a riding lawnmower ran over her child while the mower was backing up with its blades still revolving. The problem with the Chambers' reliance on *Brown* is explained by the court itself: "In presenting her common-law-negligence claim, Plaintiff argues that (1) mowers capable of being operated in reverse pose a risk of severe injuries to children; (2) the lawnmower industry in general, and Sears in particular, knew of this risk; and (3) instead of taking appropriate action to reduce this risk, Sears continued to distribute mowers that did not contain [a feature that would stop the blades while in reverse]. This claim, however, amounts to no more than an argument that even if the riding mower was not defective under § 78–15–6(2), it was nevertheless negligent of Sears to market it because an alternative safer design was available. Thus, the claim is barred by *Slisze* [*v. Stanley-Bostitch* (Utah 1999) 979 P.3d 317, 320]."

The facts in *Brown* are materially different than those

here: In *Brown*, Sears did not have an *exclusive* patent to manufacture riding lawnmowers and there was no evidence that it had actually developed a lawnmower that would stop the blades when it was put in reverse, but deliberately withheld its production until its patent on the prior lawnmower expired. Rather, in the real world, had Sears developed a mower with such a safety feature, it could have promoted that improvement in order to gain a competitive advantage in the market.

But in this case, Gilead *had no competitors* because it had the exclusive right to develop drugs based on the tenofovir molecule. And as demonstrated in Gilead's own records, *Gilead always intended to get approval for and to market TAF*, but delayed doing so only so it could maximize its return on TDF, irrespective of the injuries it ***knew*** would be inflicted on the patients who continued to be prescribed TDF.

Even the *Brown* court recognized the potential validity of the plaintiff's claim in that case, but was precluded from allowing it to go forward by the state's product liability statute. (*Brown*, *supra*, at 183 ["*Plaintiff's arguments might well be persuasive under a different test for determining whether a product is defectively designed*, see Restatement Third § 2 cmt. f; *but our task here* ***is to follow Utah law, and we are bound by § 78–15–6(2)***."].)

California, of course, has no similar statute limiting such product liability claims. The fact that Utah statutory law made it impossible to obtain damages for that defective product means

Brown has no application here. Rather, California's general liability law, Civil Code section 1714(a), applies to Gilead's conduct.

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 the causes of action set out in their respective statutes.[3] Despite the decades of development of California's 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]

And 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.

Rather, Gilead is subject to the very same foundational principle of negligence liability under California law that applies 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

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3 E.g., *Brown v. Sears, supra*. 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."].

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.

in the management of his or her property or person." (Civ. Code, § 1714(a).) 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.) Similarly, Civil Code section 43.5(c) provides, "No cause of action arises for . . . Seduction." (*Barbara A. v. John G.* (1983) 145 Cal.App.3d 369, 376.)

As our Supreme Court has steadfastly maintained, "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.)

Surely, no public policy can support any immunity from accountability for a corporation that was granted a monopoly on the marketing of its pharmaceutical product and proceeded to manipulate the market to maximize its profit with no regard to the harm it inflicted upon its own customers.

Thus, not only have Gilead and its amici failed to establish any statutory basis for an exemption from section 1714 in this case, but the other cases cited by the Chambers similarly fail to reflect California law and involve factual situations unlike the one here. (Chambers letter, *supra*, at p. 5.)

For example, *Betts v. Tow-Motor Forklift Co.* (5th Cir. 1992) 978 F.2d 1386 does not even address the question of whether a

safer product was available and should have been produced; instead it deals only with whether a forklift manufacturer could be held liable when a forklift backed up and hit the plaintiff, concluding that the "open and obvious" defense precluded liability.

Veliz v. Rental Service Corp. USA, Inc. (M.D. Fla. 2003) 313 F.Supp.2d 1317, also involved a forklift injury, but, again, the case never discussed the availability of a safer alternative and predicated its determination on misuse – a standard product liability defense.

Smith v. 2328 Univ. Ave. Corp. (N.Y. App. Div. 2008) 52 A.D.3d 216 similarly has no relevance to the issues here. That case involved a lead paint manufacturer's liability. The court's determination was based on its finding that the product was not defective or inherently dangerous and because "[a]ny problems with lead-based paint arise only after years of inadequate maintenance of the premises by the owner. Under these circumstances, a manufacturer of a product may not, as a matter of law, be found liable for harm inflicted some 50 or more years after its creation, especially in light of the duty of the landlord to abate any existing lead conditions in apartments inhabited by young children." (*Id.*, at 217-218.)

Not only does *Smith* not involve a fact pattern even remotely similar to the one here, its analysis directly conflicts with California's own strict liability cases providing that long-ago exposures to toxins do not relieve a manufacturer of liability for

the resulting injuries. (See, e.g., *Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1141, 1152 [even involving asbestos exposures occurring in the 1970s, "shielding tortfeasors from the full magnitude of their liability for past wrongs is not a proper consideration in determining the existence of a duty."].)

Neither Gilead nor its amici provide any legal analysis supporting their argument that a negligence duty cannot or should not be imposed under the facts of this case and in the face of the general negligence duty under section 1714(a).

2.

THE "JUSTIFICATIONS" FOR DELIBERATELY WITHHOLDING A SAFER DRUG FROM THE MARKET IN ORDER TO MAXIMIZE PROFITS ON A LESS SAFE DRUG ARE MERITLESS

Gilead and its amici assert several "justifications" for Gilead's decision to withhold TAF from the market and cry disaster if those decisions are not protected. The drug industries' lobbying group, PhRMA, for example, asserts: "PhRMA's members must daily make strategic and scientific decisions on where to devote research resources and how best to pursue regulatory approval of their important products in the face of scientific uncertainty." (PhARMA amicus letter, 7/7/22, p. 2.) But Gilead's own records confirm that there was no scientific uncertainty about TAF at all: Gilead knew it was at least as

effective as TDF, but safer. Yet Gilead deliberately chose to delay marketing the safer product only so that it could maximize its profits from the sale of its more injurious product before its patent expired. That was not a decision made "in the face of scientific uncertainty." It was a decision made to manipulate the market and maximize its profits, despite Gilead's absolute recognition that doing so would cause injuries to TDF users.

The Chambers also assert that "when it comes to product design, and particularly pharmaceuticals' design, manufacturers must frequently balance and trade-off safety with efficacy, costs, and feasibility. The flexibility to make these choices is essential to ensuring the availability and development of innovative and existing treatments." (Chambers' amicus letter, 7/7/22, p. 4.) Like PhRMA's analysis, however, that contention has nothing to do with this case. This is not a case where there was any balance either needed or made between efficacy, costs and feasibility. Gilead's own documents demonstrate that it knew TAF was superior in every respect and it withheld development for no reason other than to maximize its own profits, not to protect its customers or save them money.

CONCLUSION

Because the circumstances here are unique to the drug industry, the overblown fear mongering of Gilead and its amici not only fails to overcome California's own duty analysis but fails

to acknowledge that this constellation of facts does not regularly occur – or, at least it can only be hoped that they do not. And imposing negligence liability in the context of these facts can assure 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 and its amici. 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: September 28, 2022

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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 3244 words as calculated utilizing the word count feature of the Word:Mac software used to create this document.

Dated: September 28, 2022

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 **September 28, 2022**, 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

Supreme Court of California (vial electronic submission)

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

Executed on September 28, 2022 at Brookings, Oregon.

Sharon J. Arkin
SHARON J. ARKIN