

**IN THE SUPREME COURT OF
CALIFORNIA**

GILEAD TENOFOVIR CASES	)	
	)	
GILEAD SCIENCES, INC.	)	
	)	S283862
Petitioner,	)	
	)	
v.	)	Ct.App. No. A165558
	)	
SUPERIOR COURT OF THE COUNTY	)	S.F. Super. Ct.
OF SAN FRANCISCO,	)	No. CJC-19-005043
	)	
Respondent.	)	
	)	
PLAINTIFFS IN JCCP No. 5043	)	
	)	
Real Parties in Interest.	)	
	)	

**APPLICATION FOR PERMISSION TO FILE
AMICUS BRIEF and BRIEF OF THE CIVIL
JUSTICE ASSOCIATION OF CALIFORNIA,
THE CALIFORNIA MANUFACTURERS &
TECHNOLOGY ASSOCIATION, THE CALIFORNIA
BUSINESS ROUNDTABLE, THE BAY AREA
COUNCIL, and BIOCOM CALIFORNIA
AS AMICI CURIAE SUPPORTING PETITIONER
GILEAD SCIENCES, INC.**

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APPLICATION FOR PERMISSION TO FILE AMICUS BRIEF

The Civil Justice Association of California (CJAC), the California Manufacturers & Technology Association (CMTA), the California Business Roundtable (CBR), the Bay Area Council (BAC), and Biocom California (“Biocom”) apply for permission to file an amicus brief pursuant to California Rules of Court, rule 8.520 (f), supporting Petitioner Gilead Sciences, Inc..

CJAC is a nonprofit organization whose members are businesses from a broad cross section of industries. CJAC’s principal purpose is to educate the public and its governing bodies about how to make laws determining who gets paid, how much, and by whom when the conduct of some causes harm to others—more fair, certain, and economical. Toward this end, CJAC regularly appears as *amicus curiae* in numerous cases of interest to its members.

CMTA works to improve and enhance a strong business climate for California’s 30,000 manufacturing, processing, and technology-based companies. Since 1918, CMTA has worked with the state government to develop balanced laws, effective regulations, and sound public policies to stimulate economic growth and create new jobs while safeguarding the state’s environmental resources. CMTA represents 400 businesses from the entire manufacturing community—an economic sector that generates more than \$300 billion every year and employs more than 1.3 million Californians.

CBR is a California non-profit trade association focused on California's economy and the creation of jobs. Its members are companies, including major employers across the state, with a shared focus on improving economic conditions in the state and in each individual community in which they operate.

BAC has been at the intersection of business and civic leadership, shaping the future of the Bay Area since 1945. Today, its vision is to make the Bay Area the best place to live and work. More than 330 of the largest employers in the region are members of BAC and are committed to working with public and community leaders to keep the Bay Area the most innovative, globally competitive, inclusive, and sustainable region in the world.

Biocom is the advocate for California's life science sector. With more than 1,800 members, including biotechnology, pharmaceutical, medical device, genomics, and diagnostics companies, as well as research universities and institutes, Biocom drives policy initiatives to positively influence the state's life science community. Biocom works to drive public policy, build an enviable network of industry leaders, create access to capital, introduce cutting-edge workforce development and STEM education programs, and create robust value-driven purchasing programs. Biocom California harnesses the collective power and experience of the most innovative and productive life science clusters in the world, with powerful advocacy and transformative programs to help companies in their quest to improve the human condition.

Because the members of all five organizations have business operations in California, they share an interest in the predictability of California tort law. They are concerned that new judge-developed theories based on the presumption of duty that the Court of Appeal derived from Civil Code section 1714 may expose them to unanticipated liability. Accordingly, they urge this Court to keep in mind the principle that “certainty, predictability and stability in the law are the major objectives of the legal system; i.e., that parties should be able to regulate their conduct and enter into relationships with reasonable assurance of the governing rules of law.” (*Moradi-Shalal v. Fireman’s Fund Ins. Companies* (1988) 46 Cal.3d 287, 296, quoting 9 Witkin, Cal. Procedure (3d ed. 1985) Appeal, § 758.)

This amicus brief will assist the Court by providing a broader perspective on the issue before the Court than that provided by the single manufacturer who is a party to the proceeding.

No party to this appeal nor any counsel for a party authored the proposed amicus brief in whole or in part, or made a monetary contribution intended to fund the preparation or submission of the brief.

No person or entity made a monetary contribution intended to fund the preparation or submission of the brief, other than the organizations and their members.

AMICUS CURIAE BRIEF

1. Statement of the Case

This Court granted review to address whether a drug manufacturer has 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?

Although the question focuses on drug manufacturers, the reasoning of the Court of Appeal opinion under review has broader implications that this Court should have in mind in arriving at its decision. By opining that Civil Code section 1714 establishes a presumption of duty that can only be overcome by application of the factors this Court identified in *Rowland v. Christian* (1968) 69 Cal.2d 108, the Court of Appeal overstated the reach of section 1714. Adopting that view would threaten the viability of well-established limitations on the duty of care. The Court should make clear that section 1714 is not a basis for overturning a century's worth of product liability law and should not be used as a basis for overturning other well-settled limitations on tort duty.

2. Argument

A. *The Court should reject the Court of Appeal's notion that a defendant is presumed to be subject to liability for negligence.*

The Court of Appeal began its legal analysis with a reference to the "general rule" that "people owe a duty of care to avoid causing harm to others and that they are thus usually

liable for injuries their negligence inflicts.” (*Gilead Tenofovir Cases* (2024) 98 Cal.App.5th 911, 920.) That rule is drawn from Civil Code section 1714, subdivision (a) which provides: “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, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself.”

Although section 1714 on its face sweeps broadly and has been cited in opinions by this Court to support equally sweeping language, the Court has also made clear that the provision was not intended to repeal the common law of negligence. Quite to the contrary, the Court has consistently ruled that section 1714 “is to be construed as a continuation [of the common law], not as a new enactment.” (*Buckley v. Chadwick* (1955) 45 Cal.2d 183, 192-193.)¹ When it enacted section 1714, the Legislature intended “to announce and formulate existing common law principles and definitions for purposes of orderly and concise presentation and with a distinct view toward continuing judicial evolution.” (*Li v.*

¹ Citing to Civil Code section 5, which provides: “The provisions of this code, so far as they are substantially the same as existing statutes or the common law, must be construed as continuations thereof, and not as new enactments.”

Yellow Cab Co. (1975) 13 Cal.3d 804, 814.)² Unless language elsewhere in the Civil Code “clearly and unequivocally discloses an intention to depart from, alter, or abrogate the common-law rule,” section 1714 should be “construed in light of common-law decisions on the same subject.” (13 Cal.3d at p. 815, quoting *Estate of Elizalde* (1920) 182 Cal. 427, 433.)

More recently, the Court has cautioned that “[s]ection 1714 states a broad rule, but it has limits.” It imposes a general duty of care “only when it is the defendant who has ‘created a risk’ of harm to the plaintiff.” (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 214.) If the defendant has not created a risk of harm, “the default duty rule of Civil Code section 1714 did not apply.” (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1017.)

Consistent with those principles, when a party seeks to impose liability for conduct that has historically been subject to a categorical no-duty rule, this Court has not started with the assumption that the duty exists and then determined whether an exception is warranted under *Rowland*—as the Court of Appeal did here. Rather the burden is on the plaintiff to explain why an expansion of liability is justified. For example:

² See also (*Sheen v. Wells Fargo Bank, N.A.* (2022) 12 Cal.5th 905, 920 (despite the broad language of section 1714, “liability in negligence for purely economic losses ... is ‘the exception, not the rule,’ under our precedents”); *Mahoney v. Corralejo* (1974) 36 Cal.App.3d 966, 972 (Section 1714 “simply codifies the common law dichotomy of intentional torts and negligence”).

In *Biakanja v. Irving* (1958) 49 Cal.2d 647, the question was whether a notary public could be held liable to a decedent's sister for negligently failing to have the decedent's will properly attested. In deciding whether the notary owed a duty of care to the sister, the Court began by recognizing that earlier decisions had not recognized such a duty, where, as in that case, the plaintiff was not in privity with the defendant. (49 Cal.2d at pp. 648-649.) It did not presume that there was a duty. Rather, determining whether the notary owed a duty in the first instance was "a matter of policy." (49 Cal.2d at p. 650.) It was only because the "end and aim" of the notary's work for the decedent was to provide for the passing of his estate to his sister, that the notary owed a duty of care. (49 Cal.2d at pp. 650-651.)

In *Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370, the question was whether an accounting firm owed a duty of care to investors in the company that had retained the firm to perform audits. Although the opinion mentioned section 1714, the Court did not start with the presumption that there was a duty.³ Rather, it began from the principle that there is no legal duty for purely economic losses in the absence of privity of contract. (*Id.*, at p. 397.) It then articulated the need to "make pragmatic assessments of the consequences of recognizing and enforcing particular legal duties, including consideration of

³ Notably, the dissenting opinion invoked section 1714 as establishing a general rule of liability that could only be avoided by resort to the *Rowland* factors. (3 Cal.4th at p. 419.) The Court's opinion rejected that approach.

“vast if not limitless liability,” concern of large numbers of expensive and complex lawsuits of questionable merit,” and “the dubious benefits of a broad rule of liability.” (*Id.*, at p. 406.) It concluded that auditors did *not* owe a general duty of care to persons other than their clients but could be held liable to those who relied on negligent misrepresentations in an audit report connected with a transaction that the auditor “intended to influence.” (3 Cal.4th at p. 376.) The Court did not rely on the *Rowland* factors in arriving at that conclusion. Indeed, the majority necessarily rejected the view of the dissenting opinion, which would have started from the premise that liability exists under section 1714 and then evaluated whether an exception was warranted under *Rowland*. (*Id.* at p. 419, dissenting opinion.)

Similarly, in the *Southern California Gas Leak Cases* (2019) 7 Cal.5th 391, business owners who lost income because of a gas leak asked the Court to recognize a duty of care on the part of the gas company. The Court rejected the argument that section 1714 creates “a presumptive duty of care to guard against any conceivable harm that a negligent act might cause.” (7 Cal.5th at p. 399.) It reiterated the common law principle that “liability in negligence for purely economic losses . . . is ‘the exception, not the rule,’ under our precedents.” (7 Cal.5th at p. 400.) Then, after a dense and thorough policy analysis of the consequences of accepting the duty of care the plaintiffs proposed, the Court declined to expand liability beyond the parameters set by that principle. “That prevailing

rule of no recovery is, like society itself, imperfect. Yet nearly everyone follows a rule that few (if any) entirely like. California does, too.” (7 Cal.5th at p. 414.) The Court did not engage in a *Rowland* to assess whether an exception from duty would be warranted, despite acknowledging that the *Rowland* factors may well enter into any analysis of duty that ultimately turns on the “‘sum total’ of the policy considerations at play.”

In *Thing v. La Chusa* (1989) 48 Cal.3d 644, a mother who did not witness an accident in which an automobile struck and injured her child asked the Court to allow her to recover damages from the negligent driver for the emotional distress she suffered when she arrived at the accident scene. The Court began with the principle that the common law “right to recover for emotional distress” had been “limited” to a few distinct circumstances, and ultimately declined to expand the duty of care any further. (48 Cal.3d at p. 651.), The Court noted “the importance of avoiding the limitless exposure to liability that the pure foreseeability test of ‘duty’ would create,” (48 Cal.3d at p. 656) and concluded that “the right to recover for negligently caused emotional distress must be limited.” (48 Cal.3d at p. 664.)

“Experience has shown that, contrary to the expectation of the *Dillon* majority, and with apology to Bernard Witkin, there are clear judicial days on which a court can foresee forever and thus determine liability but none on which that foresight alone provides a socially and judicially acceptable limit on recovery of damages for that injury.” (48 Cal.3d at p.

668.) Therefore, “[a] ‘bright line in this area of the law is essential.” (48 Cal.3d at p. 664.) The Court held that damages for negligent infliction of emotional distress required (1) injury to closely related victim, (2) the plaintiff is present at and witnesses the accident, and (3) the plaintiff suffers serious emotional distress as a result. (48 Cal.3d at pp. 667-668.) And again, the Court delined to start from section 1714—an approach urged by the dissenting opinion. (48 Cal.3d at pp. 688-689.)

In *Brown, supra*, the Court rejected an argument by the plaintiffs (victims of sexual abuse by their taekwondo coach) that the United States Olympic Committee (USOC) owed them a duty of care. The Court began by noting that “[d]uty is not universal; not every defendant owes every plaintiff a duty of care. A duty exists only if ‘the plaintiff’s interests are entitled to legal protection against the defendant’s conduct.” (*Brown, supra*, 11 Cal.5th at p. 213, quoting *Dillon, supra*, 68 Cal.2d at p. 734.)

The Court began from the premise that the common law recognized a categorical no-duty rule where the defendant “neither performed an act that increases the risk of injury to the plaintiff nor sits in a relation to the parties that creates an affirmative duty to protect the plaintiff from harm.” (11 Cal.5th at p. 216.) This rule, the Court explained, “derives from the common law’s distinction between misfeasance and nonfeasance.” (11 Cal.5th at p.214.) The Court did *not* suggest that section 1714 had somehow overridden this longstanding

common law limitation on tort liability. It rejected the plaintiffs’ arguments for expanding that duty and further—explaining that the balance struck by the common law was appropriate. “The requirement of an affirmative duty to protect itself embodies a policy judgment of considerable standing: A defendant cannot be held liable in negligence for harms it did not cause unless there are special circumstances—such as a special relationship to the parties—that give the defendant a special obligation to offer protection or assistance.” (11 Cal.5th at p. 220.)

Because the plaintiffs had not alleged facts showing that they had a special relationship with the USOC, their negligence claim against that defendant lacked merit. The *Rowland* factors did not have any bearing on that determination. The plaintiffs had alleged sufficient facts to establish a special relationship with USA Taekwondo (taekwondo’s governing body), which then triggered an analysis of the *Rowland* factors, to determine whether policy considerations required limiting the duty that arose from the special relationship. (11 Cal.5th at p. 222.)

In this case, the plaintiffs are asking the Court to override the longstanding no-duty rule for injury arising from non-defective products and expand manufacturers’ duty of care impose a new duty of care on manufacturers. The Court should not approach this case with the presumption that such a duty exists and determine whether an exception is warranted under *Rowland*. Instead, it should engage in the type of searching

analysis that it performed in the *Biakanja*, *Bily*, *Southern California Gas Leak*, *Thing*, and *Brown* cases, and conclude, for all the reasons stated in the petitioner's briefs that there is no such duty.

B. The Court should reject the Court of Appeal's misapplication of the Rowland factors.

Even if there were a basis for imposing liability on manufacturers for not developing and marketing a better alternative to a safe product that is already on the market, application of the *Rowland* factors should convince this Court not to allow recovery on such a theory in this case.

Foreseeability of harm to the plaintiff.

Although it purported to agree with Gilead that the relevant question was whether it was foreseeable that users of the existing drug could avoid the accompanying side effects by switching to the drug under development, the Court of Appeal failed to meaningfully grapple with that question. It was enough that some users of the existing drug suffered side effects and that the new drug had exhibited a lower risk of side effects in the limited testing done when Gilead engaged in the conduct that plaintiffs based their lawsuit on.

The Court of Appeal did not consider *how* foreseeable the claimed injury was. It should have done so, because, as this Court has observed, "a court can foresee forever." (*Thing*, *supra*, 48 Cal.3d at p. 668.) In this case, too many factors stood between Gilead's conduct and the plaintiffs' injury to conclude that injury was *reasonably* foreseeable. Among other factors, Gilead would have to obtain FDA approval. It would need to

have the resources available to produce the drug in quantity. Then, the plaintiffs would have had to determine in consultation with their doctors whether they should switch to the new drug.

Degree of certainty that the plaintiff suffered injury.

Rather than address the facts presented by the record, the Court of Appeal dismissed this factor on the basis that the existing drug caused side effects in some patients. But the plaintiffs did not sue Gilead for selling the existing drug. They sued because Gilead did not make it possible for them to buy the new drug as soon as they would have liked to do so. Therefore, the Court of Appeal should have considered how certain it was that users of the current drug could avoid the side effects they have been experiencing by switching to the new drug at some point in the future. That was far from certain.

Closeness of the connection between the defendant's conduct and the injury suffered.

Here again, the Court of Appeal dismissed Gilead's arguments with only a cursory discussion. It fell back on its assumption that some patients could avoid the side effects of the current drug by switching to the new drug. It dismissed the impact of the need for FDA approval, while acknowledging that "there is often considerable uncertainty associated with it." (98 Cal.App.5th at p. 939.) It declined to even consider the fact that the patient's doctor would have to prescribe the new medication, stating in conclusory fashion that the

manufacturer would just have to expect that all doctors would do so.

Moral blame attached to the defendant's conduct.

Fixating on the plaintiffs' allegation that Gilead delayed bringing the new drug to market for financial reasons, the Court of Appeal concluded that moral blame attached to its conduct. (98 Cal.App.5th at p. 941.) But at the same time, it said that its new theory of liability did *not* depend upon the precise conduct that Gilead was alleged to have engaged in. Ignoring the enormous benefits that Gilead's existing drug had provided for ADIS patients, the Court came to the unsupported conclusion that "negligence in a decision that deprives people of a safer drug and leaves them reliant on a more dangerous drug is morally blameworthy." (98 Cal.App.5th at p. 942.

Policy of preventing future harm.

Here, the Court of Appeal should have examined "the positive *and* the negative societal consequences of recognizing a tort duty." (*Kuciemba, supra*, 11 Cal.5th at p. 1026 (emphasis supplied).) But it rejected Gilead's explanation of the societal costs that would accompany imposition of a duty out of hand, falling back on its assumption that a pharmaceutical company would only delay development of a new drug so that it could continue to profit from a drug it was already marketing. Among the many flaws in its analysis, the Court of Appeal relied on the plaintiffs' contention that the patent system had deleterious effects on innovation and competition. (98 Cal.App.5th at p. 943.) That is contrary to the settled view that "the patent system represents a carefully crafted bargain that

encourages both the creation and the public disclosure of new and useful advances in technology, in return for an exclusive monopoly for a limited period of time.” (*Pfaff v. Wells Elecs* (1998) 525 U.S. 55, 63.)

Extent of the burden to the defendant and consequences to the community

In evaluating this factor, the Court of Appeal rejected out of hand the idea that its new rule of liability might generate a flood of lawsuits. Although it thought that Gilead had “overstated” the threat, the duty that the Court of Appeal recognized would extend to any manufacturer that has new products under development and would be owed to anyone who had bought its existing non-defective products. As the Court of Appeal acknowledged, that is “a potentially large class of persons.” (98 Cal.App.5th at p. 945.) The “potential litigation explosion” that would result should have been a reason *not* to impose such a broad duty. (*Kuciemba, supra*, 14 Cal.5th at p. 1030.)

The Court of Appeal should also have considered the cost of compliance with statutory provisions and related regulations that its new duty would have required, as this Court has recognized. (See *Verdugo v. Target Corp.* (2014) 59 Cal.4th 312, 340.) According to the Court of Appeal, once a drug manufacturer has begun developing a new drug that is safer than an existing one, it has a duty to users of the original product to bring the new drug to market as soon as reasonably possible. The costs of doing so in a heavily regulated environment should have been considered.

When it comes to weighing the burdens and consequences of imposing a duty, the Court has recognized that the Legislature is “better positioned to act” in an “extensively regulated area” like the one that drug manufacturers operate in. In such circumstances, balancing the “social costs and benefits . . . is best performed by the Legislature.” (*Sheen v. Wells Fargo Bank, N.A.* (2022) 12 Cal.5th 905, 916.) That weighs in favor of establishing a new tort duty in this area by way of judicial decision.

Availability, cost, and prevalence of insurance.

The Court of Appeal declined to even address this factor, purportedly because the parties had not provided the necessary information. But this Court’s decision in *Brown v. Superior Court* (1988) 44 Cal.3d 1049 contained ample information about the difficulties of obtaining insurance. There, the Court declined to impose strict liability for defective design on drug manufacturers. In arriving at that conclusion, it acknowledged that “[t]he possibility that the cost of insurance and of defending against lawsuits will diminish the availability and increase the price of pharmaceuticals is far from theoretical.” (44 Cal.3d at p. 1064.) In addition, “the additional expense of insuring against such liability—assuming insurance would be available—and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most.” (44 Cal.3d at p. 1063.)

3. Conclusion

Although the Court of Appeal presumed that manufacturers owe a duty to purchasers of their existing products to bring better products to market without delay based on Civil Code section 1714, that provision was never intended to provide a basis for creating new negligence liability theories. This Court's precedent makes clear that the proponent of a new theory of liability must provide a strong policy basis to support it. The plaintiffs in this case have not done so. Adoption of the rule that they advocate would inhibit innovation and interfere with efforts to develop safer products. The Court should reject that rule.

/s Calvin House

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CERTIFICATE OF WORD COUNT

Counsel of Record hereby certifies that pursuant to Rule 8.520 (c)(1) of the California Rules of Court, the enclosed APPLICATION FOR PERMISSION TO FILE AMICUS BRIEF and BRIEF OF THE CIVIL JUSTICE ASSOCIATION OF CALIFORNIA, THE CALIFORNIA MANUFACTURERS & TECHNOLOGY ASSOCIATION, THE CALIFORNIA BUSINESS ROUNDTABLE, THE BAY AREA COUNCIL, and BIOCOM CALIFORNIA AS AMICI CURIAE SUPPORTING PETITIONER GILEAD SCIENCES, INC is produced using 13-point Roman type including footnotes and contains approximately 4,800 words, which is less than the total words permitted by the Rules of Court. Counsel relies on the word count of the computer program used to prepare this brief.

/s Calvin House

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