No. S283862
In the Supreme Court of California

GILEAD TENOFOVIR CASES

GILEAD SCIENCES, INC.,
Defendant and Petitioner,

vs.

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

APPLICATION FOR LEAVE TO FILE *AMICI CURIAE* BRIEF IN SUPPORT OF PETITIONER; *AMICI CURIAE* BRIEF OF DRI - CENTER FOR LAW AND PUBLIC POLICY, THE ASSOCIATION OF DEFENSE COUNSEL OF NORTHERN CALIFORNIA AND NEVADA, AND THE ASSOCIATION OF SOUTHERN CALIFORNIA DEFENSE COUNSEL

Review of Decision from Court of Appeal,
First Appellate District, Division Four, No. A165558

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AMICI CURIAE

DRI—Center for Law and Public Policy is the policy arm of a more than 12,000-member international association of defense lawyers who represent individuals, corporations, and local governments involved in civil litigation. DRI and its Center for Law and Public Policy also work with affiliated state and local defense organizations in every state and in Canada. DRI has long advocated for procedural reforms that: (1) promote fairness in the civil judicial system, (2) reduce the costs and burdens associated with litigation, and (3) advance predictability and efficiency in litigation.

The Association of Defense Counsel of Northern California and Nevada numbers approximately 700 attorneys primarily engaged in the defense of civil actions. Members represent civil defendants of all stripes, including businesses, individuals, and public entities. ADC-NCN has appeared as *amicus curiae* in many cases before both this Court and Courts of Appeal across the state to express the interests of members and their clients, a broad cross-section of California businesses and organizations.

The Association of Southern California Defense Counsel is comprised of over 1,100 leading civil defense bar attorneys in Southern California. It is active in assisting courts on issues of interest to its members. ASCDC has appeared numerous times as *amicus curiae* in this Court and the Court of Appeal.

INTEREST OF *AMICI CURIAE*

Amici have a strong and abiding interest in the outcome of this case as it affects the parties they typically represent. They are comprised of thousands of attorneys and legal professionals dedicated to the defense of civil actions across various sectors, including product liability. Their members rely on predictability in legal standards of care to best advocate for their clients and advise them in making business decisions concerning the products they develop, manufacture, and sell. The inevitable expansion of tort liability engendered by the decision below poses a significant risk to predictability in civil litigation involving product manufacturers and will confound decision-making concerning product development, manufacturing, and sale.

In particular, the Court of Appeal's unprecedented expansion of liability, if endorsed by this Court, would burden product development—particularly pharmaceutical product development—and ultimately limit the medications that manufacturers would be willing or able to develop and sell—a result that runs directly counter to Plaintiffs-Respondents' purported objective of increasing the availability of life-saving or life-enhancing pharmaceuticals. The risks imposed likewise would be costly to insure, if insurance would be available at all. These increased costs will, in turn, affect the availability of products for those who need pharmaceuticals the most, but are often unable to afford them.

CONCLUSION

Amici request that the Court accept the accompanying brief for filing in this case.

Dated: November 4, 2024

Respectfully submitted,

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By: 

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AMICI CURIAE BRIEF

I.
INTRODUCTION

The Court of Appeal has created a duty of care under which a manufacturer can be liable in tort for making and selling a safe and efficacious *non-defective* product because it then failed to develop a *different, allegedly safer product* and bring it to market more quickly. There are, however, several compelling policy considerations that should prompt this Court to reject the revolutionary affirmative duty the Court of Appeal first created, and then imposed.

Start with the fact that the benefits of the product the plaintiff-consumer actually purchased outweighed its risks, that the product was properly manufactured, and that it was accompanied by adequate warnings at the time of sale, thereby meeting the governing legal standard California law provides. Adding a purported "duty to innovate" a new and allegedly better product after the time of sale is a startling development when the product *actually marketed* to consumers is non-defective under settled law. Yet, the Court of Appeal was undeterred.

Consider further that no California court—or indeed any court of which *Amici* are aware—has created an affirmative duty to test, update, and make available a "better" product than previously sold on penalty of tort liability if there is undue delay or a decision not to sell the product at all. Nor has any California court—or any court of which *Amici* are aware—inserted tort

duties of care into corporate decision-making on whether and when to develop and market a new product to supplement a non-defective one, whether in the pharmaceutical context or any other. *Amici* submit that California, for a host of sound policy reasons, should not be the first.

On close analysis, moreover, the kind of affirmative conduct mandated by the Court of Appeal is not typically part of the basic duty—embedded in California Civil Code Section 1714—to exercise reasonable care. As this Court has said many times, tort duties are not sacrosanct, but are "only an expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection." *Dillon v. Legg*, 68 Cal. 2d 728, 734 (1968). The sum total of those policy considerations in the context of this case should lead this Court to conclude that Gilead Sciences, Inc.—and any other manufacturer targeted by plaintiffs who wish to attack the timing of product development and innovation decisions—should not be saddled with the affirmative duty the Court of Appeal has mandated. The reasons are manifest and clear.

First, the imposition of liability for failing to innovate is unprecedented and contrary to established California law. Whether brought under negligence or strict liability, any product liability claim—which this action clearly is—has always required proof that there was something wrong with the product that the plaintiff used. This core principle is deeply rooted in the law, and it reflects a proper consideration of policy factors relevant to pharmaceuticals specifically and products generally. That is to

say, the current state of California law correctly balances the social interest in having useful and beneficial products available to consumers against the interest in providing adequate remedies to those injured by products that were not reasonably safe.

Second, the duty created by the Court of Appeal is unworkable. The product development process involves a wide array of considerations, from judgment calls about whether a prospective innovation holds sufficient promise, to how to structure tests and how many to run, to cost-benefit analyses of pursuing innovation versus enhancing the marketing of existing products. Yet product manufacturers must make product development decisions in the context of finite financial resources, realistic timeframes, and over-arching regulatory standards. The Court of Appeal's opinion makes every one of those decisions a source of potential liability, to be scrutinized in hindsight and judged by juries guided only by vague notions of "reasonableness."

Third, the Court of Appeal's new duty is indeterminate, unpredictable, and uncertain in scope. The Court of Appeal purported to limit its duty to instances where a manufacturer has "invented what it knows is a safer, and at least equally effective, alternative." But when has a product been "invented"? When it was conceived? During testing, and if so, what phase of testing? When it becomes commercially viable? Or sometime in between?

And when does the manufacturer actually know that the alternative is safer, or at least equally effective, and will courts allow constructive knowledge to trigger this duty? What if the

evidence of safety and efficacy is ambiguous, which it almost always is at early stages of development? Or, what if the product could have been developed but was not because available resources were expended elsewhere? And what will keep this duty and its many variables from extending outside the pharmaceutical industry? The Court of Appeal purported to cabin this duty by building multiple assumptions and caveats into it, but its declaration of the duty itself reveals that it will accomplish exactly the opposite. Future interpretation of the duty to innovate, develop, market, and sell on whatever timeline a jury deems reasonable will open the door to the expansion of liability, not its containment.

Here, when considered in context—as it must be—the affirmative, post-sale duty of care created and imposed by the Court of Appeal is unworkable in practice and its consequences are unpredictable in application. This is not a circumstance where tort liability should be expanded, but rather when its reach should be limited, just as existing duty principles provide. This Court should reverse the Court of Appeal and so hold.

II.

ARGUMENT

A. The Court Of Appeal's Duty Ignores The Contextual Considerations That Limit Whether A Novel Duty Of Care Should Be Created And Imposed

As noted, duties of care are created in California when the "sum total" of relevant policy considerations establishes that a

specific duty of care should exist. *Dillon*, 68 Cal. 2d at 734. Those policy considerations are aimed at determining whether "the plaintiff's interests are entitled to legal protection against the defendant's conduct." *Kucimeba v. Victory Woodworks, Inc.*, 14 Cal. 5th 993, 1016 (2023) (citing *Dillon*, 68 Cal. 2d at 734). And, in making that determination, California case law makes one thing abundantly clear: Whether a duty of care will be recognized in a particular instance depends on context.

In *Kuciemba*, 14 Cal. 5th at 1031, for example, this Court held that an employer did not owe a duty of care to prevent the spread of COVID-19 to its employees' household members, even though it was "foreseeable that employees infected at work will carry the virus home and infect their loved ones." This Court observed that the imposition of any duty must take into account the fact that COVID-19 spreads quickly and easily. *Id.* at 1029. Employees could contract—and spread—COVID-19 in any number of ways (at work or otherwise); it would be nearly impossible to trace the source of exposure. *Id.* at 1024. And "[b]ecause it is impossible to eliminate the risk of infection . . . the prospect of liability for infections outside the workplace could encourage employers to adopt precautions that unduly slow the delivery of essential services to the public." *Id.* at 1028. Given these contextual considerations, this Court rejected the proposed duty because it constituted a "significant and unpredictable burden . . . on California businesses, the court system, and the community at large" and had "the potential to destroy businesses

and curtail, if not outright end, the provision of essential public services." *Id.* at 1031.

Similarly, in *Parsons v. Crown Disposal Co.*, 15 Cal. 4th 456, 461 (1997), this Court held that a garbage collector "had no duty to avoid making the regular noises" of its operations merely because it might frighten horses and cause injuries to people on an adjacent bridle path. The Court acknowledged "that the needs of a modern, industrial society often conflict with and generally must prevail over the delicate sensibilities of horses." *Id.* at 466. As a result, "[w]eighing the social utility of these machines and devices against the likelihood that horses might become frightened by the operation of such objects," courts established "a remarkably uniform rule" that "regular and necessary conduct" could not state a claim. *Id.* Moreover, the "breadth of the list of noises and things that might scare or spook a horse . . . is rivaled only by the range of socially useful activities that may produce such noises and provoke a fight." *Id.* at 474-75. After considering a number of questions to which a hypothetical defendant would need answers in order to comply with the proffered duty, this Court concluded that "imposing a duty in the present case to guard against fright to a horse might well subject all manner of actors to the same duty and potential liability, with obvious and detrimental consequences stifling to the community." *Id.* at 475. While a duty of care could be envisioned for what could be deemed as a foreseeable risk, no duty was created because the risk came from the ordinary use of "a socially beneficial machine

or apparatus." *Id.* at 474. Thus, in *Parsons*, just as in *Kuciemba*, context dictated whether a duty of care was feasible or desirable.

Likewise, in *Al Shikha v. Lyft, Inc.*, 102 Cal. App. 5th 14, 30-32 (2024), the court declined to impose a duty on rideshare companies to conduct criminal background checks on their passengers. The court acknowledged that the proposed background checks would increase safety, but found the financial and logistical burden of imposing that duty was too high. Lyft would be required to screen each passenger, requiring a "huge and unwieldy infrastructure," it would not guarantee identification of those "inclined to violence," would have a "discriminatory effect," and contravene privacy considerations. *Id.* at 28, 30-31. Further, obtaining criminal histories of each potential passenger and performing "some form of analysis" would be overly burdensome. *Id.* at 29. And, as the court further explained, even if logistics and cost were not factors, "there are significant negative social costs to creating an obligation to obtain criminal history of potential patrons to exclude them from participating in a widely available service." *Id.* Again, in context, the court rejected the proposed duty because it was unreasonable to impose it.

Further, consider *Bily v. Arthur Young & Co.*, 3 Cal 4th 370, 398-406 (1992), where this Court held that an auditor owed no duty to third parties who allegedly relied on the audits it prepared, stating that "[i]n line with our recent decisions, we will not treat the mere presence of a foreseeable risk of injury to third persons as sufficient, standing alone, to impose liability for

negligent conduct." A number of contextual considerations drove this Court's duty analysis, including the "secondary 'watchdog' role of [an] auditor" and "tenuous causal relationships between audit reports and economic losses" that would result in "potential liability far out of proportion to . . . fault[,]" the more effective use of contract liability to promote "accurate auditing," and the likely consequence of "increased expense and decreased availability of auditing services." *Id*. at 398. Once again, under appropriate scrutiny, context dictated that the proposed duty-of-care analysis be rejected.

In this case, however, the Court of Appeal created its novel duty without adequately analyzing the context in which it was imposed. And while the Court of Appeal declined to give it significant weight, where pharmaceutical products are involved, the imposition of a duty of care *must* take into account the uniqueness of the products themselves. This Court explained as much in considering the imposition of liability in *Brown v. Superior Court*, 44 Cal. 3d 1049 (1988). There, it limited the reach of tort liability principles in recognition of the fact that pharmaceuticals are life enhancing and often life saving products, whose use is often not a matter of option or convenience. For that reason, this Court limited the duty of a prescription drug manufacturer to providing a reasonably safe product accompanied by warnings of dangerous propensities that were known or reasonably scientifically knowable at the time of distribution. *Id.* at 1069.

As in the foregoing cases, this Court made its limiting declaration based on what the context demanded: "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." *Brown*, 44 Cal. 3d at 1063; *see In re Coordinated Latex Glove Litigation*, 99 Cal. App. 4th 594, 610 (2002) (limiting the reach of tort liability for latex glove manufacturers based on the policy considerations emphasized in *Brown*).

The Court of Appeal's duty analysis in this instance—when a life-enhancing pharmaceutical product is involved—needed to fully take account of the context, but did not. A principal consideration should have been the effects of its novel and expanded tort duty on the costs and availability of pharmaceuticals, as further balanced against the need for their availability. In short, the manner in which the proposed duty would impact the cost and availability of pharmaceutical products should have been paramount in the duty calculus, but it was not. As the following analysis shows, moreover, had context been given the consideration it deserved in the duty calculus, the Court of Appeal's affirmative duty would not have been imposed.

B. The Court Of Appeal's Novel Duty Is Unworkable, Impractical, And Threatens Unwarranted Adverse Consequences For Pharmaceutical Product Development

When considering and declaring novel duties of care, California courts routinely examine the burdens a proposed duty

would impose. At bottom, any proposed standard of care must be workable in practice and not overburden the defendant who would be forced to meet its requirements.

This Court's decision in *Southern California Gas Leak Cases*, 7 Cal. 5th 391 (2019) illustrates the importance of this workability principle. There, this Court held that local businesses affected by a massive gas leak could not recover in negligence for lost income. The Court "appreciated the need to safeguard the efficacy of tort law by setting meaningful limits on liability" and expressed concern over "difficult line-drawing questions . . . and deter[ing] socially beneficial behavior." *Id.* at 401-02 (citing *Bily*, 3 Cal. 4th at 398-99, 400, 404). On analysis of these meaningful limits, there were a host of practical considerations that impeded the creation of a determinable standard of care. As a result, the Court held that the gas company defendant owed no duty partly because it could see "no workable way" to limit who may recover the claimed economic losses. *Id.* at 410. The threat of such unlimited liability, moreover, exceeded the outer boundaries of where tort recoveries should be permitted under California law. *Id.* at 412-14.

Workability also drove the duty calculus in *Peter W. v. San Francisco Unified Sch. Dist.*, 60 Cal. App. 3d 814, 822 (1976), where the court refused to create a duty of a school district to provide an adequate education. There, the court explained that duties must be dictated by considerations of public policy, including social utility and the "workability of a rule of care, especially in terms of the parties' relative ability to adopt

practical means of preventing injury[.]" *Id.* (citing *Raymond v. Paradise Unified Sch. Dist.*, 218 Cal. App. 2d 1, 8 (1963)). It also observed that in "sanction[ing] new areas of tort liability, . . . the wrongs and injuries involved [must be] both comprehensible and assessable within the existing judicial framework." *Id.* at 824 (citations omitted). The issue of "educational malfeasance," by contrast, "affords no readily acceptable standards of care, or cause, or injury." *Id.* That is because "[t]he science of pedagogy itself is fraught with different and conflicting theories of how or what a child should be taught," among other things. *Id.* As a result, the court found "no conceivable" workable standard "against which defendants' alleged conduct may be measured." *Id.* at 825.

Similar workability considerations drove the duty analysis in *Smith v. Alameda County Social Services Agency*, 90 Cal. App. 3d 929, 936-37 (1979), where the court refused to impose liability on a social services agency for failure to place a child in a proper adoptive home. The court noted the difficulties in creating a standard by which any effort to impose liability would be measured. *Id.* at 937. As the court observed, "the duty sought to be imposed here does not present us with a reasonably clear or manageable standard for assessing the wrongfulness of the agency's conduct." *Id.* at 936. To start, "[a] trier of fact would have to exercise hindsight" over many years "involving difficult at least partially subjective decisions about when and with whom to place a preadoptive child." *Id.* at 936-37. And trends regarding the number of children in the social work system versus the

"demand for children to adopt" is not a precise science. *Id.* at 937. Further, "[w]hether an agency could or should have done something different . . . would involve an inquiry of a highly speculative nature." *Id.* In short, "social work methodology provides no readily acceptable standards of care or cause." *Id.*

Likewise, in *Nally v. Grace Community Church*, 47 Cal. 3d 278, 296, 299 (1988), this Court held that church and clergymen owed no "duty to refer a suicidal person to a professional therapist," in part because no "workable standards of care could be established." In this instance, the Court determined that the "obligation imposed by [the court below] is loosely phrased" and "used widely varying terminology." *Id.* at 292. Furthermore, "the indeterminate nature of liability . . . impose[d] on nontherapist counselors" was problematic for a host of practical and public policy reasons. *Id.* at 298. *Castaneda v. Olsher*, 41 Cal. 4th 1205, 1216 (2007) invoked similar considerations. There, this Court rejected a duty of care "on landlords to withhold rental units from those they believe to be gang members" because it was not "a fair or workable solution." Among other problems, such a duty would encourage "arbitrary discrimination" because gang affiliations are not readily knowable. *Id.*

As with context, whether the duty of care as proposed by the plaintiff was workable in practice should have been a critical consideration in the Court of Appeal's duty analysis. Yet, the Court of Appeal did not undertake an analysis of the burdens the proposed duty would impose, nor did it explain how the proposed

duty would be met by a pharmaceutical manufacturer when the drug development process was closely examined.

Was it realistic to impose a duty to innovate, develop, market, and sell a new and purportedly better product where an FDA-approved pharmaceutical product is concerned? The court never asked, but had it done so, it would have reached a different result. The path to approval of new and efficacious pharmaceuticals involves a high degree of uncertainty in the development of the product, as well as in evaluating its risks and benefits. These uncertainties, when combined with the costs and vagaries in the results of research, as well as in bringing a product to market, make the proposed duty unworkable in practice.

Specifically, as the FDA counsels, "The path a drug travels from a lab to [a] medicine cabinet is usually long, and every drug takes a unique route."[1] The process starts with laboratory and preclinical testing, and if results are promising, the manufacturer can propose clinical trials in humans.[2] Early-phase trials aim to determine a drug's most frequent side effects and the potential effectiveness, *i.e.*, to obtain "data on whether the drug works in

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[1] FDA, *The FDA's Drug Review Process: Ensuring Drugs Are Safe and Effective* (Nov. 24, 2017), https://www.fda.gov/drugs/information-consumers-and-patients-drugs/fdas-drug-review-process-ensuring-drugs-are-safe-and-effective.

[2] *Id.* (noting that "[m]ost . . . never even make it to human testing and review by the FDA).

people who have a certain disease or condition."[3] If early-phase research demonstrates effectiveness, the manufacturer can begin Phase 3 trials, which gather more information regarding safety, effectiveness, and dosage.[4]

If a Phase 3 study produces promising results, a New Drug Application can be considered. Only a few pharmaceuticals, however, actually make it this far.[5] At every step of the process, drug manufacturers—like manufacturers in other industries—have to decide which pathways to follow, which to abandon, and which to defer perhaps to another day. Moreover, resources are finite and obtaining FDA approval is "an iffy, arduous and expensive process that routinely runs many years and typically costs somewhere between $1.3 and $4.00 billion."[6]

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[3] *Id.*

[4] *Id.*

[5] In the end, "one of 5,000 to 10,000 compounds under development, and only about 12% of medicines entering clinical trials, secures FDA approval." Dan Troy, A California court is setting a dangerous precent over drug development (or lack thereof) liability, STAT (Feb. 13, 2024), https://www.statnews.com/2024/02/13/tdf-taf-gilead-lawsuit-ruling-hiv/.

[6] Richard Epstein, How legal adventurism stifles medical innovation, THE ORANGE COUNTY REGISTER (Feb. 16, 2024), https://www.ocregister.com/2024/02/16/how-legal-adventurism-stifles-medical-innovation/. *See also* FDA, *The Drug Development Process* (Jan. 4, 2018), https://www.fda.gov/patients/learn-about-drug-and-device-approvals/drug-development-process;

> Developing an innovative medicine is a lengthy and complex process, taking an average of 10 or more years. The clinical trial component alone takes

The Court of Appeal's opinion does not account for the reality of this complicated development process. More to the point, the Court of Appeal's opinion creates potential liability for every decision made along the way, with no limit other than a jury's hindsight vision of "reasonableness." Each decision and judgment call will be second-guessed—and out of context. As one commentator has observed, the Court of Appeal has created a scenario under which "early development of a new drug would expose [a manufacturer] to some indeterminate liability for the continued sale of its current offerings."[7] Or, as stated by the former chief counsel of the FDA, "Never before have companies been held liable for failing to progress an 'improved' or better product over one sufficiently safe and effective to have secured—and still have—FDA approval."[8]

Simply put, it is unrealistic to inject tort duties of care into the drug development process under assumptions that new or improved products can readily be brought to market and made available for sale. Research is expensive and results are

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> roughly six to seven years. With just 12 percent of drugs that enter clinical trials resulting in an approved medicine, the average research and development cost for each successful drug is estimated at $2.6 billion (including the cost of failures).

PhRMA, *Modernizing Drug Discovery, Development and Approval* at 1 (Mar. 31, 2016), https://phrma.org/-/media/Project/PhRMA/PhRMA-Org/PhRMA-Org/PDF/P-R/proactive-policy-drug-discovery.pdf.

[7] Epstein, *supra* note 7.

[8] Troy, *supra* note 6.

uncertain. Drug efficacy is equally uncertain and risks may outweigh perceived benefits. The approval process that follows is lengthy and adds further costs as well. And the costs of development and approval will be increased materially if, as the Court of Appeal envisioned, manufacturers have to consider risks and benefits to individuals who had received different pharmaceuticals already sold.

At each juncture—whether research, testing, marketability, or possible sale—decisions would have to be made regarding whether a given product in development can favorably be brought to market and whether it will represent a cost-effective improvement to products currently available. The assumptions made by the Court of Appeal in fashioning a duty to research, develop, market, and sell ignored the realities of the process itself. The result is an unworkable and unmeetable standard of care.

C. The Court Of Appeal's Novel Duty Is Unpredictable, Uncertain, And Does Not Fairly Apprise A Defendant Of The Relevant Standard Of Care

Tort duties of care, at their essence, must be capable of being complied with prospectively so that liability can be avoided. A standard of care therefore must be predictable and fairly apprise a party of what compliance entails.

Once again, this Court has made the point. In *Ramirez v. Plough, Inc.*, 6 Cal. 4th 529, 542 (1993), for example, it declined to impose on drug manufacturers a duty to warn in Spanish, even though they knew that non-English speakers used the product.

Because drug manufacturers were already subject to well-defined duties under product liability law, namely a duty to warn purchasers about risks, this Court observed that the issue then is "the nature and scope of the acknowledged duty." *Id.* at 546. It further explained that courts must "determine and formulate the standard of conduct to which the duty requires the defendant to conform." *Id.* (citation omitted); *see also id.* at 548-50 (discussing federal and state labeling requirements). Given the heavily regulated nature of the conduct and "the importance of uniformity and predictability in this sensitive area of the law," this Court rejected "plaintiff's attempt to place on nonprescription drug manufacturers a duty to warn that is broader in scope and more onerous than that currently imposed by applicable statutes and regulations." *Id.* at 542, 555.

This Court similarly underscored the necessity for a predictable standard in *Elden v. Sheldon*, 46 Cal. 3d 267 (1988). There, it rejected a duty to avoid causing emotional distress to a plaintiff who observed a fatal injury to an unmarried cohabitant. *Id.* at 276. Such a determination "would require a court to undertake a massive intrusion into the private life" of the couple, for example "emotional attachments," exclusivity of the relationship, "degree of economic cooperation," and other relationship-specific considerations. *Id.* at 276-77. As a result, that standard "would not provide a sufficiently definite and predictable test to allow for consistent application from case to case" and would be "an unreasonable extension of the scope of liability." *Id.*

And in *Donnell v. California Western School of Law*, 200 Cal. App. 3d 715, 717 (1988), predictability concerns were stage center when the court considered whether to impose a duty on a law school to protect its student invitees from foreseeable crime. The court declined to expand the duty owed by a premises owner because "[t]he existing standard for premises liability. . . provides predictability and reasonably clear limits" that are "consistent with the general policy underlying much of tort law." *Id.* at 726.

Yet, here again, the Court of Appeal's duty analysis fails to account for whether it will be predictable and certain when carried into practice. And again, that analysis would have revealed that the affirmative duty created and imposed would not be predictable or certain in the context involved.

For example, the first premise of the Court of Appeal's duty is that the manufacturer "invented" another product. But the term "invented" is neither defined nor definable. As explained above, manufacturers develop products in phases, so the Court of Appeal's duty will leave them guessing exactly when a product has transformed from a promising idea (which would not trigger a duty of care) into a full-blown invention (which now gives rise to a legal duty to develop and push to market without delay). There is nothing in the Court of Appeal's opinion that prevents courts from imposing this new duty on products earlier and earlier in their development cycles.

The Court of Appeal similarly defined its duty in terms of the manufacturer having "knowledge" that an alternative therapy is "safer, and at least equally as effective." The required

knowledge is again undefined. The duty could apply when a manufacturer actually knew of an alternative, or it could apply to constructive knowledge, if the hindsight view of a lay jury was that the manufacturer should have interpreted the evidence it had differently.

Even the concept of an "alternative" is open to interpretation, as many conditions are treatable with different kinds of therapies. Some might consider chemotherapy to be an alternative to radiation for some kinds of cancers, and others might not. There are multiple drugs that physicians prescribe to treat conditions like high blood pressure. The Court of Appeal's duty may (or may not) consider some of those drugs to be alternatives to others, even though they are different kinds of medicines. Under those circumstances, a manufacturer who "knows" of a promising new therapy may now have a duty to develop and market that therapy, even if the current product continues to safely and effectively treat patients and the "alternative" is in a completely different drug class.

Most bedeviling is the idea that a manufacturer could ever "know" that an early-phase product is "safer, and at least equally as effective" in the context of the pharmaceutical industry. All drugs have risks, and early-phase studies and clinical research will always reveal some potential side effects. And the reality is that pharmaceutical products do not affect every patient the same way. That is why prescription drugs are available only by prescription, so healthcare providers can use their learned discretion to prescribe drugs they believe to be best for their

individual patients. In these circumstances, whether one drug is "safer" than another or "at least as effective" is anything but a straightforward proposition. Yet, that very question will now determine whether a manufacture is potentially liable to an individual who is not among the class of persons for whom the product was intended in the first place.

Finally, as Petitioner and other *Amici* have noted, the Court of Appeal's duty analysis could readily be extended to other industries as well. Products routinely are tested and developed in multiple industries and there is no reason to think that "innovation" liability will not otherwise become the norm where allegations are made that a safer product should have been made available but was not.

In this instance, although the Court of Appeal attempted to articulate a "limited" duty, the practical reality is exactly the opposite. Any one of the Court of Appeal's limiting factors is susceptible to interpretation in ways that expand potential liability, not cabin it. Worse yet, the indeterminate nature of those supposed limiting factors provides no ascertainable guidance for manufacturers to know when their product development decisions will place them at risk and when they will not. In this respect, the Court of Appeal's proposed duty will present unpredictable risks, with no way to effectively determine how or when liability can be avoided. California law does not support the creation of a duty with these consequences.

III.

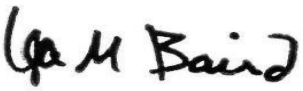
CONCLUSION

California law already defines the duty that a manufacturer owes to the users of its products, and that well-defined duty amply protects consumers from products that are not reasonably safe. The Court of Appeal's new duty improperly and improvidently departed from the law's well-established limitations and this Court should restore them, just as the proper duty of care calculus would require.

Dated: November 4, 2024

Respectfully submitted,

REED SMITH LLP

By: 

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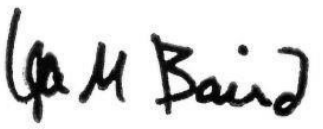
CERTIFICATION OF COMPLIANCE
WITH CAL. R. CT. 8.204(c)(1) AND 8.520(b) AND (c)

Pursuant to California Rule of Court 8.204(c)(1) and 8.520(b) and (c), I certify that the foregoing *Amici Curiae* brief, contains 5,758 words (not including the cover, Table of Contents, Table of Authorities, signature block, Application for Leave to File *Amici Curiae* brief, and any certificates). It is 1.5-spaced and utilizes 13-point Century Schoolbook font. In preparing this certificate, I have relied on the word court of Microsoft Office Word 2016, the computer program used to prepare the document.

Executed on November 4, 2024, in Los Angeles, California.



Lisa M. Baird

PROOF OF SERVICE

In re Gilead Tenofovir Case; *Gilead Sciences, Inc. v. San Francisco County Superior Court*,
California Supreme Court No. S283862,
First Appellate District, Div. 1, No. A165558,
San Francisco County Superior Court No. CJC 19005043,

I am a resident of the State of California, over the age of eighteen years, and not a party to the within action. My business address is REED SMITH LLP, 101 Second Street, Suite 2000, San Francisco, CA 94105-3659; ekroll@reedsmith.com. On November 4, 2024, I served the following document(s) by the method indicated below:

APPLICATION FOR LEAVE TO FILE AMICI CURIAE BRIEF IN SUPPORT OF PETITIONER; AMICI CURIAE BRIEF OF DRI - CENTER FOR LAW AND PUBLIC POLICY, THE ASSOCIATION OF DEFENSE COUNSEL OF NORTHERN CALIFORNIA AND NEVADA, AND THE ASSOCIATION OF SOUTHERN CALIFORNIA DEFENSE COUNCIL

X	by causing the document(s) listed above to be placed in a sealed envelope with postage thereon fully prepaid, in the United States mail at San Francisco, California addressed as set forth below. I am readily familiar with the firm's practice of collection and processing of correspondence for mailing. Under that practice, it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in this Declaration.
X	by causing e-service through TrueFiling to the parties listed below:
	by transmitting via email to the parties at the email addresses listed below:

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☑	by causing the document(s) listed above to be placed in a sealed envelope with postage thereon fully prepaid, in the United States mail at San Francisco, California addressed as set forth below. I am readily familiar with the firm's practice of collection and processing of correspondence for mailing. Under that practice, it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in this Declaration.

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

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 San Francisco, California.

Eileen Kroll

Eileen Kroll