A165558

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

GILEAD SCIENCES, INC.,
Petitioner,

v.

SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF SAN FRANCISCO,
Respondent,

and
GILEAD TENOFOVIR CASES,
Real Parties in Interest.

Superior Court of California, San Francisco County
Hon. Andrew Y.S. Cheng | Case No. CJC-19-005043

APPLICATION OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE CALIFORNIA CHAMBER OF COMMERCE, THE ALLIANCE FOR AUTOMOTIVE INNOVATION, AND THE WASHINGTON LEGAL FOUNDATION FOR LEAVE TO FILE AMICI CURIAE BRIEF IN SUPPORT OF PETITIONER; PROPOSED AMICI CURIAE BRIEF

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CERTIFICATE OF INTEREST ENTITIES OR PERSONS

Except for the parties and any entities or persons already identified by the parties, counsel for Amici Curiae knows of no entity or person that must be listed in this Certificate under Rule 8.208(e) of the California Rules of Court.

Dated: October 3, 2022 DLA PIPER LLP (US)

By: */s/ Justin R. Sarno*
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Attorney for Amici Curiae,
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Pursuant to California Rules of Court, rule 8.487(e), the Chamber of Commerce of the United States of America, the California Chamber of Commerce, the Alliance for Automotive Innovation, and the Washington Legal Foundation ("Amici Curiae") respectfully request leave to file the attached amici curiae

brief in support of Petitioner Gilead Sciences, Inc. ("Gilead" or "Petitioner").

The aim of this brief is to assist the Court in understanding why it should reverse the Superior Court's improper ruling imposing a duty on product manufacturers to prevent injuries caused by *non-defective* products. The Superior Court's ruling opened the door to a boundless standard of manufacturer liability—one that is divorced from established precedent in California which predicates liability on the dangerousness, or defectiveness, of a product.

The Superior Court has adopted a novel theory of liability that would hold a manufacturer liable for failing to hurriedly innovate the "safest" product. This theory runs counter to established law and will have far-reaching consequences for a host of industries and the public at large.

The proposed amici curiae brief does not repeat the compelling legal arguments that Petitioner has offered as to why this Court should vacate the trial court's ruling. Rather, this proposed brief seeks to highlight other ways in which the trial court drastically departed from settled tort law—including the law of other jurisdictions—and the potentially devastating public policy consequences of such a departure. This Court's intervention is required.

Respondent's return was filed on September 19, 2022. This application has been timely filed within 14 days following the filing of Respondent's return. (See Cal. Rules of Court, rule 8.487(e)(3).)

STATEMENT OF INTEREST

The Chamber of Commerce of the United States of America ("U.S. Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country—including throughout the State of California. An important function of the U.S. Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and federal and state courts. To that end, the U.S. Chamber regularly files amicus curiae briefs in cases, like this one, that raise issues of concern to the business community. Many of the U.S. Chamber's members are companies and professional organizations which seek to enforce their rights in the courts. Indeed, the U.S. Chamber routinely files amicus curiae briefs in cases pending before California courts, including cases involving pharmaceutical and labor and employment matters.

The California Chamber of Commerce ("CalChamber") has more than 13,000 members, both individual and corporate, representing virtually every economic interest in the State. While CalChamber represents several of the largest corporations in California, seventy-five percent of its members have 100 or fewer employees. CalChamber acts on behalf of the business community to improve the State's economic and employment climate by representing business on a broad range of legislative, regulatory, and legal issues.

Formed in 2020, the Alliance for Automotive Innovation ("Auto Innovators") is a respected, collective organization representing the voice of the automotive industry. Focused on creating a safe and transformative path for sustainable industry growth, Auto Innovators represents the manufacturers producing nearly 98 percent of cars and light trucks sold in the United States. The organization is directly involved in regulatory and policy matters affecting the light-duty vehicle market across the country. Members include motor vehicle manufacturers, original equipment suppliers, as well as technology and other automotive-related companies.

The Washington Legal Foundation ("WLF") is a nonprofit, public-interest law firm and policy center with supporters nationwide, including many in California. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as amicus curiae to oppose novel state-law tort duties that second-guess the safety of federally regulated products. (*See*, *e.g.*, *Burningham v. Wright Med. Tech., Inc.* (Utah 2019) 448 P.3d 1283; *McNair v. Johnson & Johnson* (W.Va. 2018) 818 S.E.2d 852.) Such suits undermine the very goals of public health and safety that tort law is intended to further. WLF's Legal Studies division also regularly publishes articles by outside experts on state-law approaches to product liability. (*See*, *e.g.*, John J. Park, Jr., Law Rejecting "Innovator Liability" Theory Restores Civil Justice Sanity to Alabama, WLF Legal Opinion Letter (June 19, 2015).)

Pursuant to California Rules of Court, rules 8.487(e)(5) and 8.200(c)(3), amici curiae declare that no party or counsel for a party in the pending case authored the proposed amici curiae brief in whole or in part or made a monetary contribution intended to fund the preparation or submission of this proposed brief. Furthermore, no person or entity other than the amici, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of the proposed brief.

Dated: October 3, 2022 DLA PIPER LLP (US)

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AMICI CURIAE BRIEF

I. INTRODUCTION

This Court's intervention is needed to correct the Superior Court's erroneous determination that a plaintiff can recover damages from manufacturers for injuries allegedly caused by *non-defective products*. In so ruling, the trial court imposed a new, unprecedented tort duty on manufacturers to innovate a maximally safe product. Because that duty finds no basis in tort law, and, if accepted, would have significant adverse consequences, summary judgment should have been granted in favor of Petitioner.

If allowed to stand, the Superior Court's ruling would discourage manufacturers from developing new and improved products and would thwart the incentives for innovation that both tort and patent law seek to foster. Moreover, the trial court's expansion of liability would disrupt business operations across all industries and ultimately harm the public at large, who would have access to fewer innovative and improved products and would pay more for products that already exist. These concerns weigh heavily against recognizing the novel duty theory in this Judicial Council Coordination Proceeding ("JCCP") with more than 24,000 plaintiffs.

From amici curiae's perspective, the issue tendered in the writ petition is "of widespread interest." (*Omaha Indemnity Co. v. Superior Court* (1989) 209 Cal.App.3d 1266, 1273; *Brandt v. Superior Court* (1985) 37 Cal.3d 813, 816.) Indeed, thousands of

businesses that take great care in ensuring their products are safe are now exposed to liability by the trial court's unjustified departure from established product liability law in California. If it is undisputed (as here) that an existing product is already safe—and thus, by definition, satisfying the applicable standard of care—further safety innovations undertaken by a manufacturer are no basis for imposing a new and unheard-of duty to innovate faster or for a finding of negligence. Amici curiae ask this Court to reverse the trial court's ruling.

II. ARGUMENT

Where it is undisputed that an original product is not defective, there is no duty under California law for a manufacturer to market a potentially safer alternative.

The necessary, underlying predicate for liability—a product defect—is absent here, yet the trial court seeks to elevate the baseline standard upon which a manufacturer can be held accountable in tort. Indeed, the trial court has imposed an amorphous duty on Gilead—and, indeed, all product manufacturers—in a novel, unprecedented ruling, which cannot be allowed to stand. The imposition of such a duty not only conflicts with settled tort principles and Evidence Code section 1151, but also contravenes sound public policy and would have serious adverse consequences for industry and the public at large. Accordingly, this Court should grant writ relief to correct the trial court's error of law before the first bellwether trial in this JCCP.

A. California law does not impose on manufacturers the affirmative duty to innovate a maximally safe product.

The trial court erred by imposing an unprecedented duty on product manufacturers that lacks any basis in the law. Specifically, Plaintiffs seek to recover for injuries caused by Gilead's tenofovir disoproxil fumarate ("TDF") medications—lifesaving HIV medications that Plaintiffs concede are *not* defective—on the novel theory that Gilead is liable for not quickly developing tenofovir alafenamide ("TAF"), an entirely different medication that Plaintiffs claim constitutes a safer alternative. In allowing such a claim to proceed, manufacturers would be liable for injuries caused by otherwise safe products because of a manufacturer's choice to not develop and then immediately commercialize an alternative "safest" product.

A manufacturer does not have an affirmative duty to market the "safest" products. Rather, "the negligence inquiry asks if the manufacturer failed to use the amount of care in designing the product that a reasonably careful designer or manufacturer would have used in similar circumstances." (*Howard v. Omni Hotels Management Corp.* (2012) 203 Cal.App.4th 403, 430.) Determining whether a manufacturer used reasonable care requires "balanc[ing] what [a manufacturer] knew or should have known about the likelihood and severity of potential harm from the product against the burden of taking safety measures to reduce or avoid the harm." (*Id.*) That is the framework that governs Plaintiffs' claims, and those claims are foreclosed—at the outset—

by Plaintiffs' concession that none of the TDF medications at issue were defective in the first place.

Even in the context of strict liability, "manufacturers are not insurers of their products and are liable in tort only when defects in their products cause injury." (*Taylor v. Elliot Turbomachinery Co., Inc.* (2009) 171 Cal.App.4th 564, 576.) A defect is an essential element for a negligence claim alleging that a product caused unwarranted injury. (*See e.g.*, *Brady v. Calsol, Inc.* (2015) 241 Cal.App.4th 1212, 1218.) That is why, even when "asserting a claim for negligence, the plaintiff **must prove the defect in the product** was due to the defendant's negligence." (*Id.*)

Yet, unlike a typical plaintiff who claims that the injury that the plaintiff suffered is the consequence of a defective product, Plaintiffs make no allegation that TDF was defective. The trial court's ruling acknowledged that Plaintiffs do not contend that Gilead should have stopped selling TDF or that the risks of TDF outweighed the benefits. (10 App. 3247 [MSJ Ruling].) That should have been the end of it. Yet Plaintiffs nonetheless insist they can recover for injuries allegedly resulting from the use of TDF, because Gilead's conduct in the development and release of a separate product was negligent (*i.e.*, unreasonable). (10 App. 3186 [Pls.' Motion In Limine No. 1] ["The jury will be asked to evaluate whether Gilead acted reasonably when it delayed the development and availability of TAF."].) In so doing, Plaintiffs seek an unwarranted transformation of the ordinary duty of care. They ask this Court to endorse a boundless, safety-maximizing standard of care that would impose on manufacturers a duty to

innovate the safest possible product. And according to Plaintiffs, Gilead violated this duty because it did not more quickly develop and commercialize TAF, a new medication. Thus, at its core, Plaintiffs' duty theory embraces a "safety maximization" requirement under which a manufacturer is liable for injuries resulting from the use of safe, non-defective products merely because it was possible, or hypothetically possible, to make the product even safer.

No such duty to innovate the safest product possible exists. Without a foundational showing that the TDF medications were defective, Gilead was under no duty to release a different, safer medication. (*Cf., S. California Gas Leak Cases* (2019) 7 Cal.5th 391, 401 ["What Civil Code section 1714 does *not* do is impose a presumptive duty of care to guard against any conceivable harm that a negligent act might cause." [emphasis added]].) The California Supreme Court has consistently acknowledged that the goal of tort law is not to ensure that products are maximally safe, because an exclusive focus on safety deters innovation: "[p]ublic 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 v. Superior Court* (1988) 44 Cal.3d. 1049, 1063 [emphasis added].)

Indeed, the "feasibility of an alternative safer design" is only one of several factors relevant to assessing whether a product's design is defective. (*See* Judicial Counsel of California Civil Jury Instructions, CACI 1204 (Strict Liability – Design Defect – Risk-

Benefit Test – Essential Factual Elements – Shifting Burden of Proof) (2022).) When a plaintiff alleges that a defectively designed product caused injury, California products liability law affords manufacturers sufficient space and flexibility to balance the competing considerations of costs, efficacy, feasibility, risk, benefit, and practicality, among other relevant factors. (*See Kim v. Toyota Motor Co.* (2018) 6 Cal.5th 21, 36–37 [noting that "risk-benefit balancing" is typical in both strict liability and negligence cases]); *see also* Judicial Council of California Civil Jury Instructions, CACI No. 1221 (Negligence – Basic Standard of Care) (2022) ["[Y]ou should balance what [a manufacturer] knew or should have known about the likelihood and severity of potential harm from the product against the burden of taking safety measures to reduce or avoid the harm."].) But without a foundational showing that the manufacturer's existing product is defective, the existence of an alternative safer product does not constitute, by itself, its own independent avenue for redress. These bedrock principles of California products liability law demonstrate why this Court should reverse the trial court's creation of a new tort duty to release a maximally safe product even if the existing product is not defective.

Following these same tort principles, courts in other jurisdictions have also rejected a safety-maximization duty as infeasible. (*See*, *e.g.*, *Brown v. Sears, Roebuck Co.* (10th Cir. 2003) 328 F.3d 1274, 1283 [refusing to recognize a duty under Utah law "to refrain from marketing a non-defective product"]); *Castillo v. Am. Laundry Mach. Inc.* (10th Cir. 1996) 74 F.3d 1248, 1996 WL

1182 at *2 [noting that under Oklahoma law, "a manufacturer has no duty to produce a perfectly safe product."]; *Batts v. Tow-Motor Forklift Co.* (5th Cir. 1992) 978 F.2d 1386, 1395 [noting that Mississippi law does not impose a "duty to provide a perfectly safe product"]; *Veliz v. Rental Service Corp. USA, Inc.* (M.D. Fla. 2003) 313 F.Supp.2d 1317, 1330 ["The Defendant is, as a matter of law, under no duty to produce a fail-safe product"]; *Smith v. 2328 Univ. Ave. Corp.* (N.Y. App. Div. 2008) 52 A.D.3d 216, 217 [holding that New York law "does not impose a duty upon a manufacturer to refrain from the lawful distribution of a non-defective product"]; *Slisze v. Stanley-Bostitch* (Utah 1999) 979 P.2d 317, 320 [rejecting plaintiffs' invitation "to create a new duty" that would render a manufacturer negligent for marketing a safe product].)

In the end, California law already rejected the recognition of an affirmative manufacturer duty to innovate maximally safe products. To create such a new duty urged by Plaintiffs—and recognized by the Superior Court—would be to upend California negligence law limiting manufacturer liability to injuries caused by defective products, which does not make manufacturers legally responsible for failing to develop the "safest" alternative product.

B. Plaintiffs' negligence theory collides with Evidence Code section 1151's exclusion of evidence of subsequent remedial measures.

Evidence of subsequent remedial measures, such as Gilead's innovation of an alternative, safer product, are generally

inadmissible to prove negligence. (*See* Evid. Code, § 1151[1]; 1 Witkin, Cal. Evid. 5th Circum. Evid § 170 (2022); Thomas, et al., California Civil Practice Torts (May 2022 Update), ch. 24, Products Liability, § 24:78; Fleming, *Admissibility of Evidence of Repairs, Change of Conditions, or Precautions Taken After Accident—Modern State Cases* (1993) 15 A.L.R.5th 119.) The "public policy rationale" behind the rule rests on the grounds that "the admission of evidence of subsequent repairs to prove negligence would substantially discourage persons from making repairs after the occurrence of an accident." (*Ault v. International Harvester Co.* (1974) 13 Ca1.3d 113, 119 [citation omitted].) Nonetheless, because a manufacturer of an injurious and defective product would face innumerable future lawsuits if the defect is not remedied, the exclusionary rule was deemed unnecessary in strict liability actions alleging defective design. (*See id.* at p. 120 ["[S]ection 1151 is not applicable to a strict liability case"].)

But here, Plaintiffs' claim is not founded on strict liability, and Plaintiffs do not claim that the older TDF medications are defective. Instead, Plaintiffs insist they bring only a negligence claim, one focused entirely on Gilead's conduct. If that is the case, then the exclusionary rule of section 1151 applies to bar evidence of Gilead's subsequent development of another "safer" product.

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[1] Section 1151 provides, in pertinent part: "When, after the occurrence of an event, remedial or precautionary measures are taken, which, if taken previously, would have tended to make the event less likely to occur, evidence of such subsequent measures is inadmissible to prove negligence or culpable conduct in connection with the event." (Evid. Code, § 1151.)

(*See Scott v. C.R. Bard, Inc.* (2014) 231 Cal.App.4th 763, 782 [noting that "Evidence Code 1151 would not have required the exclusion [of remedial FDA regulatory actions] if this case were based only on strict liability. However, the Scotts also claimed Bard was negligent."][2].)

Indeed, the important policy considerations underpinning section 1151 dictate that it should be applied here and demonstrate that Plaintiffs' claims conflict with California public policy. Consider Plaintiffs' theory of negligence. Plaintiffs agree that the older TDF medications are safe and non-defective and should not be withdrawn from the market. Their core claim is that TAF is safer and should have been released earlier. Had Gilead not innovated the newer TAF medications, then there would be no conceivable tort claim against Gilead at all. Thus, Plaintiffs assert that Gilead's subsequent innovation is *itself proof of negligence*.

Pointing to a manufacturer's innovation of an already safe product as a basis to support a negligence claim leads precisely to the adverse policy consequences that section 1151 seeks to avoid—discouraging the innovation of safer products. And if the subsequent innovation can be exploited to authorize a negligence claim, then manufacturers of safe products have little reason to innovate. For this reason, Plaintiffs' unprecedented theory of

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[2] In *Scott*, the Fifth Appellate District admitted the subsequent FDA regulatory actions because they "were taken by a third party," and "imposition of liability is not sought against the person taking the remedial action." (*Scott*, *supra*, 231 Cal.App.4th at p. 782.) Unlike the manufacturer of the medical device in *Scott*, Gilead undertook innovation of a new drug product, and imposition of liability is sought against Gilead.

negligence collides with section 1151 and should not be allowed to stand.

C. No duty arises from a manufacturer's efforts to develop new pharmaceuticals.

Plaintiffs also press the related assertion that their claims can proceed on the theory that Gilead "owes a duty of care arising from its undertaking" to develop TAF medications. (Return at p. 43.) But a manufacturer's efforts to develop new pharmaceuticals—such as Gilead's efforts to develop TAF—cannot give rise to liability under the doctrine of negligent undertaking.

Undertaking a course of conduct to aid another creates liability only if the failure to exercise due care "increases the risk of harm or if the harm is suffered because the other relied on the undertaking." (*Paz v. State of California* (2000) 22 Cal.4th 550, 558–59). *See also Williams v. State of California* (1983) 34 Cal.3d 18, 23 [citing Rest.2d Torts, § 323].) In other words, the undertaking itself must either exacerbate existing risk or cause additional injury. Plaintiff cannot show either.

Nor can Plaintiffs establish that Gilead "should have recognized" its research and development of TAF was "necessary for the protection" of third parties, since it is undisputed that TDF was never defective in the first place. (*Artiglio v. Corning Inc.* (1998) 18 Cal.4th 604, 613618 [California Supreme Court affirming summary judgment, finding no negligent undertaking as a result of Dow Corning's silicone toxicology research].) Moreover, there is no evidence that Gilead "failed to exercise reasonable care

in the performance of its undertaking," especially considering that Plaintiffs have premised its flawed duty argument on the notion that TAF was, in fact, a more efficacious alternative. (*Id.* at p. 614)

The development of new pharmaceuticals does not increase risk or cause injury. Nor is there any reliance by Plaintiffs on Gilead's efforts to develop TAF medications. Although the eventual release of a new product may decrease risk, the withholding of it does not increase risk and so cannot support a claim for negligent undertaking. (*See City of Santee v. County of San Diego* (1989) 211 Cal.App.3d 1006, 1015 [dismissing a negligent undertaking claim because "the failure to report the light outage did not *increase* the risk posed by an inoperative light; instead, the risk posed by the inoperative light remained unaltered"].) When a company withholds a product from market, "nothing changed but the passage of time" and "a failure to alleviate a risk cannot be regarded as tantamount to increasing that risk." (*Paz*, *supra*, 22 Cal.4th at p. 560 [dismissing negligent undertaking claim against contractor who did not manage to install traffic signals at a dangerous intersection before plaintiff's collision].) Similarly, a plaintiff cannot recover for relying on the development of new pharmaceuticals unless reliance on the undertaking "worsened her position." (*Williams*, *supra*, 34 Cal.3d at p. 28 [dismissing a negligent undertaking claim because reliance on a police officer who failed to investigate the scene of an accident did not cause any additional harm to the victim].)

Against this backdrop, Plaintiffs' negligent undertaking claim falls short. It is not enough to merely point at Gilead's

development of TAF, because "the negligent undertaking theory of liability requires more than simply establishing defendants' undertaking to another." (*Paz*, *supra*, 22 Cal.4th at p. 560.) Plaintiffs must show either that Gilead's development of TAF increased the risk of their harm or that Plaintiffs' reasonable reliance on the development of TAF was the cause of their harm. Plaintiffs cannot do so, because nothing Gilead did or did not do altered the harm alleged to have occurred from taking TDF medications. Because Plaintiffs cannot show that Gilead's undertaking worsened their position, the negligent-undertaking claim fails.

D. If allowed to stand, the trial court's ruling would have serious adverse policy consequences.

The decision of whether to carve out an exception to a recognized duty or to create a new duty "is ultimately a question of public policy." (*Murray v. UPS Cap. Ins. Agency, Inc.* (2020) 54 Cal.App.5th 628, 639–40; *Kurtz-Ahlers, LLC v. Bank of Am., N.A.*, (2020) 48 Cal.App.5th 952, 959–60.) And courts "should create one only where 'clearly supported by public policy.' " (*Cabral v. Ralphs Grocery Co.*, (2011) 51 Cal.4th 764, 771 [quoting *Rowland v. Christian* (1968) 69 Cal.2d 108, 112].) The duty imposed by the trial court here not only lacks clear support in public policy, but also contradicts public policy in numerous ways: (1) it stifles innovation, (2) it creates considerable business uncertainty, and (3) it undermines the patent system.

Above all, allowing Plaintiffs' negligence claims to proceed to trial contravenes public policy by deterring product innovation—particularly the incremental improvement of existing products that tort law is designed to help promote. (*See* American Med. Ass'n, Report of the Board of Trustees, Impact of Product Liability on the Development of New Medical Technologies (1988) ["Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance."].) The California Supreme Court has repeatedly recognized that it is the strong public policy of the State to foster the development and commercialization of new pharmaceutical products, such as the groundbreaking HIV medications at issue here. (*Brown*, *supra*, 44 Cal.3d at pp. 1063–65.) In *Brown*, for example, the Court recognized that "[p]ublic policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction." (*Id.* at p. 1063.) It further cautioned that the over-extension of tort liability on drug manufacturers has the potential to "substantially impair[]" the public's interest in such innovation. (*Id.* at p. 1067.) That is because of "the possibility that the cost of insurance and of defending against lawsuits will diminish the availability and increase the price of pharmaceuticals." (*Id.* at p. 1064.)

Although Plaintiffs claim these concerns are "hyperbolic contentions" (*see* Return, at p. 49), the *Brown* Court admonished that these adverse consequences are "far from theoretical" (*id.* at p. 1064), as reflected by a "host of examples of products which have

greatly increased in price or have been withdrawn or withheld from the market because of the fear that their producers would be held liable for large judgments." (*Id.* at pp. 1064–65 [discussing examples].) For this reason, the Court concluded that imposing novel forms of liability on pharmaceutical manufacturers "would not further the public interest in the development and availability of these important products." (*Id.* at p. 1065.) So too here.

Excessive liability is inversely related to investment in research and development. (*See* Michael J. Moore & W. Kip Viscusi, *Product Liability Entering the Twenty-first Century: The U.S. Perspective* 25, 27 (2001) [collecting studies].) As recognized by the American Medical Association's Board of Trustees, "innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance." (American Med. Ass'n, *Report of the Board of Trustees*, *supra*.) Novel and expanded forms of liability also impede public access to beneficial pharmaceuticals by causing the discontinuation of clinical trials, and by forcing already-approved drugs and interested companies from the marketplace. (*See* E. Patrick McGuire, *The Impact of Product Liability* 17 (The Conference Bd., Res. Rpt. No. 908, 1988).)

The example of Bendectin, a drug approved by the FDA for preventing nausea and vomiting during pregnancy ("NVP"), is instructive. While Bendectin was available in the United States, it is estimated that 25%–30% of all pregnant women received this medication to treat NVP. (*See* Nuangchamnong & Niebyl, *Doxylamine succinate-pyridoxine hydrochloride (Diclegis) for the*

management of nausea and vomiting in pregnancy: an overview, Int J Womens Health, vol. 6 401–9 (Apr. 12, 2014).) But in the 1970s, despite the lack of scientific evidence, countless lawsuits were filed alleging that Bendectin caused fetal abnormalities, and as a result, "the manufacturer of Bendectin elected to discontinue production of Bendectin, not because Bendectin was hazardous, but because insurance premiums had become untenable." (*Id.*; *see also* Determination That Bendectin Was Not Withdrawn From Sale for Reasons of Safety or Effectiveness, 64 Fed. Reg. 43190-02 (Aug. 9, 1999).) Consumers were not well-served by the discontinuance of Bendectin, as hospital admissions for NVP doubled in the years after Bendectin was taken off the market. (*Nuangchamnong & Niebyl*, *supra.*) And indeed, a version of Bendectin remained available in Canada and other countries with no indication that it harmed fetal safety. (*Id.*)

This case confirms these concerns—namely, that gratuitous tort liability can adversely affect "[a] manufacturer's incentive to develop what it might consider a superior product." (*Brown*, *supra*, 44 Cal. 3d at pp. 1067–68.) Imposing liability on Gilead (and other manufacturers) for not releasing a safer version of an admittedly non-defective product would do just that. The mere risk of unpredictable liability of the magnitude contemplated by this vast JCCP involving over 24,000 plaintiffs would inevitably lead manufacturers to decrease investment in the development of innovative products, as they seek to fund or offset their potential liabilities. (*See* William Smith III, *Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 Case W. Res. L. Rev.

207, 218 & n.80 (1992) [discussing efforts to shape product liability law to avoid "deter[ring] the marketing of new products for fear of large adverse monetary judgments"].) Manufacturers would have less financial incentive to develop—much less launch—new products, ever conscious of their ballooning and unpredictable tort exposure. And they would face pressure to increase the prices of their existing products to offset potential liabilities. All of this would, in turn, result in fewer new products being developed, fewer existing products being improved, less public access to valuable drugs, and consequentially worse public health and economic outcomes for the public at large.

As the California Supreme Court has recognized, "discourag[ing] the development and availability of life-sustaining and lifesaving drugs" has the effect of "defeating a strong public interest." (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1126–27.) Yet such an outcome flows directly from Plaintiffs' untenable theory of liability. They repeatedly stress that Gilead is liable, in large part, because it was "already developing" a "safer drug" but delayed its release. (*See* Return, at p. 49 & n.8.) But if a manufacturer faces liability merely because it is "already developing" (or has already developed, but not sold) a newer, safer product, then there will be far fewer incentives for it to invest in development efforts in the first place—as *Brown* recognized. Or consider Plaintiffs' newfound "negligent undertaking claim" based on the premise that Gilead assumed a tort duty of care to the public at large by undertaking efforts to research and develop TAF medications. (Return at pp. 43–48.) A manufacturer would be

deterred from innovating if its mere efforts to research and develop an innovative new product had the effect of subjecting it to amorphous tort duties of care under an overbroad "undertaking" theory. The consequences would be immediate and significant. Rather than focusing on ensuring products are safe and defect-free—as tort law requires—manufacturers will have to weigh the risks of enormous, incalculable liabilities *before* they even decide to invest in research and development. Many will decide the risks outweigh the benefits. And, surely, few will have any incentive to expend considerable resources researching improvements for existing, non-defective products, since doing so would inevitably risk creating liability that would not otherwise arise.

The result of the Superior Court's ruling, then, is to invert the traditional tort-law incentives to improve existing products: while the threat of tort liability typically creates incentives for firms to improve existing products, in this case the threat of tort liability creates powerful *disincentives* against innovation, since any efforts to invest in innovation could itself be the new basis for tort liability. All of this is particularly troubling in the pharmaceutical context, where many products are improved incrementally over time. (Joanna Shepherd, *Deterring Innovation: New York v. Actavis and the Duty to Subsidize Competitors' Market Entry*, 17 Minn. J.L. Sci. & Tech. 663, 703–04 (2016) ["According to analysis of FDA data, two-thirds of new drug approvals are for incremental innovations.... And according to the World Health Organization, over sixty percent of drugs deemed necessary for

combating prevalent diseases are the result of incremental innovations."].)

These concerns are not limited to the pharmaceutical industry. Numerous industries would be harmed by the imposition of tort liability on companies that fail to develop and successfully commercialize improved versions of their existing products. A duty to develop the safest products possible is a duty that seems to have no logical limit or predictable stopping point. Put otherwise, if there were in fact a legally enforceable duty to maximize safety by developing the safest product that achieved a particular goal, then it would seem to be impossible for a manufacturer to know whether or when it had satisfied such a duty. In that sense, the duty proposed by Plaintiffs appears to be a duty that it is impossible for anyone to predictably satisfy. The uncertain scope of liability would by paralyzing.

Indeed, a host of industries would be adversely affected by the uncertainty and potential liabilities that would arise if this Court were to adopt Plaintiffs' duty formulation. This issue is of particular concern for the members of *amicus* Auto Innovators. Auto manufacturers are constantly innovating new technologies to improve roadway safety, which entails significant investments in the research, development and in-depth testing of new systems. It simply cannot be the case than an automaker may be held liable for not developing and marketing a new safety feature fast enough. If it were, further innovation would come to a grinding halt.

As the United States Supreme Court has recognized, to be a "profitable business," a company "must have some degree of

certainty beforehand as to when it may proceed to reach decisions without fear of later evaluations labeling its conduct" as unlawful. (*First Nat'l Maint. Corp. v. NLRB* (1981) 452 U.S. 666, 679.) Those concerns are particularly acute here. Under the new tort rule adopted by the Superior Court, there would be no way for any manufacturer to research, develop, or market a product without risking uncertain liabilities. The Superior Court has made clear that the jury—armed with the benefit of hindsight—will be tasked with determining the reasonableness of "a business decision … possibly informed by medical and financial concepts." (10 App. 3275 [Omnibus Order].) And Plaintiffs proposed a liability standard through which "[t]he jury will be asked to evaluate whether Gilead acted reasonably when it delayed the development and availability of TAF." (10 App. 3186 [Pls.' Motion in Limine No. 1].)

Essentially, the Superior Court's ruling allows Plaintiffs to bring negligence claims against companies because they disagree with the companies' business decisions. A company selling a lifesaving product, such as an automatic external defibrillator, may now be exposed to liability on the theory that it did not act reasonably in setting too high a price for the product. Or on the theory that it failed to act reasonably in not producing enough units of the product. Or even on the theory that it chose to sell a less efficacious (but concededly non-defective) version of the product. Such a nebulous standard of care—and the inevitable business uncertainty that would accompany it—contravenes public policy, because it is unpredictable and without limitation.

Finally, Plaintiffs' proposal to foist a novel duty on manufacturers also conflicts with sound public policy because it would subject Gilead (and all manufacturers) to liability for engaging in precisely what the United States patent system strongly encourages. Plaintiffs argue that Gilead should be held liable because it sought to maximize its profits while it enjoyed the exclusive right to sell TDF medications—a right Gilead gained lawfully after engaging in the costly, time-consuming, and unquestionably beneficial process of researching, developing, and marketing those innovative, breakthrough HIV medications. Distilled to its essence, Plaintiffs' chief complaint is that Gilead "chose to delay its release [of TAF] to manipulate its exclusivity and make more money." (*See* Return, at p. 49 n.8; *see also id.* at 44 [complaining that Gilead sought "to maximize profits"].) That is not a tort. Gilead was simply exercising its exclusive right to market a product, which the U.S. patent system rightfully guarantees.

Preserving that system promotes the important public policy of fostering innovation. (*Brown*, *supra*, 44 Cal.3d at pp. 1064–65.) When a company receives a patent for a product it invented, the company gains the exclusive right to commercialize that product for a fixed period (in exchange for, among other things, placing the design information in the public domain, which in turn fosters future innovation). No one else can copy that product and commercialize it during the exclusivity period. As a result, the exclusive rights that come with a patent ensure that inventors can recoup their development costs, and also earn revenue from their

invention—revenue that they can then use to research and develop new innovative products. So when the Plaintiffs admit that their claims are based on the fact that Gilead was unreasonably "monopolizing tenofovir-based antiretroviral compounds" (see Return at p. 44), they are actually complaining that Gilead was lawfully exercising its patent rights.

There is nothing wrong—legally or otherwise—with inventors seeking to charge market prices from their innovations. To the contrary, it is such a fundamental part of our history that the founding fathers enshrined it in the Constitution, granting Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." (U.S. Const., art. I, § 8, cl. 8.)

Fostering innovation has particular benefits in the pharmaceutical industry, where developing and obtaining approval for new products can require enormous financial investment and risk over many years. As a result, "commandeering brand manufacturers' operations and preventing them from operating in a profit-maximizing way may harm innovation and drug development throughout the pharmaceutical industry." (*Shepherd*, *supra*, at p. 704.) "Numerous studies have found that policies that increase pharmaceutical profitability lead to increases in new clinical trials, new molecular entities, and new drug offerings," whereas "[o]ther studies have found that policies that reduce expected profitability lead to decreases in R&D spending." (*Id.* at pp. 704–05 [citing studies].) The public

otherwise will fail to reap the substantial health benefits of pharmaceutical innovations. (*Id.* at p. 706 [citing studies for proposition that "actions that reduce brand innovation will have long-term negative effects on consumer health and health care spending"].)

In short, the new duty proposed by Plaintiffs—and adopted by the trial court—should not be recognized because it contravenes public policy.

III. CONCLUSION

For the foregoing reasons, amici respectfully urge this Court to grant the relief requested in Gilead's petition.

Dated: October 3, 2022

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WORD COUNT CERTIFICATE

This Amici Curiae Brief complies with the type limitations of the California Rules of Court, Rules 8.204(b)-(c). This brief contains 13-point font, in Century Schoolbook typeface, and, together with the accompanying Application for leave to file it, contains 6,157 words, not including the Tables of Contents and Authorities, the caption page, signature blocks, Certificate of Interested Parties, and this Word Count Certificate.

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PROOF OF SERVICE

I am a citizen of the United States, over 18 years of age, and not a party to the within action. I am employed by the law firm of DLA Piper LLP (US). My business address is 2000 Avenue of the Stars, Suite 400, Los Angeles, CA 90067.

On October 3, 2022, I served the within **APPLICATION OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE CALIFORNIA CHAMBER OF COMMERCE, THE ALLIANCE FOR AUTOMOTIVE INNOVATION, AND THE WASHINGTON LEGAL FOUNDATION FOR LEAVE TO FILE AMICI CURIAE BRIEF IN SUPPORT OF PETITIONER; PROPOSED AMICI CURIAE BRIEF** on the parties interested in this proceeding, as addressed below, by causing true copies thereof to be distributed as follows:

All Counsel—As listed on TrueFiling Servicing Notifications List (Via TrueFile)

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

Executed October 3, 2022, at Los Angeles, California.

/s/ Alicia Prado
Alicia Prado