No. S283862

IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

GILEAD SCIENCES, INC.,
Petitioner,
v.

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

GILEAD TENOFOVIR CASES,
Real Parties In Interest.

San Francisco County Superior Court Case No. CJC-19-005043
Honorable Andrew Y.S. Cheng

APPLICATION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF AND PROPOSED BRIEF OF *AMICUS CURIAE* PRODUCT LIABILITY ADVISORY COUNSEL, INC. IN SUPPORT OF PETITIONER

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APPLICATION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF

Pursuant to Rule 8.520(f) of the California Rules of Court, the Product Liability Advisory Council, Inc. ("PLAC") requests permission to file this *Amicus Curiae* Brief in Support of the Petitioner.

INTEREST OF *AMICUS CURIAE*

PLAC is a non-profit corporation with numerous corporate members representing a broad cross-section of American and international industries. Its corporate members include manufacturers and sellers of a wide range of products, from automobiles to electronics to pharmaceutical products to consumer goods.[1] PLAC seeks to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products and those in the supply chain. In addition, several hundred of the leading products liability defense attorneys in the country are sustaining (that is, non-voting) members of PLAC.

PLAC's primary purpose is to file *amicus curiae* briefs in cases with issues that affect the development and administration of products-liability law or otherwise potentially impact the rules governing liability of PLAC's members. PLAC has submitted over 1,200 *amicus curiae* briefs in state and federal courts, including many in this Court.

[1] A current list of PLAC's corporate members is available at https://plac.com/PLAC/Membership/corporate_members_pdf.aspx.

HOW PLAC'S BRIEF WILL ASSIST THE COURT

PLAC'S proposed brief puts Plaintiffs' negligence claim and the Court of Appeal's opinion in the context of larger principles of products liability law.

The Court of Appeals' opinion is at odds with decades of authority—both within and outside of California—by effectively eliminating the requirement of proving a defect from what is unequivocally a products liability case. Further, it creates an end-run around the Court's opinion in *Brown v. Super. Ct.* (1988) 44 Cal.3d 1049, 1059.

NO PARTY OR COUNSEL FOR A PARTY AUTHORED OR CONTRIBUTED TO THIS BRIEF

PLAC provides the following disclosures required by Rule 8.200(c)(3) of the California Rules of Court: (1) no party or counsel for a party in this appeal authored or contributed to funding of this brief, and (2) no one other than amicus curiae or its counsel in this case made a monetary contribution intended to fund preparation or submission of this brief.

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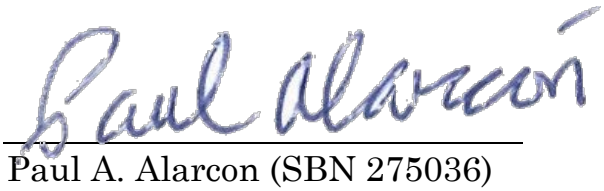
CONCLUSION

For the foregoing reasons, amicus requests that the Court permit the filing of PLAC's *Amicus Curiae* brief attached hereto.

DATED: November 4, 2024

BY: 

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BRIEF OF AMICUS CURIAE PLAC

The Court of Appeal's decision disregards several principles foundational to products liability law.[2] First, "under either a negligence or a strict liability theory of products liability, to recover from a manufacturer, a plaintiff must prove that a defect caused injury." (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 479 (*Merrill*).) Second, the scope of a general duty of care is limited to ""'risks which make . . . conduct *unreasonably* dangerous . . . .'"" (*Delgado v. Trax Bar & Grill* (2005) 36 Cal.4th 224, 234–235 (*Delgado*), italics added.) Third, "the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use." (*Brown v. Super. Ct.* (1988) 44 Cal.3d 1049, 1063 (*Brown*).)

By disregarding these principles, the Court of Appeal concocted a new rule, which—if allowed to stand—would subject all manufacturers, including prescription drug manufacturers, to dramatically increased liability to the detriment of the public interest. To protect the public interest, this Court should reverse the Court of Appeal's decision below.

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[2] "'Products liability is the name currently given to the area of the law involving the liability of those who supply goods or products for the use of others to purchasers, users, and bystanders for losses of various kinds resulting from so-called defects in those products.'" (*Merrill, supra*, 26 Cal.4th at p. 478, quoting Prosser & Keeton, Torts (5th ed. 1984) § 95, p. 677.)

I. Proof of a product defect has always been required to hold a manufacturer liable in negligence for a product-caused injury.

The Court of Appeal's initial error was to disregard the well-established rule that "under either a negligence or a strict liability theory of products liability, to recover from a manufacturer, a plaintiff must prove that a defect caused injury." (See *Merrill, supra*, 26 Cal.4th at p. 479.) The court claimed that "logic" and "jurisprudential history" justified ignoring the rule. (*Gilead Tenofovir Cases* (2024) 98 Cal.App.5th 911, 924 (*Gilead*).) But the court got it backwards. Logic and products liability history show that proof of a product defect has always been—and must always be—required to hold a manufacturer liable for a product-caused injury in all but a few exceptional cases not relevant here.[3]

A. *Caveat emptor*, privity requirements, and general immunity from products liability (1607–1916).

Under Romano-British law, sellers of certain goods were strictly liable for defects in those goods under an implied warranty of quality against defects. (See Owen, *The Evolution of Products Liability Law* (2007) 26 Rev. Litig. 955, 956 (Owen).) By the Middle Ages, British law had mostly abandoned the warranties, enforcing them only for non-obvious defects. (*Ibid.*) The exception was food and drink, to which courts would continue

[3] The exceptional cases are those "where a defendant's false statements cause the harm." 1 Owen & Davis on Products Liability (4th ed. 2024) § 1:15 (Owen & Davis).)

to give special treatment throughout the subsequent history of Anglo-American law. (See 1 Owen & Davis, *supra*, § 5:2.)

By 1600, as the British were preparing to colonize what would become the United States, courts had abandoned implied warranties of quality for non-foodstuffs entirely. (1 Owen & Davis, *supra*, § 1:9; Owen, *supra*, 26 Rev. Litig. at pp. 958–959.) Under the prevailing doctrine of *caveat emptor*, buyers were responsible to protect themselves from product defects (both obvious and hidden), except where a manufacturer had committed fraud or made an express warranty. (1 Owen & Davis, *supra*, §§ 1:10, 5:2.) The doctrine survived the American Revolution and was the law in every state but South Carolina throughout the first half of the nineteenth century. (*Id.* at § 1:10.)

Modern products liability law began to emerge as the country industrialized in the latter half of the nineteenth century, when American courts increasingly abandoned *caveat emptor* in favor of implied warranties of quality for all defective products, not just unwholesome food and drink. (*Id.* at §§ 1:10, 5:2.) But as manufacturers increasingly delegated the retail sale of their products to third parties, the resulting lack of contractual privity between manufacturers and product users increasingly prevented injured persons from invoking the protections of these implied contractual warranties. (*Ibid.*; *Owen*, *supra*, 26 Rev. Litig. at p. 962.)

Likewise, although the law of negligence had developed as a general theory for recovery, it had little impact on products liability law because American courts followed the rule of

Winterbottom v. Wright, requiring privity in tort as in contract. (1 Owen & Davis, *supra*, § 1:10.) At the turn of the nineteenth century, American courts still recognized only a few exceptions to the privity requirement in tort, generally applicable only in cases of fraud or when defects arose in the production of "imminently" or "inherently" dangerous products such as poisons, guns, and explosives. (See *ibid.*)

During this era, this Court heard its first products liability case, *Lewis v. Terry* (1896) 111 Cal. 39 (*Lewis*). (See Prosser, *Strict Liability to the Consumer in California* (1966) 18 Hastings L.J. 9, 9.) Lewis had been injured when a "folding bed" collapsed in on her arm. (*Lewis, supra*, 111 Cal. at p. 43.) This Court acknowledged that absence of privity between the parties would have barred the claim but for Lewis successfully pleading what amounted to an exception for fraud. (*Id.* at p. 45.)

B. *MacPherson* and the recognition of products liability in negligence (1916–1960).

In the early twentieth century, courts began to re-evaluate how to best allocate the financial burden of injuries caused by product defects. (Traynor, *The Ways and Meaning of Defective Products and Strict Liability* (1965) 32 Tenn. L.Rev. 363, 363.) *MacPherson v. Buick Motor Co.* (N.Y. 1916) 111 N.E. 1050 (*MacPherson*) is generally seen as the case that began this transition.

MacPherson had bought a Buick vehicle from a dealer, so he lacked privity with Buick when he sued it for injuries he sustained after a wooden spoke on one of the vehicle's wheels

collapsed. (*MacPherson, supra*, 111 N.E. at p. 1051.) Judge Cardozo, writing for New York's highest court, upheld MacPherson's negligence claim despite the absent privity, reasoning that the exception for "imminently" dangerous products could extend to include any product that would be foreseeably "dangerous if defective." (*Id.* at p. 1053.)

Understood this way, the exception swallowed the rule that privity of contract was generally necessary in tort. (Prosser & Keeton, Torts, *supra*, § 96, pp. 682–683.) The new rule attributed to *MacPherson* was gradually adopted across the country and applies to this day: a manufacturer is liable for any injury that foreseeably results from negligently designing, manufacturing, or marketing a defective product. (*Id.* at pp. 682–683; 1 Owen & Davis, *supra*, § 2:2; see, e.g., *Kalash v. Los Angeles Ladder Co.* (1934) 1 Cal.2d 229.)

To establish such a claim—as with any negligence claim—a plaintiff must prove that the *defendant* proximately caused the plaintiff's injury by breaching a duty of care to the plaintiff. (See 1 Owen & Davis, *supra*, § 2:1.) But in every products liability claim it is a *product*—not the *defendant*—that directly caused the plaintiff's injury. So, for a plaintiff to ultimately meet the requirement of showing the *defendant* proximately caused the plaintiff's injury, the plaintiff must causally link the injury-causing product to the defendant breaching its duty of care. That is, the plaintiff must prove that the product contained some flaw that made the product unreasonably dangerous (that is, a defect), that the defect caused the plaintiff's injury, and that the defect

resulted from the manufacturer's failure to exercise due care and so was present when the product left the manufacturer's control. (See Prosser, *Strict Liability to the Consumer in California*, *supra*, 18 Hastings L.J. at pp. 50–51; see, e.g., *Rexall Drug Co. v. Nihill* (9th Cir. 1960) 276 F.2d 637, 642–643 [holding plaintiff could not sustain products liability negligence claim against manufacturer of permanent hair-wave solution because there was no evidence a defect in solution caused plaintiff's hair loss].)

Courts recognized that the doctrine of *res ipsa loquitur* could sometimes be used to circumvent a plaintiff's need to identify the manufacturer's specific negligent acts or omissions giving rise to the product defect. (See *Escola v. Coca Cola Bottling Co. of Fresno* (1944) 24 Cal.2d 453, 457–461.) But that doctrine applies only if the defect were of such a nature that it could have arisen only if the manufacturer had been acting negligently. (*Id.* at pp. 457–458.) Still, motivated by a desire to incentivize product safety, courts in this era began invoking the doctrine even where there was little justification to do so, "to the point where the mere fact of a product defect supported an inference of negligence." (Henderson & Twerski, *Closing the American Products Liability Frontier: The Rejection of Liability Without Defect* (1991) 66 N.Y.U. L. Rev. 1263, 1270 (Henderson & Twerski); see also Traynor, The Ways and Meaning of Defective Products and Strict Liability, *supra*, 32 Tenn. L.Rev. 363, 364.) Courts also began to chip away at the privity requirement for advancing a warranty claim, first recognizing implied warranties without privity for food products, and then, by the 1950s, extending the exception to

other products for "intimate bodily use" such as hair dye and cosmetics. (Prosser, *The Fall of the Citadel* (*Strict Liability to the Consumer*) (1966) 50 Minn. L.Rev. 791, 791–792.)

C. *Henningsen*, *Greenman*, and the expansion of strict products liability (1960–1982).

By 1960, the expanding lists of exceptions were poised to swallow what remained of the rules barring manufacture liability without either privity of contract or proof of a negligently caused defect. The tipping point was *Henningsen v. Bloomfield Motors, Inc.* (N.J. 1960) 161 A.2d 69, 83–84 (*Henningsen*), where New Jersey's high court exempted all products from the privity requirement for implied warranty claims, which, as contract claims, already did not require plaintiffs to prove that a product was defective due to the manufacturer's negligence.

This Court was the first to acknowledge what was really going on. In *Greenman v. Yuba Power Products, Inc.* (1963) 59 Cal.2d 57, 62–63 (*Greenman*), the Court approved *Henningsen*'s result but rejected the fiction that absent privity of contract the expanded liability could arise from contract law. Instead, the Court acknowledged that it was creating a conceptually new theory of liability—a form of strict liability in tort. (*Ibid.*) The Court summarized the new rule as follows: "[a] manufacturer is strictly liable in tort when an article he places on the market, knowing that it is to be used without inspection for defects, proves to have a defect that causes injury to a human being." (*Id.* at p. 62.)

The new rule was soon embraced by section 402A of Restatement Second of Torts (Second Restatement). The American Law Institute ("ALI") had already drafted section 402A, calling for liability to attach if a food product was in a "defective condition unreasonably dangerous." (Shepherd, *Products Liability and Economic Activity: An Empirical Analysis of Tort Reform's Impact on Businesses, Employment, and Production* (2013) 66 Vand. L. Rev. 257, 265–266; Wade, *On the Nature of Strict Tort Liability for Products* (1973) 44 Miss. L.J. 825, 830.) Nearly every state has adopted the rule. (Owen, *supra*, 26 Rev. Litig. at p. 977, n. 109.) In response to *Greenman*, ALI extended the rule to apply generally all products (with certain exceptions, like for prescription drugs). (*Ibid.*) Now, across the country, under this strict liability theory, all that would matter is that the product was defective—the plaintiff did not *also* need to prove that the manufacturer was negligent and that such negligence caused the defect.

Dean Prosser, the Second Restatement's reporter, emphasized that "[i]t would be easy to overestimate the importance of the shift of theory in the *Greenman* case" because "[t]he substance of the liability itself remains unchanged." (Prosser, *Strict Liability to the Consumer in California*, *supra*, 18 Hastings L.J. at p. 20.) He explained: "there will obviously be few instances in which [a negligence claim] will accomplish anything that the strict liability does not," in large part because "[t]he proof of strict liability for a defective product does not appear to differ in any significant respect from the proof of negligence." (*Id.*

at pp. 21, 50.) As in every products liability negligence claim, plaintiffs would still have to prove: (1) the product caused the injury; (2) the product caused the injury *because it was defective*; and (3) the defect existed when the product left the manufacturer's control. (*Id.* at pp. 50–51.)[4] In short, because negligence theories already required plaintiffs to prove that their injury was caused by a product defect that existed when the product left the defendant's control—the new "strict liability" standard merely lightened plaintiffs' burden by not also requiring plaintiffs to prove the specific negligent acts or omissions that caused the product to be defective.

More significant than the recognition of "strict products liability," manufacturer liability proliferated because "courts developed a second major front in the products liability war—they focused attention on, and imposed liability for, generic product hazards—that is, for hazards that inhered in the design and marketing of products rather than in their production." (Henderson & Twerski, *supra*, 66 N.Y.U. L. Rev. 1263, 1270.)

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[4] This Court cited this passage of Dean Prosser's article in *Merrill*, *supra*, 26 Cal.4th at p. 479 for the proposition that "under either a negligence or a strict liability theory of products liability, to recover from a manufacturer, a plaintiff must prove that a defect caused injury." The Court of Appeal has concluded that this Court misunderstood Prosser, writing that Prosser "did not purport to opine on the requirements of a negligence claim in products liability actions . . . ." (*Gilead*, *supra*, 98 Cal.App.5th at p. 930.) But that is precisely what Dean Prosser did. (See Prosser, *Strict Liability to the Consumer in California*, *supra*, 18 Hastings L.J. at pp. 50–51 [opining that proof of negligence *in products liability actions* and proof of strict liability *in products liability actions* "do[] not appear to differ in any significant respect"].)

Before the 1960s, almost all products liability claims were production (that is, manufacturing) defect claims. (Prosser & Keeton, Torts, supra, § 96, p. 684; 1 Owen & Davis, *supra*, § 7:1.) Now, plaintiffs could also recover from manufacturers on "design defect" and "warning defect" theories—that is, claims that it was unreasonable for the manufacturer to sell the product as designed or without additional warnings or instructions. (Henderson & Twerski, *supra*, 66 N.Y.U. L. Rev. at p. 1271 & fn. 25; see, e.g., *Pike v. Frank G. Hough Co.* (1970) 2 Cal.3d 465 [first recognizing liability for obvious design hazards].)

As these new types of product liability claims proliferated, courts struggled to define the standards by which to evaluate the claims. (See, e.g., *Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 428 (*Barker*).) Courts began to craft defect tests based on foreseeability and risk-utility balancing. (1 Owen & Davis, *supra*, § 5:29.) But they wrestled with how to maintain a doctrinal distinction between these strict liability claims and negligence claims in the products liability context, which are also based on product defects, foreseeability, and risk-utility balancing. (See 1 Owen & Davis, *supra*, §§ 5:1, 5:29; see, e.g., *Barker*, *supra*, 20 Cal.3d at pp. 431–435.)

Consistent with the era's trend of expanding manufacturer liability, some courts considered eliminating the foreseeability requirement altogether in the failure-to-warn context, implementing truly "strict liability" whenever there was a failure to warn. rejecting negligence principles altogether in favor of implementing "strict liability" in spirit as well as name. In what

commentators call the "high-water" mark of manufacturer liability, the New Jersey Supreme Court held in *Beshada v. Johns-Manville Products Corp.* (N.J. 1982) 447 A.2d 539, 549 (*Beshada*) that a product's warnings could be "defective," and the manufacturer thus held liable, regardless of whether the manufacturer could have foreseen a risk and guarded against it. (See *Owen, supra*, 26 Rev. Litig. at p. 978.)

D. *Feldman*, *Brown*, and the close of the products liability frontier (1982–present).

Backlash from *Beshada* signaled yet another turning point in the history of products liability. Commentators rejected "the absurdity of a duty to warn of the unknowable, to say nothing of its unfairness or policy implications." (Owen, *supra*, 26 Rev. Litig. at p. 978.) And just two years later, in *Feldman v. Lederle Laboratories* (N.J. 1984) 479 A.2d 374, 387–388 (*Feldman*), the New Jersey court retreated from *Beshada*'s harsh logic, finding that it could not impose liability on a pharmaceutical manufacturer for failing to warn about something that was unknown and unknowable.

This Court "certified [*Feldman*'s] rectitude in another prescription drug case in 1988, *Brown v. Super. Ct.* [(1988) 44 Cal.3d 1049], and then announced a broad rejection of strict liability principles in defective warning cases three years later [in *Anderson v. Owens-Corning Fiberglas Corp.* (1991) 53 Cal.3d 987.]." (Owen, *supra*, 26 Rev. Litig. at p. 978.) Although the Court retained the label "strict liability," it recognized that in products liability cases the "doctrine has incorporated some well-settled

rules from the law of negligence and has survived judicial challenges asserting that such incorporation violates the fundamental principles of the doctrine." (*Anderson v. Owens-Corning Fiberglas Corp.* (1991) 53 Cal.3d 987, 1002.)[5] And as explained, below (§ III), in certifying California's adoption of comment k to § 402A, *Brown* also recognized the importance of tailoring the tests on which manufacturers' liability turn to ensure that the pursuit of marginally safer products does not stifle innovation and raise prices, thus undermining the public interest in obtaining essential products.

"The significance of *Feldman* and *Brown* in the development of modern American products liability law cannot be overstated. Together they represent a national rejection of the doctrine of [literal] strict manufacturer liability in tort by the very two courts that had led the products liability revolution during the 1960s and 1970s." (*Owen, supra*, 26 Rev. Litig. at p. 979.) Today, under these authorities, a manufacturer cannot be liable, even in strict liability, if it "could not reasonably foresee its risks at the time of sale, nor is it defective if there was no

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[5] Like courts in most other states, this Court has abandoned true no-fault "strict" liability in most design defect and warning defect cases. But it has maintained distinctions between products liability negligence and "strict liability" claims in other ways. (See 1 Owen & Davis, *supra*, § 8:16.) Although both claims rely on negligence principles, the Court has shifted some of the negligence burdens to defendants in "strict liability" claims and has relaxed the burden on plaintiffs who cannot identify the manufacturer's specific negligent acts or omissions that led to the product becoming "defectively" dangerous. (See *ibid.*)

reasonable way to remove its hazards." (1 Owen & Davis, *supra*, § 1:15.) "A product's design and warnings, in other words, need only be as safe as reasonably possible under the prevailing 'state of the art.'" (*Ibid.*)

In an influential law review article published in 1991, the Third Restatement's reporters, Professors Twerski and Henderson described how "[l]egally and conceptually, the frontier of American products liability has closed." (Henderson & Twerski, *supra*, 66 N.Y.U. L. Rev. 1263, 1329.) The professors surveyed American products liability law's "systematic eliminating of conceptual barriers to plaintiffs' recovery" between the 1960s and early 1980s. (*Id.* at 1269–1273.) They then explained why manufacturer liability could not conceptually expand any further—why "the next logical step" of "eliminat[ing] the plaintiff's need to show any type of defect at all" would not, and cannot, ever be taken—not just because it would be socially harmful, but because it would judicially unadministrable. (*Id.* at pp. 1267–1268, 1279–1292, 1329–1330.) As they say, "defect is the conceptual linchpin that holds products liability law together; a system of liability without defect is beyond the capacity of courts to implement." (*Id.* at p. 1267.)

Here, the Court of Appeal Court of Appeal imposed a kind of "defect-free" liability on Gilead—that is, defect-free liability purportedly based on "ordinary negligence." (See *Gilead*, *supra*, 98 Cal.App.5th at p. 935 & fn. 15.) As shown above, and explained below, an "ordinary negligence" claim in the products

liability context makes no sense without a product defect.[6] "A manufacturer or other supplier can hardly be faulted for supplying consumers with a 'good' product—one that is *not* defective." (1 Owen & Davis, *supra*, § 5:29, italics in original.) "So, a finding that a product is not defective for purposes of strict liability in tort logically precludes a finding that the manufacturer or other supplier was negligent in making or selling it in that condition." (*Ibid.*) "An early Minnesota decision succinctly captured the essence of this point: 'If a product is not . . . defective . . . , it is not negligence to manufacture it that way.'" (*Ibid.*, quoting *Halvorson v. American Hoist & Derrick Co.* (Minn. 1976) 240 N.W.2d 303, 307 abrogated on other grounds by *Holm v. Sponco Mfg., Inc.* (Minn. 1982) 324 N.W.2d 207; see also *Prentis v. Yale Mfg. Co.* (Mich. 1984) 365 N.W.2d 176, 181–182 ["Like the courts in every other state, whether a suit is based upon negligence or implied warranty, we require the plaintiff to prove that the product itself is actionable—that something is wrong with it that makes it dangerous"].)[7]

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[6] A products liability negligence claims is simply an "ordinary negligence" claim where a product's design, manufacture, or lack of adequate warnings caused the plaintiff's injury. As in any other "ordinary negligence" claim, the plaintiff must prove that the defendant failed to use ordinary care in its conduct for the safety of others; meaning, the plaintiff must prove that the defendant-manufacturer failed to use ordinary care in designing, manufacturing, and marketing its products. (See above.)

[7] This is a well-established rule across the country. (See, e.g., *Hawkins v. Montgomery Indus., Int'l., Inc.*, (Ala. 1988) 536 So.2d 922, 927; *Gomulka v. Yavapai Mach. & Auto Parts, Inc.* (Ariz. Ct.

App. 1987) 745 P.2d 986, 990; *Garner v. Goodyear Tire & Rubber Co.* (Ark. Ct. App. 2021) 2021 Ark. App. 332, 14 *Merrill*, *supra*, 26 Cal.4th at p. 479; *Walker v. Ford Motor Co.* (Colo. 2017) 406 P.3d 845, 852; *Bifolck v. Philip Morris, Inc.* (Conn. 2016) 152 A.3d 1183, 1208; *Consol. Aluminum Corp. v. Braun* (Fla. Dist. Ct. App. 1984) 447 So.2d 391, 392; *Udoinyion v. Michelin N. Am., Inc.* (Ga. Ct. App. 2011) 721 S.E.2d 190, 193; *Corbridge v. Clark Equipment Co.* (Idaho 1986) 730 P.2d 1005, 1007; *Carrizales v. Rheem Mfg. Co., Inc.* (Ill. App. Ct. 1991) 589 N.E.2d 569, 580; *Kovach v. Caligor Midwest* (Ind. 2009) 913 N.E.2d 193, 197; *Chown v. USM Corp.* (Iowa 1980) 297 N.W.2d 218, 220; *Lane v. Redman Mobile Homes, Inc.* (Kan. Ct. App. 1981) 624 P.2d 984, 988; *Primal Vantage Co., Inc. v. O'Bryan* (Ky. 2022) 677 S.W.3d 228, 245; *W. Cas. & Sur. Co. v. Adams* (La. Ct. App. 1980) 381 So.2d 923, 925; *Ford Motor Co. v. General Acc. Ins. Co.* (Md. 2001) 779 A.2d 362, 370; *Carey v. Gen. Motors Corp.* (Mass. 1979) 387 N.E.2d 583, 587; *Mulholland v. DEC Intern. Corp.* (Mich. 1989) 443 N.W.2d 340, 349; *Halvorson v. American Hoist & Derrick Co.* (Minn. 1976) 240 N.W.2d 303, 307; *Elliott v. El Paso Corp.* (Miss. 2015) 181 So.3d 263, 268; *Strong v. Am. Cyanamid Co.* (Mo. Ct. App. 2007) 261 S.W.3d 493, 528; *Duncan v. Rockwell Mfg. Co.* (Mont. 1977) 567 P.2d 936, 939; *Masi v. R. A. Jones Co.* (N.J. Super. Ct. App. Div. 1978) 394 A.2d 888, 891; *Beckford v. Pantresse, Inc.* (N.Y. App. Div. 2008) 51 A.D.3d 958, 959; *Red Hill Hosiery Mill, Inc. v. MagneTek, Inc.* (N.C. Ct. App. 2000) 530 S.E.2d 321, 326; *Love v. Mack Trucks, Inc.* (Ohio Ct. App. 1985) 500 N.E.2d 328, 333; *Atkins v. Arlans Dept. Store of Norman, Inc.* (Okla. 1974) 522 P.2d 1020, 1022; *Roach v. Kononen* (Or. 1974) 525 P.2d 125, 129; *Sherk v. Daisy-Heddon, a Div. of Victor Comptometer Corp.* (Pa. 1982) 450 A.2d 615, 617; *Thomas v. Amway Corp.* (R.I. 1985) 488 A.2d 716, 721; *Branham v. Ford Motor Co.* (S.C. 2010) 701 S.E.2d 5, 8; *Estate of Olsen v. Agtegra Cooperative* (S.D. 2024) 9 N.W.3d 763, 769; *Browder v. Pettigrew* (Tenn. 1976) 541 S.W.2d 402, 404; *Toshiba Intern. Corp. v. Henry* (Tex. App. 2004) 152 S.W.3d 774, 785; *Gudmundson v. Del Ozone* (Utah 2010) 232 P.3d 1059, 1070; *Evans v. Nacco Materials Handling Group, Inc.* (Va. 2018) 810 S.E.2d 462, 469; *McLaughlin v. Michelin Tire Corp.* (Wyo. 1989) 778 P.2d 59, 64.)

Henderson and Twerski have proven prescient. Today, "[p]roducts liability is [still] circumscribed by defect." (1 Frumer, *et al.*, Products Liability, § 11:01.) "Whether the underlying cause of action sounds in negligence or warranty or strict liability, unless there is an 'imperfection that causes inadequacy or failure; a shortcoming,' there can be no compensation to an injured plaintiff." (*Ibid.*)

After products liability's rapid expansion in the 1960s and 1970s, the intervening decades have been marked by relative stability. The Restatement Third of Torts, Products Liability (Third Restatement), published in 1998, did not propose to expand the scope of manufacture liability as the Second Restatement did under § 402A. The greatest change the Third Restatement proposed is "abandoning distinctions between negligence and strict liability and submitting cases to juries according to the type of proof required for the type of defect plaintiff has alleged." (1 Owen & Davis, *supra*, § 5:29.)

In sum, the history of products liability in this country and within this State is ultimately a search for balance between the desire to compensate those injured by using a product and the need to maintain some fault-based boundaries against absolute manufacturer liability. The pendulum swung in favor of the consumer for much of the twentieth century until it went too far in *Beshada* and it found equilibrium in *Feldman* and *Brown*. The primary fulcrum has been the requirement that there be something wrong with the product to find liability. Because this Court's rule that "under either a negligence or a strict liability

theory of products liability, to recover from a manufacturer, a plaintiff must prove that a defect caused injury" (*Merrill, supra*, 26 Cal.4th at p. 479) is supported by "logic" and "jurisprudential history," the Court of Appeal's decision below ignoring that rule should be reversed.

II. A manufacturer cannot breach a general duty of care by failing to sell alternatives for non-defective products.

Even if there were not a well-established rule barring products liability negligence claims without proof of a product defect (§ I), the Court of Appeal still would have erred in ruling against Gilead. Based on the false assumption that Civ. Code § 1714 imposes a duty to mitigate *any* risk the defendant created, the Court of Appeal errantly concluded "that Gilead has not established its entitlement to summary adjudication under an 'ordinary negligence' theory pursuant to section 1714." (See *Gilead, supra*, 98 Cal.App.5th at p. 935.)

The Court of Appeal is mistaken. The scope of section 1714's general duty of care is limited to *unreasonable* risks created by the defendant. (*Delgado v. Trax Bar & Grill, supra*, 36 Cal.4th at pp. 234–235 ["'[a]s a general principle, "a defendant owes a duty of care to all persons who are foreseeably endangered by his conduct, *with respect to all risks which make the conduct unreasonably dangerous*,"' quoting *Tarasoff v. Regents of Univ. of Cal.* (1976) 17 Cal.3d 425, 434–435, italics added]; *Lugtu v. Cal. Highway Patrol* (2001) 26 Cal.4th 703, 716 ["Under general negligence principles, of course, a person ordinarily is obligated to

exercise due care in his or her own actions so as to not to create an unreasonable risk of injury to others, and this legal duty generally is owed to the class of persons who it is reasonably foreseeable may be injured as the result of the actor's conduct"], citing § 1714.)

Thus, where a plaintiff fails to allege or present evidence that a risk of harm the defendant created was an *unreasonable* risk of harm, no reasonable jury could find that the defendant breached the general duty of ordinary care. (See *McEvoy v. Am. Pool Corp.* (1948) 32 Cal.2d 295, 298 ["The conclusion that certain conduct is negligent involves the finding both of a legal duty to use due care and a breach of such duty by the creation of an unreasonable risk of harm."].) In the products liability context, a defective product is a product failing "'to match a standard of safety defined in terms of conditions that create *unreasonable risks of harm*.'" (*Rattagan v. Uber Techs., Inc.* (2024) 17 Cal.5th 1, 22, italics in original.) Accordingly, if a plaintiff fails to allege or present evidence that a product is defective, then no reasonable jury could find that the manufacturer breached its general duty of care.[8]

[8] In these situations where no jury could find the defendant had breached the duty of care, there is no need to consider whether the *Rowland* factors would justify *exempting* the defendant from the duty. (See *Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 217 ["The multifactor test set forth in *Rowland* was not designed as a freestanding means of establishing duty, but instead as a means for deciding whether to limit a duty derived from other sources."]; *Krupnick v. Hartford Accident & Indemnity Co.* (1994) 28 Cal.App.4th 185, 200 ["[C]onsideration of the seven *Rowland*

These are the precise grounds on which the Seventh Circuit recently rejected the position (that the Court of Appeal held here) that a manufacturer "could face liability 'based on the general duty of ordinary care' even if its products were not defective." (See *Burton v. E.I. du Pont de Nemours & Co., Inc.* (7th Cir. 2021) 994 F.3d 791, 817.) In that case, the plaintiffs argued (as Plaintiffs argue here) that proof of a defect was required only for strict liability claims because under Wisconsin law (like California law) "negligence focuses on the defendant's conduct whereas strict liability focuses on the condition of the product." (See *ibid.*) "That is true enough," the Seventh Circuit acknowledged, but "it does not obviate the need for a product defect" because all it means is "that 'under a negligence theory, a plaintiff will not prevail by showing *only* that a product was defective.'" (*Ibid.*) The court explained the logic of the rule this way: "Requiring a product defect for negligence claims makes sense because otherwise a defendant might be found negligent merely for making and selling a potentially dangerous product." (*Id.* at 818.)

The Seventh Circuit's observations are on point. The Court of Appeal's reconfiguration of products liability law is inconsistent with California's general duty of ordinary care, which like Wisconsin's, requires only that manufacturer's use reasonable care to protect consumers from unreasonable risks arising from their products. An "unreasonable" risk is that posed

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factors can only occur if it first be determined that there is a duty present and that it has been breached."].)

by a defective product. Because Plaintiffs abandoned their claim that Gilead's TDF-based drugs were defective, as a matter of law, TDF could not pose an "unreasonable" risk to them. And Gilead owed no duty to protect patients from the reasonable risk presented by TDF. Thus, even if Plaintiffs' negligence claims could have survived the abandonment of their defect allegations (they could not), the Court of Appeal should have still ruled in Gilead's favor because Plaintiffs failed to allege or prove a negligent act or omission within the scope of Gilead's general duty of care.

III. The Court of Appeal's "ordinary negligence" standard does an end-run around *Brown*.

The Court of Appeal's decision to eliminate the defect requirement and to impose a new duty to produce alternatives to non-defective products is inconsistent with—indeed, antithetical to—"the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use." (*Brown*, *supra*, 44 Cal.3d at p. 1063.) The new standard will likely expose drug manufacturers to equal or greater liability than the strict liability standards to which this Court refused to subject manufacturers in *Brown*. The Court's reasons for refusing to subject manufacturers to that strict liability standard, therefore, apply with equal or greater force against subjecting manufacturers to the Court of Appeal's "ordinary negligence" standard here.

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A. The Court of Appeal's "ordinary negligence" standard will likely expose drug manufacturers to equal or greater liability than the strict liability standards considered in *Brown*.

The Court of Appeal's "ordinary negligence" standard would hold a manufacturer liable if it knew or should have known about a mechanically feasible alternative design that would have been safer for the plaintiff. (*Gilead, supra*, 98 Cal.App.5th at p. 933.) In comparison, the strict liability risk-benefit test allows the imposition of liability only "if, on balance, the risk of danger inherent in the challenged design outweighs the benefits of the design." And under that standard, the existence of a safer alternative design is just one of the factors against which the benefits of the design are weighed. (See *Brown, supra*, 44 Cal.3d at pp. 1057, 1063.) The Court of Appeal thus took one of the several factors considered in determining whether a product is defective and elevated it to a stand-alone standard of liability, in a case where plaintiffs have disclaimed the existence of a defect.

In other words, though this Court determined that the overall threat to manufacturers from defending against strict liability claims was too great, the Court of Appeal created a cause of action that allows a plaintiff to prevail based on merely a single element of the risk-benefit test. Drug manufacturers' theoretical exposure under the Court of Appeal's "ordinary negligence" standard that makes the existence of a safer alternative design outcome determinative is greater than it would have been under a products liability "strict liability"

standard that considers the existence of a safer alternative design as one factor among many.

The Court of Appeal contends its standard applies only to manufacturers who *know* of a safer alternative design and are *motivated* by a desire to maximize profits (see *Gilead*, *supra*, 98 Cal.App.5th at p. 933), but these are not meaningful or workable limitations. Under the strict liability standard, a manufacturer's knowledge of safer alternatives is bound up in the issue of an alternative design's mechanical feasibility given the state of the art. (See *Kim v. Toyota Motor Corp.* (2018) 6 Cal.5th 21, 31; Owen & Davis, *supra*, § 8:12.) That is particularly true for innovative manufacturers (the ones most deserving of comment k's protections), whose knowledge tends to define the state of the art.

Similarly, making liability conditional on a profit motive will do nothing to limit the exposure of private sector manufacturers, whether of drugs or anything else, for whom a consideration of profit and return on investment are inherent in a free-market economy. In fact, to the extent such a profit motive is relevant under the Court of Appeal's standard, the condition would increase manufacturers' liability across the board. The prejudice that discussing a manufacturer's profit motive can engender in a jury will tend to increase both the likelihood and size of a verdict against a manufacturer. (See 1 Owen & Davis, *supra*, § 5:29 ["[S]easoned plaintiff's counsel and an important empirical jury study conclude that juries respond far more favorably to plaintiffs—in both verdict likelihood and size of awards—on the 'hot' rhetoric of negligence than on the 'cold' logic

of strict liability."].)[9] And any standard premised on divining the defendant's particular motives for a specific design decision would make summary judgment a dead letter in most "ordinary negligence" cases.

B. The reasons for shielding drug manufacturers from the strict liability standards in *Brown* compel shielding drug manufacturers from the Court of Appeal's "ordinary negligence" standard here.

Because the Court of Appeal's ostensible "ordinary negligence" standard is likely to expose drug manufacturers to equal or greater liability than a strict liability standard, the reasons motivating this Court to shield drug manufacturers from any strict liability standard apply with equal or greater force in favor of shielding drug manufacturers from the Court of Appeal's "ordinary negligence" standard.

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[9] The referenced study conducted a mock negligence trial and a mock strict liability trial under identical facts; only 26% of jurors in the strict liability trial awarded damages whereas 38% of jurors in the negligence trial awarded damages, and when jurors did award damages in strict liability trials, they were on average about half the size of awards jurors awarded in the negligence trial. (See Cupp & Polage, *The Rhetoric of Strict Products Liability Versus Negligence: An Empirical Analysis* (2002) 77 N.Y.U. L. Rev. 874, 936–937.)

1. The Court's reasons for shielding drug manufacturers from the consumer-expectation test apply in favor of shielding them from the Court of Appeal's "ordinary negligence" standard.

This Court reasoned it would be inappropriate to apply the consumer-expectation test to prescription drugs because it would lead to the absurd result of holding a manufacturer liable "if it has provided appropriate warnings and the doctor fails in his duty to transmit these warnings to the patient or if the patient relies on inaccurate information from others regarding side effects of the drug." (See *Brown, supra*, 44 Cal.3d at p. 1062.) It would be even more absurd were the Court of Appeal's "ordinary negligence" standard allowed to stand, thereby allowing a drug manufacturer to be held liable even where the manufacturer provides appropriate warnings to doctors, the doctors transmit these warnings to the patients, and *relying on those warnings, a plaintiff voluntarily assumes a reasonable risk of taking a prescription drug*.

2. The Court's reasons for shielding drug manufacturers from the risk-benefit test apply in favor of shielding them from the Court of Appeal's "ordinary negligence" standard.

This Court declined to apply the strict liability risk-benefit test to prescription drugs because the costs of doing so would exceed the benefits. (*Brown, supra*, 44 Cal.3d at pp. 1062–1065.) The Court considered the following benefits: (1) deterring manufacturers from selling unsafe drugs, (2) making the drugs

that are still sold even safer, and (3) spreading the cost of drug-caused injuries across all the drug's purchasers. (*Id.* at pp. 1062–1063.) And the Court considered the following costs: (1) making drugs less affordable, (2) deterring the release of available safer alternatives, and (3) deterring research to develop additional safer alternatives. (*Id.* at pp. 1063–1064.) The Court reasoned these costs outweighed the benefits because: (1) prescription drugs "may be necessary to alleviate pain and suffering or to sustain life," and (2) "harm to some users from prescription drugs is unavoidable." (*Id.* at p. 1063.)

Each of these costs is likely to be exacerbated under the Court of Appeal's "ordinary negligence" standard. First, that single-element standard will make drugs even less affordable. As explained above, "ordinary negligence" will likely expose drug manufacturers to even greater liability. And that increased liability will proportionately increase manufacturers' insurance premiums (assuming they can still get coverage) and litigation budgets, so manufacturers will ultimately have to charge consumers more to absorb these costs.

Second, the "ordinary negligence" standard will do more than the strict liability standard to deter manufacturers, not only from releasing new drugs, but also from conducting research to develop new drugs. Strict liability would have deterred this beneficial conduct only by increasing manufacturer's liability for injuries caused by defects in newly developed and released products, thereby decreasing the profit manufacturers could expect to enjoy from selling those products. The Court of Appeal's

"ordinary negligence" standard will have that same effect, and more. The new standard will further deter manufacturers from researching and developing alternative drugs because doing so will expose the manufacturers to liability for injuries caused by their *non-defective* drugs.

Finally, the Court of Appeal's opinion is inconsistent with *Brown* in one further respect: The Court of Appeal defends its "ordinary negligence" standard as a legitimate legal theory separate from a negligent-design theory because Gilead's liability will not be based on an evaluation "in the abstract" of "whether TDF should have been marketed at all," but rather, it will be based on Gilead's failure to sell an alternative to TDF that would have been safer for the particular plaintiffs at bar. (See *Gilead, supra*, 98 Cal.App.5th at p. 933.) But one of the very reasons this Court in *Brown* disapproved of the approach from *Kearl v. Lederle Laboratories* (1985) 172 Cal.App.3d 812 (where the court effectively required a mini-trial to determine whether the drug should be judged by the liability standard of comment k or under strict liability standards) was that "the question of the superiority of one drug over another would have to be decided *not in the abstract but in reference to the plaintiff*." (*Brown, supra*, 44 Cal.3d at p. 1068, italics added.) That is a problematic approach, this Court explained, because "in one case the drug that injured the plaintiff might be the better choice, while this would not be true as to another user." (*Ibid.*) What this Court declared to be a bad rule in *Brown* cannot be the justification for expanding manufacturer liability here.

CONCLUSION

The Court of Appeal's ruling against Gilead is a radical departure from established products liability law—namely, that proof of a defect is a necessary element of products liability negligence claim; that a general duty of reasonable care cannot require manufacturers to do anything beyond selling non-defective products; and that a drug manufacturer's liability must be limited to protect the public's interest in innovative and affordable prescription drugs. To restore California products liability law to the reasoned bounds of these three principles, PLAC joins Gilead in asking this Court to reverse the Court of Appeal's decision below.

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CERTIFICATE OF WORD COUNT

Pursuant to Rule 8.520(c)(1) of the California Rules of Court and in reliance on the word count of the computer program used to prepare this Proposed Amici Curiae Brief, counsel certifies that the text of this brief (including footnotes) was produced using 13-point type and contains 6,994 words. This includes footnotes but excludes the tables required under Rule 8.204(a)(1), the cover information required under Rule 8.204(b)(10), the Certificate of Interested Entities or Persons required under Rule 8.208, the Application to File Amici Curiae Brief required under Rule 8.520(f), this certificate, and the signature blocks. (See Rule 8.204, subd. (c)(3).)

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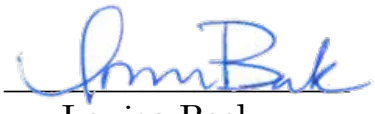
PROOF OF SERVICE

I am employed in the County of Orange, State of California. I am over the age of 18 and not a party to the within action. My business address is at Bowman and Brooke LLP, 2929 N. Central Avenue, Suite 1900, Phoenix, AZ 85012. On November 4, 2024, I served the APPLICATION FOR LEAVE TO FILE AMICUS CURIAE BRIEF AND PROPOSED BRIEF OF AMICUS CURIAE PRODUCT LIABILITY ADVISORY COUNSEL, INC. IN SUPPORT OF PETITIONER on the interested parties identified below in this action through TrueFiling e-service, except for those referenced as being served by U.S. Mail with first class postage.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct. Executed on November 4, 2024, at Phoenix, Arizona.



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