S283862

IN THE SUPREME COURT OF CALIFORNIA

GILEAD TENOFOVIR CASES

GILEAD SCIENCES, INC.,
Petitioner

v.

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

and

PLAINTIFFS IN JCCP NO. 5043,
Real Parties in Interest

Review of a Decision by the Court of Appeal,
First Appellate District, Division Four, Case No. A165558
San Francisco County Superior Court Case No. CJC-19-005043
Hon. Andrew Y.S. Cheng

APPLICATION OF INTERNATIONAL ASSOCIATION OF DEFENSE COUNSEL FOR LEAVE TO FILE AMICUS BRIEF AND AMICUS BRIEF IN SUPPORT OF PETITIONER GILEAD SCIENCES, INC.

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APPLICATION OF INTERNATIONAL ASSOCIATION OF DEFENSE COUNSEL FOR LEAVE TO FILE AMICUS CURIAE BRIEF

Pursuant to Rule 8.520(f) of the California Rules of Court, the International Association of Defense Counsel ("IADC") requests permission to file the attached Amicus Brief in support of Petitioner Gilead Sciences, Inc. ("Gilead").

Interest of Amicus Curiae

Founded in 1920, the IADC is an association of approximately 2,500 invitation-only, peer-reviewed attorneys who work in corporations, for insurers, and at law firms and whose practices are concentrated on the defense of civil lawsuits. The IADC is dedicated to the just and efficient administration of civil justice and the continual improvement of the civil justice system. The IADC supports a justice system in which plaintiffs are fairly compensated for genuine injuries, responsible defendants are held liable only for appropriate damages, and non-responsible defendants are exonerated without unreasonable cost. The IADC's activities seek to benefit the civil justice system and the legal profession.

In particular, the IADC maintains an abiding interest in the fair and efficient administration of actions involving liability over the use of products. The IADC's Product Liability Committee consists of more than 900 members, publishes regular newsletters and journal articles, and presents education

seminars both internally and to the legal community at large. The IADC has participated as amicus curiae in several cases before the California Supreme Court involving products liability issues. *See, e.g.*, *Kim v. Toyota Motor Corp.*, 6 Cal.5th 21 (2018); *T.H. v. Novartis Pharms., Corp.*, 4 Cal.5th 145 (2017); *Ramos v. Brenntag Specialties, Inc.*, 63 Cal. 4th 500 (2016).

How the Attached Amicus Brief Will Assist the Court.

In this case, Gilead has asked the Court to consider whether (1) a plaintiff who sues a manufacturer claiming injury from the manufacturer's product must prove that the product is defective, and (2) a manufacturer of a non-defective product has a duty to develop, without delay, a different product that is safer for some consumers. (Opening Br. at 8.) The Court's resolution of these issues will have profound consequences not just for the pharmaceutical industry but for any manufacturer that seeks to sell its products in California, the world's fifth largest economy. The Court's resolution of these issues also will profoundly affect consumers, who stand to benefit or lose depending on whether manufacturers are incentivized to produce products that are both innovative and safe.

The IADC respectfully submits that the attached Amicus Brief will assist the Court in resolving these issues in a way that protects both manufacturers and the consumers who use and rely on their products. The arguments presented by the IADC are

complementary to, but not duplicative of, the briefing submitted by Gilead.

No Party or Counsel for a Party Authored or Contributed to the Attached Amicus Brief

Pursuant to Rule 8.520(f)(4) of the California Rules of Court, the IADC affirms that (1) no party or counsel for a party in this proceeding authored or contributed to the funding of the attached Amicus Brief, and (2) no one other than the IADC, its members, or its counsel in this case made a monetary contribution intended to fund the preparation or submission of the attached Brief.

Conclusion

For the foregoing reasons, the IADC requests that the Court permit the filing of the attached Amicus Brief in support of Gilead.

Dated: November 4, 2024

Respectfully submitted,

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I. INTRODUCTION.

After years of litigation, Plaintiffs capitulated and said they did not want to pursue a claim that TDF was defective in design. Plaintiffs' renunciation of that claim should come as no surprise. TDF medications have allowed countless people with HIV to escape a death sentence and live normal lives. That life-saving benefit unquestionably outweighs the extremely remote risks of bone density and kidney effects associated with TDF, which Gilead fully disclosed to patients and physicians through labeling approved by the federal Food and Drug Administration ("FDA"). (Opening Br. at 11-12.) Under the circumstances, it is highly unlikely any jury would conclude that the potential risks of TDF outweigh its benefits—and, indeed, Plaintiffs do not argue otherwise.

When Plaintiffs admitted they would not seek to prove TDF was defective, that should have ended the matter. The trial court should have dismissed their negligence claim by applying a well-settled rule of law that has existed for a century—namely, that a plaintiff seeking to recover in negligence for personal injury caused by a product *must* prove that the product is defective. But the trial court refused to do so. And the Court of Appeal then sanctioned that error by acquiescing in Plaintiffs' bid to repackage what is in essence a garden variety negligent design claim into a novel claim based on an unprecedented duty—*i.e.*, to

develop and market without delay a new medication (TAF) as an alternative to a non-defective one (TDF). Moreover, the Court of Appeal justified that new duty by relying solely on Plaintiffs' contested allegations rather than evidence in the summary-judgment record, as required.

This Court should recognize Plaintiffs' claim for what it is. Plaintiffs contend that the remote risks associated with TDF are unacceptably high, and that TAF provided a safer alternative. Contrary to the Court of Appeal's conclusion, that claim is not "meaningfully different" from a "typical" negligent design claim. *Gilead Tenofovir Cases*, 98 Cal.App.5th 911, 931, 933 (2024) ("*Gilead*"). It *is* a negligent design claim—albeit one that fails because Plaintiffs have renounced any intention to prove a defect.

Moreover, the reasons offered by the Court of Appeal for treating Plaintiffs' claim as something other than a typical negligent design claim do not pass muster. The court emphasized that Plaintiffs' claim does not depend on balancing the risks and benefits of TDF in isolation. But that misapprehends the actual balancing to which their claim should be subject. Because Plaintiffs' claim is based on the existence of an ostensibly safer alternative design, this Court's precedents require a jury to balance the risks and benefits of TDF against those of TAF, not to judge with the benefit of hindsight whether Gilead acted reasonably based on little more than proof that TAF might be

safer for a narrow subset of patients. Further, Gilead's alleged financial motive for delaying commercialization of TAF is not conduct "independent" of TDF's design, as the court incorrectly believed. Instead, a jury could take that purported profit motive into account as part of its risk-benefit balancing—as juries may do in any design-defect case. Because Plaintiffs' claim at its core is no different than a typical negligent design claim, the Court should resolve that claim by applying settled California law, which requires proof of a defect.

By exempting Plaintiffs' claim from the defect requirement, the Court of Appeal effectively erased the standard of liability in design-defect cases that this Court crafted more than 50 years ago. And it did so without *any* showing that changed circumstances somehow justify a new rule of liability. That is not acceptable. Under the new liability test adopted by the Court of Appeal and urged by Plaintiffs, a jury would no longer need to conduct *any* meaningful risk-benefit balancing. So long as a particular plaintiff's injury could have been avoided by use of an alternative design, a jury may impose liability even if the benefits of the product used exceed the risks, and even if the alternative design would have created a risk of harm to other users. That is no different than absolute liability for injury from a product, which this Court long has rejected. Moreover, there is no limiting principle that would confine this new liability test to the

pharmaceutical context. To the contrary, the Court of Appeal's new test could apply across all industries.

The Court of Appeal justified this radical departure from precedent by invoking Civil Code section 1714. But the purpose of that statute is merely to provide a code foundation for judicial development of common-law rules—such as the defect requirement, which has been the law in California for a century. Section 1714 does not authorize courts to expand existing duties of care in derogation of established common law in the absence of some compelling justification, which does not exist here. Moreover, the new duty recognized by the Court of Appeal—to develop and commercialize without delay an alternative to a non-defective product—turns products liability law on its head by penalizing manufacturers for actions taken with respect to products that do not reach the marketplace. That is the opposite of how products liability law works.

Finally, the damage created by the Court of Appeal's decision is not just doctrinal. It will have seismic consequences in the real world. Due to the innumerable trade-offs inherent in the design process, the boundless duty recognized by the Court of Appeal is bound to stifle innovation, reduce consumer choice, threaten consumer safety, and subject manufacturers across all industries to limitless liability for just about any decision they could make when developing and marketing new products. In

other cases, this Court has been careful to impose meaningful limits on liability to avoid undesirable outcomes such as these. It should do the same here. To strike the appropriate balance between consumer safety and access to innovative products, this Court should reject any duty that would require a manufacturer to develop and market an alternative to a non-defective product.

II. THIS COURT SHOULD REVERSE BY APPLYING SETTLED LAW TO PLAINTIFFS' FAILED PRODUCTS LIABILITY CLAIM.

The Court of Appeal recognized that Plaintiffs are asserting a "products liability" claim founded on negligence. *Gilead*, 98 Cal.App.5th at 930-31, 933. That fact should have resulted in dismissal of their claim. For almost 100 years, this Court has conditioned a plaintiff's right to recover in negligence for injury caused by a product on proof of a defect. Rather than apply this Court's precedents, however, the Court of Appeal cast them aside in favor of a new rule permitting recovery in negligence "even when there is no showing that the injury resulted from a product defect." *Id.* at 925. None of the reasons the court gave for its break from precedent withstands scrutiny. Accordingly, this Court should reaffirm that the legal concept of a "defect" remains the outer boundary of a manufacturer's liability in products liability cases.

A. Plaintiffs Unquestionably Are Pursuing a Products Liability Claim.

The Court of Appeal was correct to observe that Plaintiffs assert a products liability claim. After all, "products liability" claims are those that seek to recover for harm caused by "products placed on the market." *Pike v. Frank G. Hough Co.*, 2 Cal.3d 465, 470, 474 (1970). As one court recognized, the very "essence" of a "products liability" claim is that a plaintiff sustained "injury" due to use of a "product." *Moreno v. Sayre*, 162 Cal.App.3d 116, 124 (1984).

That is what this case is about. As the opening paragraphs of the Court of Appeal's decision recite, Plaintiffs allege they sustained skeletal and kidney damage "from their use of TDF," and they contend TAF could have been "as effective as TDF at treating HIV/AIDS, while carrying a lower risk of adverse effects." *Gilead*, 98 Cal.App.5th at 916. Moreover, Plaintiffs *themselves* contend that Gilead's sale of TDF is what gave rise to its purported duty not to delay commercialization of TAF. (Answer Br. at 19.) Thus, there is no question that Plaintiffs are asserting a products liability claim. *See also* Prosser & Keaton, THE LAW OF TORTS (5th ed. 1984) § 95, p. 677 ("Products liability is the name currently given to the area of the law involving the liability of those who supply goods or products[.]").

The problem, discussed next, is that Plaintiffs are unwilling to prove the key element of a products liability claim—to wit, that the product that allegedly injured them is defective.

B. The Court of Appeal Erred in Holding that a Products Liability Claim Sounding in Negligence Does Not Require Proof of a Defect.

The Court of Appeal veered off the rails by excusing Plaintiffs from their burden to prove TDF is defective. There is no support for that holding.

For years, California law has recognized three types of product defects: manufacturing defects, design defects, and warning defects. *See, e.g.*, *Webb v. Special Electric Co.*, Inc., 63 Cal.4th 167, 180 (2016); *Anderson v. Owens-Corning Fiberglas Corp.*, 53 Cal.3d 987, 995 (1991); *Barker v. Lull Eng'g Co.*, 20 Cal.3d 413, 428 (1978). And for years, California law also has recognized that a plaintiff may pursue a products liability claim under either a strict liability theory or a negligence theory. *See, e.g.*, *Webb*, 63 Cal.4th at 181; *Merrill v. Navegar, Inc.*, 26 Cal.4th 465, 478 (2001); *Jiminez v. Sears, Roebuck & Co.*, 4 Cal.3d 379, 383 (1971); *Vandermark v. Ford Motor Co.*, 61 Cal.2d 256, 260-61 (1964).

Regardless of which theory a plaintiff chooses, however, the plaintiff *must* prove that a defect caused injury. *See, e.g.*, *Merrill*, 26 Cal.4th at 479 ("[U]nder 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."); *Jiminez*, 4 Cal.3d at 383 ("[I]n a products liability case the plaintiff in order to recover in strict liability in tort must prove that he was injured by a defect in the product and that the product was defective when it left the hands of the retailer or manufacturer; whereas to recover in negligence the plaintiff must prove the same two elements plus an additional element, namely, that the defect in the product was due to negligence of the defendant."); *Vandermark*, 61 Cal.2d at 261 (both strict liability and negligence "focus responsibility for defects . . . on the manufacturer"); *see also* RESTATEMENT (THIRD) OF TORTS, PRODS. LIAB. § 2 ("Negligence rests on a showing of fault leading to product defect. Strict liability rests merely on a showing of product defect.").

Indeed, this is one of the "basic tort principles" that has guided California courts for decades. *Merrill*, 26 Cal.4th at 478; *see also Soule v. General Motors Corp.*, 8 Cal.4th 548, 568 n.5 (1994) (manufacturers "are liable in tort *only* when 'defects' in their products cause injury") (emphasis added). Moreover, this "basic" principle is not unique to California. It applies across jurisdictions. *See, e.g.*, *Prentis v. Yale Mfg. Co.*, 365 N.W.2d 176, 181-82 (Mich. 1984) ("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. This idea of 'something wrong' is usually expressed by the adjective 'defective' and the plaintiff must, *in every case, in every jurisdiction*, show that the product was defective.").[1]

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[1] *See also Knepfle v. J-Tech Corp.*, 48 F.4th 1282, 1297 (11th Cir. 2022) (under either a negligence or strict liability theory, "a plaintiff must show" that "a defect was present in the product") (internal quotation marks omitted); *Burton v. E.I. du Pont de Nemours & Co.*, 994 F.3d 791, 818 (7th Cir. 2021) (negligence and strict liability have "one thing in common: Both causes of action require a plaintiff to prove that the product causing injury was 'defective'") (internal quotation marks omitted); *Kosmynka v. Polaris Indus., Inc.*, 462 F.3d 74, 86 (2d Cir. 2006) ("Both negligence and strict products liability . . . require a showing of a product 'defect.'"); *Brown v. Sears, Roebuck & Co.*, 328 F.3d 1274, 1278 (10th Cir. 2003) (negligence and strict liability are "[a]lternative theories" to prove "different categories of defective product") (internal quotation marks omitted); *Tipton v. Michelin Tire Co.*, 101 F.3d 1145, 1150 (6th Cir. 1996) ("proof of a *defective product* is essential" under both negligence and strict liability theories); *Reagan v. Hi-Speed Checkweigher Co., Inc.*, 30 F.3d 947, 948 (8th Cir. 1994) ("Where strict liability or negligent design, or both, are alleged, a plaintiff must prove that there was a defect in the defendant's product[.]"); *Sexton By & Through Sexton v. Bell Helmets, Inc.*, 926 F.2d 331, 336 (4th Cir. 1991) ("proof of a defective product is essential" to both a negligence and a strict liability claim); *Garrett v. Hamilton Standard Controls, Inc.*, 850 F.2d 253, 257 (5th Cir. 1988) ("[A]lthough a negligence claim requires a different showing from a strict liability claim, a manufacturer logically cannot be held liable for failing to exercise ordinary care when producing a product that is not defective[.]"); *Murray v. Fairbanks Morse*, 610 F.2d 149, 157 (3rd Cir. 1979) ("The advantage of strict products liability theory is that the plaintiff need only prove the existence of a product defect and not that negligence caused it.").

Not surprisingly, before the lower court abandoned this settled rule, other California courts uniformly embraced it, agreeing that the defect requirement applies in both strict liability *and* negligence cases. *See, e.g.*, *Defries v. Yamaha Motor Corp.*, 84 Cal.App.5th 846, 858-59 (2022); *Mize v. Mentor Worldwide LLC*, 51 Cal.App.5th 850, 861 (2020); *Trejo v. Johnson & Johnson*, 13 Cal.App.5th 110, 125 (2017); *Sherman v. Hennessy Indus., Inc.*, 237 Cal.App.4th 1133, 1139 (2015); *Brady v. Calsol, Inc.*, 241 Cal.App.4th 1212, 1218 (2015); *Johnson v. United States Steel Corp.*, 240 Cal.App.4th 22, 30-31 (2015); *Scott v. C.R. Bard, Inc.*, 231 Cal.App.4th 763, 773 (2014); *Chavez v. Glock, Inc.*, 207 Cal.App.4th 1283, 1304 (2012); *Taylor v. Elliott Turbomachinery Co.*, 171 Cal.App.4th 564, 575 (2009); *Stephen v. Ford Motor Co.*, 134 Cal.App.4th 1363, 1370-71, 1373 (2005).

In fact, the Court of Appeal below acknowledged that "no California case" has decided that an injured plaintiff who asserts a products liability claim may recover in negligence "when there is no showing that the injury resulted from a product defect." *Gilead*, 98 Cal.App.5th at 925. That is true, but it is only half the story. What the Court of Appeal failed to acknowledge is that other courts have considered and *rejected* theories like the one adopted below that would dispense with the defect requirement.

For example, in *Valentine v. Baxter Healthcare Corp.*, 68 Cal.App.4th 1467 (1999), the plaintiffs argued that a

manufacturer of silicone breast implants was negligent not only in designing, manufacturing, and warning about the implants, but also in failing to sufficiently test and inspect them. *See id.* at 1475. The court rejected that theory, reasoning a duty to test and inspect "has no significance apart from the results of the product's design, and manufacture and the relevant warnings." *Id.* at 1485.

Other courts have reached similar results. For example, the *Trejo* court confirmed that "under either a negligence or a strict liability theory of products liability," a plaintiff "must prove that a defect caused injury." 13 Cal.App.5th at 125. Based on that settled principle, the jury's finding that the manufacturer was negligent in failing to warn was "fatally inconsistent" with its finding that the manufacturer was not strictly liable for failing to warn, because *both* claims were premised on the same warning "defect." *Id.* at 127-28. Similarly, in *Lambert v. General Motors*, 67 Cal.App.4th 1179 (1998), the court held that where the design of an automobile was not defective, thereby eliminating strict liability, the manufacturer could not be liable in negligence for failing to exercise reasonable care in testing or designing the vehicle. *See id.* at 1185.

Undeterred by these authorities and the absence of any case law supporting its position, the Court of Appeal below charted an unprecedented course by drawing a bright line

between a products liability claim and a claim for general negligence—notwithstanding the court's obviously correct observation that Plaintiffs in fact *are* asserting a products liability claim against Gilead for harm allegedly caused by TDF. The court attempted to justify that demarcation based on its view that a general negligence claim for injury caused by a product "[i]n theory" does not require proof of a defect. *Gilead*, 98 Cal.App.5th at 924. Not only is that wrong for the reasons stated, but the court reached that erroneous conclusion based on two false premises.

1. The defect requirement arose in the negligence context.

First, the court asserted that the sole "purpose" of the defect requirement "is to prevent strict liability from expanding into absolute liability." *Id.* at 923. That is not true.

Strict liability did not *add* the defect requirement to California law, as the court incorrectly assumed. To the contrary, the defect requirement *pre-dates* this Court's adoption of strict liability in *Greenman v. Yuba Power Products, Inc.*, 59 Cal.2d 57 (1963)—by more than *three decades*. *See, e.g.*, *Stultz v. Benson Lumber Co.*, 6 Cal.2d 688, 690 (1936) ("The recovery by third persons on the basis of negligence for injuries by reason of defective material used in manufacture arose as an exception to the general rule that recovery for such injuries may be had only

by the party to the contract of sale."); *see also Vandermark*, 61 Cal.2d at 261 ("[E]ven before such strict liability was recognized, the manufacturer of a completed product was subject to vicarious liability for the negligence of his suppliers or subcontractors that resulted in defects in the completed product."); *Escola v. Coca Cola Bottling Co. of Fresno*, 24 Cal.2d 453, 460 (1944) (permitting recovery in negligence for injury resulting from "defective bottle"); *Sheward v. Virtue*, 20 Cal.2d 410, 412 (1942) (same, where injury resulted from "a defective leg in a chair"); *Kalash v. Los Angeles Ladder Co.*, 1 Cal.2d 229, 233 (1934) (same, where injury resulted from "defective" ladder).

2. No authority justifies abandoning the defect requirement.

Second, the court believed that a few California courts had permitted injured plaintiffs to recover in negligence in the absence of any showing "that the injury resulted from a product defect." *Gilead*, 98 Cal.App.5th at 926. That is wrong too. None of the cases identified by the court permitted recovery without a showing that a product defect caused the plaintiff's injury. To the contrary, the existence of a defect was implicit in the negligence claims asserted in each of those cases.

Take *Mexicali Rose v. Superior Court*, 1 Cal.4th 617 (1992). The Court in *Mexicali Rose* did *not* "hold" that a plaintiff may recover under the doctrine of negligence for harm caused by a

product "notwithstanding the plaintiff's inability to prove a product defect." *Gilead*, 98 Cal.App.5th at 925. Instead, the Court simply adopted a rule under which a plaintiff could pursue both a strict liability claim and a negligence claim for "foreign" defects in prepared food products, but could pursue only a negligence claim for "natural" defects in such products.[2] *Mexicali Rose*, 1 Cal.4th at 620-21, 633; *see also id.* at 644 ("I see no reason to breathe new life into an arbitrary and artificial distinction between natural and foreign defects in food products.") (Mosk, J., dissenting). That rule derived from the Court's adoption of a "reasonable expectation" standard applicable to both strict liability *and* negligence claims in the context of prepared foods as well its reliance on *Loyacano v. Continental Insurance Co.*, 283 So.2d 302 (La.Ct.App. 1973), which authorized negligence claims but not strict liability claims where the "defect" is a "natural one." *Id.* at 621, 627-28, 632; *see also Loyacano*, 283 So.2d at 305-06. Moreover, there *was* a "natural" defect in *Mexicali Rose*—a chicken bone that did not belong in a customer's chicken enchilada. *See* 1 Cal.4th at 620. That defect is no different than a typical manufacturing defect. On top of that, this Court

[2] This rule is similar to the one applicable in the pharmaceutical context, where prescription drug manufacturers are subject to negligence liability for design defects but not strict liability. *See Brown v. Superior Ct.*, 44 Cal.3d 1049, 1069 & n.12 (1988); *Scott*, 231 Cal.App.4th at 773.

expressly stated that its "holding" was "limited in application to commercial restaurant establishments." *Id.* at 619 n.1. Given all this, *Mexicali Rose* does *not* "demonstrate" that a manufacturer's duty of reasonable care "can extend more broadly than the duty to make a non-defective product." *Gilead*, 98 Cal.App.5th at 925. Far from it.

The Court of Appeal was equally wrong to conclude that *Lunghi v. Clark Equipment Co.*, 153 Cal.App.3d 485 (1984), and *Hernandez v. Badger Construction Equipment Co.*, 28 Cal.App.4th 1791 (1994), "permitted recovery under claims of negligence in the absence of a defect." *Id.* at 926-27. The *Lunghi* and *Hernandez* courts simply held that even though juries found the products at issue were not defective in design when placed into the stream of commerce, the manufacturer defendants were subject to liability under a failure-to-warn theory and/or a failure-to-retrofit theory based on post-sale evidence showing the products became dangerous over time when used in a reasonably foreseeable manner. *See Lunghi*, 153 Cal.App.3d at 494; *Hernandez*, 28 Cal.App.4th at 1828-31. Contrary to the Court of Appeal's suggestion, these types of claims are rooted in a theory of product defect, as confirmed by the Judicial Council-approved jury instruction governing such claims. *See* CACI 1223 (plaintiff must prove defendant became aware of "this defect" after the product was sold); *see also Johnson & Johnson Talcum Powder*

Cases, 37 Cal.App.5th 292, 318 (2019) (citing *Hernandez* as an example of a "manufacturer['s] alleged negligence in failing to correct a defect affecting an earlier model of a product still in use"); *Roberts v. Electrolux Home Prods., Inc.*, 2013 WL 7753579, at *13 (C.D. Cal. Mar. 4, 2013) (citing *Lunghi* for proposition that duty to retrofit can arise when post-sale knowledge puts manufacturer on notice of "a dangerous product defect"). That is why the *Lunghi* court stressed that the trial court was "analytically correct" that "a finding of no defect would preclude recovery for negligence." 153 Cal.App.3d at 492.

In short, California law always has conditioned recovery for personal injury caused by a product—whether under a strict liability theory *or* a negligence theory—on proof of a defect. In concluding otherwise, the Court of Appeal erred.

C. The Court of Appeal Erred in Finding that Plaintiffs Are Not Asserting What Is in Effect a Negligent Design Claim.

The Court of Appeal also erred in finding that Plaintiffs' negligence claim was "meaningfully different" from a "typical" negligent design claim. *Gilead*, 98 Cal.App.5th at 931, 933. That error derives from Plaintiffs' bid to "characterize" their claim as one for ordinary negligence untethered to a design defect. *Id.* at 917. If the Court of Appeal believed it was compelled to accept Plaintiffs' characterization of their claim, it was mistaken. As this Court confirmed more than 20 years ago, a plaintiff may not

avoid California's long-standing defect requirement "simply by declining to use the word 'defect' or 'defective'" and "reformulating their claim" as one based only on a manufacturer's "negligent conduct." *Merrill*, 26 Cal.4th at 478, 481. Instead, when a plaintiff's allegations "fit within the risk/utility test for defective design that applies in a products liability action under both negligence and strict liability theories"—as Plaintiffs' allegations here do (*see infra* Part II.C.1)—courts should treat the claim for what it is: a design-defect claim. *Merrill*, 26 Cal.4th at 481.

Further, the Court of Appeal's acquiescence in Plaintiffs' mischaracterization of their claim reflects a fundamental misunderstanding of the law governing design-defect claims. When a plaintiff asserts a products liability claim challenging a product's design, the jury must weigh multiple factors to determine whether the design is defective. This is true regardless of whether the plaintiff proceeds under a strict liability theory or a negligence theory.

In a strict liability action based on defective design, a product is defective if "the benefits of the challenged design do not outweigh the risks of danger inherent in such design." *Barker*, 20 Cal.3d at 418.[3] In applying this risk-benefit test, a

[3] A plaintiff also may establish a design defect through the consumer-expectations test. *See Barker*, 20 Cal.3d at 418. This alternative test, however, is reserved for a special category of

jury may consider, among other relevant factors, (1) the gravity of the danger posed by the challenged design, (2) the likelihood that such danger would occur, (3) the feasibility of a safer alternative design, (4) the financial cost of an improved design, and (5) the adverse consequences to the product and the consumer that would result from an alternative design. *See id.* at 431; *see also* CACI 1204.

As with a strict-liability claim under the risk-benefit test, the test for negligent design involves "a balancing of the likelihood of harm to be expected from a machine with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm." *Pike*, 2 Cal.3d at 470. In other words, the "evidentiary matters" relevant to the existence of a defect in the strict liability context are the same as those in the negligence context. *Barker*, 20 Cal.3d at 431; *see also Kim v. Toyota Motor Corp.*, 6 Cal.5th 21, 36 (2018). This explains why the Court recognized in *Merrill* that "the risk/utility test for defective design" "applies in a products liability action under both negligence and strict liability

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cases in which the everyday experience of the product's users permits a conclusion that the product's design violated minimum safety assumptions and is thus defective regardless of expert opinion about the merits of its design. *See Soule*, 8 Cal.4th at 567. Unless the facts permit such a conclusion, the jury "must engage" in the balancing of risks and benefits required under *Barker*. *See id.* at 568.

theories." 26 Cal.4th at 481. The difference between the two theories is that unlike a strict liability claim, a negligent design claim requires proof that the defect resulted from the manufacturer's negligence. *See id.* at 479.

When Plaintiffs insisted they did not seek to prove TDF was defective, the Court of Appeal should have dismissed their negligence claim. As even the Court of Appeal acknowledged, a negligent design claim *requires* proof of a defect—just like a strict liability claim. *See Gilead*, 98 Cal.App.5th at 934 n.14 ("[T]he trial court's ruling was in error to the extent it suggested plaintiffs can pursue a claim for negligent design without proving the equivalent of a design defect.").

Instead of doing that, however, the Court of Appeal accepted Plaintiffs' argument that their negligence claim was somehow different than any other claim challenging a product's design. *See id.* at 931, 933. The court offered two explanations to support that conclusion. Neither holds water.

1. The court failed to take account of the actual risk-benefit balancing that a jury must undertake.

First, the court reasoned that Plaintiffs' claim "does not depend on an evaluation of the risks and benefits of TDF as an HIV/AIDS medication, as would be necessary in a claim for negligent design," and that "[t]he risks and benefits of TDF *relative to each other* are irrelevant to plaintiffs' claim." *Id.* at

933. But the court's reasoning misapprehends the actual balancing of risks and benefits at issue.

By its very nature, a design-defect claim "envisions a comparison" between the "challenged design" of a product and the design of "some comparatively safe alternative." K. Hylton, *The Law and Economics of Products Liability*, 88 NOTRE DAME L. REV. 2457, 2492 (2013). In California, that comparison is required under both a strict liability theory *and* a negligence theory. *Compare Barker*, 20 Cal.3d at 431 (enumerating the factors a jury must weigh in assessing a strict liability claim, which include the advantages and disadvantages of an alternative design), *with Pike*, 2 Cal.3d at 470 (same as to negligence claim).

Thus, under this Court's precedents, Plaintiffs' claim would require that a jury balance the risks and benefits of TDF against those of an alternative design—namely, TAF. *See Barker*, 20 Cal.3d at 434 ("weighing the extent of the risks and the advantages posed by alternative designs is inevitable in many design defect cases"); *see also Soule*, 8 Cal.4th at 563 (the "complex weighing of risks, benefits, and practical alternatives is 'implicit' in so many design-defect determinations"). After all, the gravamen of Plaintiffs' claim is that "TAF presented a safer alternative to TDF." *Gilead*, 98 Cal.App.5th at 919; *see also id.* at 920, 931, 933 (emphasizing that Plaintiffs' claim is premised on

TAF's purported "superiority"). Underpinning that claim is Plaintiffs' contention that TDF posed an unreasonable risk of "serious side effects that it knew TAF would have enabled patients to avoid." *Id.* at 931. That is why the Court of Appeal acknowledged that "the characteristics of TDF" and the alleged "equivalent efficacy and superior safety" of TAF are "central" and "critical" to Plaintiffs' claim. *Id.* at 933.

In adjudicating *that* claim, a jury cannot assess the risks and benefits of TDF in isolation. Instead, a jury must assess the risks of benefits of *both* TDF *and* TAF "*relative to each other*." *Id.* That is what *Barker*, *Pike*, and this Court's other precedents teach—namely, that a jury must weigh the risks and benefits of an alleged injury-producing product against those of an alternatively designed one. *See, e.g.*, *Brown*, 44 Cal.3d at 1062 (under a risk-benefit balancing, the risks and benefits of a purportedly "safer" drug would be compared against those of the challenged drug); *see also Kim*, 6 Cal.5th at 26 (the relevant inquiry turns on "the jury's evaluation of whether the product is as safely designed as it should be, considering the feasibility and cost of alternative designs"); *Finn v. G. D. Searle & Co.*, 35 Cal.3d 691, 699 (1984) (in a design case, the jury "weigh[s] the reasonableness of the design against alternative designs presented by the plaintiff") (internal quotation marks omitted).

By defying this Court's precedents and holding that Plaintiffs need not prove a defect, however, the Court of Appeal's decision, if allowed to stand, ensures that a jury will not engage in this required risk-benefit balancing. Instead, a jury will be preoccupied with deciding whether Gilead's "conduct" was reasonable under a nebulous, hindsight-driven test. *Gilead*, 98 Cal.App.5th at 924, 926, 931. So long as Plaintiffs can prove TAF would have been safer for *them* (a small subset of all TDF patients), a jury can find that Gilead acted unreasonably in delaying its commercialization—no matter that the benefits of TDF undisputedly exceed its risks (both for them and all other patients who took the medication), and regardless of whether TAF poses a risk of harm to *other patients*. That is perverse.

In short, if Plaintiffs' claim is "meaningfully different" from a "typical" negligent design claim, *id.* at 931, 933, it is only because the Court of Appeal allowed Plaintiffs to pursue that claim without regard to the one requirement that is common to *all* design claims whether based on strict liability *or* negligence—*i.e.*, proof of a defect.

2. A jury may consider Gilead's alleged profit motive as part of its risk-benefit balancing.

Second, the Court of Appeal believed Plaintiffs' claim was distinguishable from a "typical negligent design" claim because Plaintiffs couched their claim in Gilead's "alleged financially

motivated deferral of the development of TAF." *Gilead*, 98 Cal.App.5th at 931. The court viewed that as "discrete conduct independent of the design and marketing of TDF." *Id.* Here too, the court mis-stepped.

In a design-defect case, a jury must consider the economic consequences posed by an alternative design. Again, that is true regardless of whether a plaintiff proceeds under a theory of strict liability or negligence. *Compare Barker*, 20 Cal.3d at 431 (strict liability claim requires jury to consider the "financial cost" and "adverse consequences to the product and to the consumer" of an alternative design), *with Pike*, 2 Cal.3d at 470 (negligence claim requires jury to consider "the burden of the precaution which would be effective to avoid the harm").

In *Kim*, this Court held that in assessing those economic consequences in the context of a strict liability claim, a jury may consider a plaintiff's evidence that a defendant intentionally chose not to use a safer alternative design because it saw no competitive advantage in doing so. *See* 6 Cal.5th at 35, 38. The plaintiffs in *Kim* alleged that the design of Toyota's Tundra pickup truck was defective because it did not include vehicle stability control ("VSC"), a relatively new safety feature that, using the Court of Appeal's terminology below, was "known" to be "safer" for some consumers. *See id.* at 26-27. At issue was the admissibility of industry custom and practice evidence, including

evidence that none of Toyota's competitors included VSC on their pickup trucks, and that all major automobile manufacturers, including Toyota, included VSC on their sports-utility vehicles, which had similar loss-of-control risks to the Tundra. *See id.* at 28, 35.

This Court held the evidence was relevant and admissible to bolster the plaintiffs' argument that Toyota designed the Tundra without VSC "because it valued profits over safety." *Id.* at 35. The evidence also was relevant to the plaintiffs' argument that Toyota "knowingly disregarded" the safety risk posed by the absence of VSC because it saw "no competitive advantage" in including VSC as standard equipment on its pickup trucks. *Id.* at 35, 38. As the Court explained, the evidence not only "illuminate[d] 'the relative complexity of design decisions and the trade-offs that are frequently required in the adoption of alternative designs,'" *id.* at 35 (quoting *Barker*, 20 Cal.3d at 418), but it also tended to show that "Toyota's decision not to make VSC standard equipment was unrelated to legitimate design considerations," *id.* at 38.

Kim thus establishes that in assessing the merits of a manufacturer's decision-making vis-à-vis an alternative design, a jury may consider evidence of the competitive landscape in which a manufacturer operates. That evidence is no less relevant when a plaintiff asserts a negligent design claim instead of a strict

liability claim as in *Kim*. To the contrary, the evidence is even *more* relevant in the negligent design context, where the focus is squarely on "the reasonableness of the manufacturer's conduct." *Barker*, 20 Cal.3d at 434; *see also Scott*, 231 Cal.App.4th at 774.

The parallels to this case are obvious. Plaintiffs allege that before Gilead even obtained regulatory approval to market TDF, Gilead knew that TAF was more efficacious and less toxic to the kidneys and bones than TDF. *See Gilead*, 98 Cal.App.5th at 918. Nevertheless, Plaintiffs claim that Gilead delayed developing TAF because it wanted to maximize sales of TDF while using the later release of TAF to extend the patent coverage of tenofovir-related medications. *See id.*

Regardless of whether those allegations are true—Gilead demonstrated they are false (Reply Br. at 11-14)—the critical point is this: contrary to the Court of Appeal's conclusion, Gilead's purported financial motivation does *not* differentiate Plaintiffs' claim from a "typical negligent design" claim, nor does it render Gilead's alleged conduct "independent of the design and marketing of TDF." *Gilead*, 98 Cal.App.5th at 931.

Instead, by virtue of the risk-benefit balancing required in the design-defect context, products liability law *already* affords any plaintiff the opportunity to voice concerns about a manufacturer's allegedly profit-driven behavior in the context of a jury's assessment of whether the product at issue is defective.

There is no reason to cast this existing framework aside in favor of an amorphous "reasonableness" standard.

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In short, the reasons offered by the Court of Appeal for treating Plaintiffs' claim differently from a negligent design claim fall flat. Because Plaintiffs' claim "squarely fit[s] within the risk/utility test for defective design that applies in a products liability action under both negligence and strict liability theories," *Merrill*, 26 Cal.4th at 481, Plaintiffs' claim is—and should be treated like—a typical negligent design claim. And because Plaintiffs insist they will not seek "to prove that TDF is defective," *Gilead*, 98 Cal.App.5th at 916-17, this Court can and should reverse.

D. The Court of Appeal Erred by Relying on Plaintiffs' Allegations to Save Their Failed Products Liability Claim.

The Court of Appeal erred not only by holding that Plaintiffs need not prove a defect and mis-framing their claim as something other than a negligent design claim. The court also committed a serious procedural error by denying Gilead's summary judgment motion based solely on the controverted allegations in Plaintiffs' complaint—and without regard to the parties' voluminous evidentiary record.

A defendant may move for summary judgment if "the action has no merit." Code Civ. Proc. § 437c(a)(1). If a defendant

does so, "the court shall consider all of the evidence" submitted in support of and opposition to the motion. *Id.* § 437c(c); *see also id.* § 437c(b)(1)-(3). The court must grant the motion if the evidence shows the plaintiff cannot establish a necessary element of the plaintiff's cause of action. *See id.* § 437c(c) & (p)(2). What the court *cannot* do is deny an otherwise meritorious evidence-based motion by relying on "the allegations" in the plaintiff's complaint. *Id.* § 437c(p)(2). After all, the purpose of section 437c never has been "'to test the sufficiency of the pleadings.'" *Coyne v. Krempels*, 36 Cal.2d 257, 262 (1950) (quoting *Eagle Oil & Ref. Co. v. Prentice*, 19 Cal.2d 533, 560 (1942)). To the contrary, the purpose of the summary judgment procedure is to "cut *through* the parties' pleadings" and thereby determine whether, "*despite* their allegations," a trial is necessary. *Aguilar v. Atlantic Richfield Co.*, 25 Cal.4th 826, 843 (2001) (emphasis added).

Section 437c(c)'s command to "'consider all of the evidence'" is a cardinal rule that courts "must apply" in ruling on summary judgment motions. *Id.* In plain disregard of that rule, however, the Court of Appeal affirmed the trial court's denial of Gilead's motion based *solely* on Plaintiffs' allegations, waiving off the record evidence that Gilead offered to rebut those allegations. *See Gilead*, 98 Cal.App.5th at 919, 921-22 & n.4.

The Court of Appeal tried to justify that statutorily proscribed approach by noting Gilead did not seek summary

judgment "on the ground" that undisputed evidence established it lacked actual knowledge that TAF was safer and at least as effective as TDF. *Id.* at 922 n.4. But Gilead did not need to move on that "ground." Section 437c(a)(1) gave Gilead the unqualified right to seek summary judgment if it contended Plaintiffs' action had no merit. Gilead sought summary judgment on that basis, contending Plaintiffs' negligence claim "fails as a matter of state law." (1.App.110-11.) And in full compliance with section 437c(b)(1), Gilead accompanied its motion with "supporting evidence" showing TAF "was not known to be safer" than TDF and was not "an available safer alternative" to TDF. (1.AA.138, 151-53.) That is all Gilead needed to do.

III. THE COURT OF APPEAL EFFECTIVELY REWROTE THE RISK-BENEFIT TEST WITHOUT ANY SHOWING THAT A RULE CHANGE WAS NEEDED.

As a result of mis-framing Plaintiffs' claim and giving dispositive effect to their allegations, the Court of Appeal fundamentally altered the risk-benefit test, which has governed design-defect claims sounding in both strict liability and negligence since the 1970s. This Court should correct that error to ensure this balancing test remains a vital fixture of California's products liability law for generations to come.

For the common law to function properly, courts should "adhere to known principles and well-settled law." *Eddy v. Simpson*, 3 Cal. 249, 253 (1853). Thus, a common-law rule that

has persisted through generations should not be discarded unless "the conditions and needs of the times have . . . so changed as to make further application of it the instrument of injustice." *Rodriguez v. Bethlehem Steel Corp.*, 12 Cal.3d 382, 394 (1974).

The rule adopted by the Court of Appeal and urged by Plaintiffs here would do violence to these time-honored principles. That rule would jettison the defect requirement and allow a products liability claim to proceed without any showing that the product is defective, thereby effectively freeing juries from having to engage in any meaningful risk-benefit balancing before imposing liability. Such a radical departure from the common law cannot be sanctioned where, as here, there has been *no* showing that the defect requirement, and by extension the risk-benefit test, has become an "instrument of injustice." To avoid that outcome, this Court should reverse.

A. The Court of Appeal Created an Unacceptably Relaxed Standard for De Facto Design-Defect Liability that Would Apply Across All Industries.

In a typical design-defect case, a jury must weigh the risks and advantages of both the challenged design and any alternative design. *See Barker*, 20 Cal.3d at 434. As part of that "inevitable" balancing, the jury must consider whether the challenged design "achieve[s] reasonable and practical safety under a multitude of varying conditions." *Id.* Similarly, the jury must consider

whether an alternative design, "while averting the particular accident, would have created a greater risk of injury in other, more common situations." *Id.* at 433. Not surprisingly, this Court has recognized that a standard of liability that precludes a jury from weighing these "competing considerations" can be misleading and unfair. *Id.* at 434.

The new liability test fashioned by the Court of Appeal and urged by Plaintiffs suffers from this precise flaw. Under that new test, a prescription drug manufacturer would be subject to liability if, in a bid to maximize profits, it delayed commercialization of a new drug that it knew would enable "some users" to avoid the risks associated with the manufacturer's existing non-defective drug. *Gilead*, 98 Cal.App.5th at 931, 939. It would make no difference whether the benefits of the challenged drug exceed its risks or whether the new drug's alternative design may pose a risk of injury to other patient populations. Instead, all that would matter is whether the new drug's alternative design may be safer for the particular "patient concerned." *Id.* at 939.

By eliminating the need to weigh the competing considerations involved in designing prescription drugs, this new standard of liability would effectively erase the risk-benefit test, which has governed design-defect claims for decades, and replace it with a new test that is tantamount to absolute liability

whenever there is a safer alternative, which this Court long has rejected. *See, e.g.*, *Daly v. General Motors Corp.*, 20 Cal.3d 725, 733 (1978); *Cronin v. J.B.E. Olson Corp.*, 8 Cal.3d 121, 133-34 (1972); *see also Carlin v. Superior Ct.*, 13 Cal.4th 1104, 1121 (1996) ("Products liability is not absolute liability[.]").

Moreover, this new test would not be limited to the prescription drug context. The Court of Appeal ensured that outcome by grounding it in a statute that on its face applies to "'[e]veryone.'" *Gilead*, 98 Cal.App.5th at 920 (quoting Civ. Code § 1714(a)). Beyond that, the court emphasized that the legal duty of *any* "manufacturer" can extend "beyond the duty to market a defective product," *id.* at 917, and it broadly pronounced that a plaintiff may recover in negligence for harm caused by *any* "product" notwithstanding the plaintiff's inability to prove "a product defect," *id.* at 926. Not surprisingly, courts already are beginning to apply *Gilead* outside the pharmaceutical context. *See Williams v. J-M Mfg. Co.*, 102 Cal.App.5th 250, 262-63 (2024) (exposure to alleged asbestos-cement pipe).

In addition, the reasoning that led the Court of Appeal to abandon the defect requirement and hold Gilead had a duty not to delay commercialization of TAF—*i.e.*, because TDF "created a risk" of harm that Gilead allegedly knew TAF could have enabled Plaintiffs to avoid, *Gilead*, 98 Cal.App.5th at 935—can apply just as easily to products across *all* industries.

Consider *Bell v. Bayerische Motoren Werke Aktiengesellschaft*, 181 Cal.App.4th 1108 (2010). The plaintiff there was injured in a roll-over accident when his head hit the ground through the soft top of his convertible. *See id.* at 1113. The evidence at trial showed the manufacturer knew through pre-market product testing that an occupant of the car would experience head-to-ground contact in the event of a rollover but nevertheless decided not to "complete the development" of a rollover protection system. *Id.* At issue was whether the car's aesthetics—which included the absence of a rollover bar—was a relevant factor to consider under the risk-benefit test. *See id.* at 1131. The Court of Appeal held it was, reasoning that a car "is not a strictly utilitarian product" and that "much of the perceived benefit of a car lies in its appearance." *Id.* Thus, under *Bell*, a manufacturer that failed to incorporate a known design feature that might have increased safety for some users under some circumstances could avoid liability if a jury determined that the benefits of the product's design outweighed the risks.

That would no longer be true under *Gilead*, however. If *Gilead* is allowed to stand, an automaker that sells a non-defective car but failed to complete development of and bring to market a known alternative design that might be safer for some users would be subject to liability no matter which way the scale tips under a risk-benefit balancing. As the *Bell* court understood,

consumers are not motivated solely by safety to the exclusion of all other factors. But under *Gilead*, automakers who wish to avoid design-defect liability would have to consider brushing aside all the market influences that have driven their businesses to date and start building excessively safe cars that consumers may not want.

Further, since *Gilead* is fundamentally about consumer access to improved products, *see* 98 Cal.App.5th at 919, and since the duty recognized by the Court of Appeal relates to decisions "about" the commercialization of an alternatively designed product that a manufacturer already "invented," *id.* at 922, there is no reason to expect this new duty would be limited to cases involving alternatively designed products that have not reached the market. To the contrary, even manufacturers who put such products on the market may be subject to liability over *how* they chose to commercialize them.

For example, a manufacturer of industrial equipment may give customers a choice between a standard safety feature and an optional safety feature, each of which is designed to protect against the same risk. A plaintiff who sustains injury while using the product might argue that the standard safety feature created a risk of injury that the optional safety feature would have avoided.

That was the case in *Camacho v. JLG Industries, Inc.*, 93 Cal.App.5th 809 (2023), which involved a scissor lift (a type of aerial work platform). To protect against the risk of falling while working at height, the manufacturer designed the lift with a steel chain to guard the entrance, and it also sold an after-market retrofit kit to replace the chain with a self-closing gate. *See id.* at 818. The plaintiff, who was injured when he fell from the lift after neglecting to secure the entrance, argued that the chain design invited human error that the alternative gate design would have avoided. *See id.* at 813, 823-24. Under this Court's precedents, there was no question that the manufacturer's liability depended on proof that a defect caused injury. *See id.* at 816-17. But under *Gilead*, the existence of a defect would be immaterial. Because the chain design allegedly created a risk of injury, all that would matter is whether the manufacturer, in a bid to "maximize" its after-market profits, failed to equip the scissor lift with the alternative gate design, which "could have avoided" the accident. *Gilead*, 98 Cal.App.5th at 931, 938.

The *Gilead* court's new standard of liability could apply to consumer products just as easily as industrial ones. For example, a plaintiff injured in an automobile accident may claim that the vehicle's standard mirrors created a risk of injury by providing insufficient visibility under a particular set of circumstances, and that an optional "blind spot indicator"—a safety feature that

detects a vehicle in an adjacent lane—could have avoided the risk. Under this Court's precedents, the manufacturer's liability would depend on proof that the vehicle was defective because it lacked that optional safety feature. *See, e.g.*, *Kim*, 6 Cal.5th at 30, 35; *Campbell v. General Motors Corp.*, 32 Cal.3d 112, 118, 125 (1982); *see also Camacho*, 93 Cal.App.5th at 825 (a jury would consider "the risks, benefits, and relative costs of the two alternative safety designs"). But under *Gilead*, the manufacturer's liability would turn on whether it sought to gain a competitive advantage by omitting a safety feature that might have avoided the plaintiff's accident—regardless of whether that feature would have increased the price point for the car, and even if it introduced independent safety risks by, for example, inducing drivers to drive more erratically in reliance on the blind-spot indicator.

In short, one of the major flaws with the rule adopted by *Gilead* is that it purports to authorize the imposition of liability *whenever* one plaintiff's harm could have been avoided through use of a safer alternative design, no matter the benefits of the challenged design or the risks that the alternative design may pose to others. Although the court insisted this new rule does not create a "'perfect product' law," *Gilead*, 98 Cal.App.5th at 944, that is exactly what it does. And in so doing, it tramples on a core principle that underlies *all* risk-benefit balancing—namely,

that a manufacturer is not required to design "the safest possible" product, even if one can be or is being developed. *Soule*, 8 Cal.4th at 571 n.8; *see also Barker*, 20 Cal.3d at 430 (risk-benefit test asks whether challenged design embodies "excessive" preventable danger); *Pike*, 2 Cal.3d at 470 (manufacturers must design their products to be "safe," not "accident-proof").[4]

B. Plaintiffs Made No Showing that This Unprecedented Rule Change Is Warranted.

Not only does the Court of Appeal's new liability test discard the defect requirement—and with it the need to balance

[4] Again, California is not unique in this regard. Courts across the country agree that a manufacturer is not required to design the "safest possible" product so long as the design adopted is reasonably safe. *E.g.*, *Gideon v. Johns-Manville Sales Corp.*, 761 F.2d 1129, 1145 (5th Cir. 1985); *Mitchell v. Ford Motor Co.*, 533 F.2d 19, 20 (1st Cir. 1976); *Fajardo v. Boston Scientific Corp.*, 267 A.3d 691, 712 (Conn. 2021); *Oanes v. Westgo, Inc.*, 476 N.W.2d 248, 252 n.5 (N.D. 1991); *Ford Motor Co. v. Miles*, 967 S.W.2d 377, 386 (Tex. 1998); *Graham v. Sprout-Waldron & Co.*, 657 So.2d 868, 870 (Ala. 1995); *Boudreau v. Baughman*, 368 S.E.2d 849, 859 (N.C. 1988); *Thibault v. Sears, Roebuck & Co.*, 395 A.2d 843, 847 (N.H. 1978); *Hunt v. Blasius*, 384 N.E.2d 368, 372 (Ill. 1978); *Voynar v. Butler Mfg. Co.*, 463 So.2d 409, 412 (Fl. App. 1985); *Torre v. Harris-Seybold Co.*, 404 N.E.2d 96, 109 (Mass. App. 1980); *Westinghouse Elec. Corp. v. Nutt*, 407 A.2d 606, 611 (D.C. App. 1979); *accord Slisze v. Stanley-Bostitch,* 979 P.2d 317, 320 (Utah 1999) ("We have never, *nor has any other jurisdiction*, recognized a duty on the part of a manufacturer to refrain from marketing a non-defective product when a safer model is available[.]") (emphasis added).

the myriad competing considerations that guide any manufacturer's product-development decisions—but Plaintiffs made *no* showing that such a sea change in the law is even warranted by "the conditions and needs of the times." *Rodriguez*, 12 Cal.3d at 394.

More than 50 years ago, this Court recognized that its "pioneering efforts" in the field of products liability law led to the creation of a finely calibrated system of jurisprudence that provides injured plaintiffs with dual remedies—negligence and strict liability—while protecting manufacturers from absolute liability. *See Cronin*, 8 Cal.3d at 133. The defect requirement is the common foundation underlying *both* remedies. *See id.* at 129 (by adopting strict liability, *Greenman* "dispense[d] with negligence as the basis for recovery in defective product cases"). When it decided *Cronin* in 1972, this Court found "no difficulty" applying that requirement "to the full range of products liability situations, including those involving design defects," because "a cluster of useful precedents" had developed that gave "content to the defectiveness standard." *Id.* at 134 & n.16 (internal quotation marks omitted).

When it decided *Barker* several years later, the Court further defined "the contours" of the defect requirement in design-defect cases. 20 Cal.3d at 418. The Court recognized that, "in typical common law fashion, the accumulating body of product

liability authorities would give guidance for the formulation of a definition." *Id.* Those authorities led the Court to formulate the risk-benefit test, which governs design claims sounding in strict liability and which largely mimics the balancing test applicable to design claims sounding in negligence. *See id.* at 431; *see also Merrill*, 26 Cal.4th at 481. And the Court affirmed that this test constitutes "a balanced approach" that protects both plaintiffs and manufacturers from "extreme" results. *Barker*, 20 Cal.3d at 435.

Against this historical backdrop, the Court of Appeal understandably emphasized that "the legal concept of a 'defect' is extraordinarily useful." *Gilead*, 98 Cal.App.5th at 926. It *is*. Yet, perplexingly, the court refused to acknowledge that concept as the "outer boundary of a manufacturer's liability" in a products liability case founded on negligence. *Id.* A legal concept that has proven itself—decade after decade—to be extraordinarily useful in protecting both plaintiffs and manufacturers should not be cast aside without a showing that contemporary conditions require such an extreme course correction. But Plaintiffs made *no* such showing, and the Court of Appeal did not require one.

Indeed, Plaintiffs do not contend that the defect requirement has failed to prevent the market from being flooded with products that are not reasonably safe. Nor do they contend that the defect requirement is an obstacle to a plaintiff receiving

fair compensation when a product that is not reasonably safe does cause injury. They also do not contend that manufacturers of non-defective products are routinely refusing to innovate in a bid to maximize their profits. To the contrary, they emphasize it is "*rare*" that a prescription drug manufacturer would choose not to proceed with development of an ostensibly safer drug. (Answering Br. at 20.)

Instead, Plaintiffs object that federal preemption provides manufacturers with "near blanket immunity" from design-defect liability in the prescription drug context. (Answering Br. at 46.) Plaintiffs oversell this point. (Reply Br. at 19-20.) In fact, one court in California recently held that a design claim alleging Gilead should have sought FDA approval of TAF instead of TDF was *not* preempted. *See Holley v. Gilead Sciences, Inc.*, 379 F.Supp.3d 809, 818-25 (N.D. Cal. 2019). In any event, if Plaintiffs are unhappy with federal preemption, their remedy is to petition Congress. Their dissatisfaction with federal law, however, provides no basis for dispensing with a "basic tort principle[]" that has served litigants in California well for the last century. *Merrill*, 26 Cal.4th at 478.

This Court's task is to *promote* "meaningful" and "finely tuned" rules like the defect requirement that litigants and lower courts can apply, not to abolish them without justification. *Southern Cal. Gas Leak Cases*, 7 Cal.5th 391, 412 (2019). The

defect requirement continues to serve an important purpose. This Court should preserve it and thereby ensure that the risk-benefit test continues to function as intended.

IV. CIVIL CODE SECTION 1714 DOES NOT IMPOSE A DUTY TO COMMERCIALIZE AN ALTERNATIVE TO A NON-DEFECTIVE PRODUCT.

After dismantling this Court's design-defect jurisprudence, the Court of Appeal proceeded to erect a new duty on a statutory foundation that does not and cannot support it. Before the Court of Appeal did so, no court ever suggested, let alone held, that Civil Code section 1714 obligates a manufacturer to develop and market an alternative to a non-defective product. And for good reason. The imposition of that unprecedented duty is flatly inconsistent with the purpose of section 1714, the decades of case law applying the defect requirement, and the basic premise underlying the law of products liability.

A. As a Codification of the Common-Law, Section 1714 Provides a Foundation for Development of Rules Like the Defect Requirement.

Section 1714 provides that "[e]veryone" is responsible for an injury occasioned to another "by his or her want of ordinary care." Civ. Code § 1714(a). This Court repeatedly has recognized that the statute states only a "general rule" governing duty. *E.g.*, *Kuciemba v. Victory Woodworks, Inc.*, 14 Cal.5th 993, 1016 (2023); *Buckley v. Chadwick*, 45 Cal.2d 183, 192-93 (1955). That

characterization is apt, because the purpose of section 1714 is simply to state a broad principle around which more specific tort rules can develop, not to create "new" duties from thin air governing behavior under all circumstances. *Cabral v. Ralphs Grocery Co.*, 51 Cal.4th 764, 783 (2011).

Indeed, when the Legislature enacted the Civil Code in 1872, it sought to "announce and formulate existing common law principles." *Li v. Yellow Cab Co.*, 13 Cal.3d 804, 814 (1975). Consistent with that objective, the Legislature enacted section 1714 to enshrine "the basic rule of negligence," knowing it would provide the foundation for subsequent judicial development of the common law. *Id.* at 821. Among the rules built on that foundation is the defect requirement—pursuant to which a plaintiff seeking to recover under a negligence theory of products liability "*must* prove that a defect caused injury" and "must *also* prove 'an additional element, namely, that the defect in the product was due to the negligence of the defendant.'" *Merrill*, 26 Cal.4th at 479 (emphasis added).

Because section 1714 codified the common law, courts applying the statute in a particular context must construe it "'in light of common-law decisions on the same subject.'" *Li*, 13 Cal.3d at 815 (quoting *Estate of Elizalde*, 182 Cal. 427, 433 (1920)); *see also In re Apple*, 66 Cal. 432, 434 (1885) ("where the code is silent, the common law governs"). This means that courts

should not rely on section 1714 to expand an existing duty of care—such as a manufacturer's duty to produce a defect-free product—without considering whether the expanded duty "would exceed the boundaries established over decades of product liability law." *O'Neil v. Crane Co.*, 53 Cal.4th 335, 365 (2012); *see also Parsons v. Crown Disposal Co.*, 15 Cal.4th 456, 462 (1997) (refusing to use section 1714 to expand a defendant's existing duty where "the nature and scope" of the duty was "established" by a "considerable line of authority"); *Kentucky Fried Chicken of Cal., Inc. v. Superior Ct.*, 14 Cal.4th 814, 824, 828 (1997) (rejecting argument that section 1714 imposed a duty on shopkeeper to comply with robber's demands, reasoning the statute "has never been construed" that way and "no state" has imposed such a duty).

B. The Relevant Duty under Section 1714 Is to Supply a Defect-Free Product.

The Court of Appeal below understood it needed to apply section 1714 in a manner consonant with California products liability law. That is why the court purported to find in the statute a duty to commercialize TAF as an alternative to TDF—*i.e.*, "*[b]ecause*" it believed the law already obligated manufacturers to do more than supply non-defective products. *Gilead*, 98 Cal.App.5th at 935 (emphasis added).

The Court of Appeal was wrong about that, however. California law does *not* impose any such duty in the context of personal injury caused by a product. It never has. To the contrary, the duty imposed on product manufacturers in such cases always has been tied to the defect requirement.

Indeed, this Court confirmed long ago that the "duty" owed by a manufacturer is to produce a product "free from dangerous defects." *Vandermark*, 61 Cal.2d at 261; *see also Merrill*, 26 Cal.4th at 479 (under a negligence theory, a plaintiff "must" prove "the defect in the product was due to the negligence of the defendant"); *Pike*, 2 Cal.3d at 471 (manufacturer has a "duty to produce a product reasonably safe for its intended use"). The Courts of Appeal have reached the same conclusion. *See, e.g.*, *Milwaukee Elec. Tool Corp. v. Superior Ct.*, 15 Cal.App.4th 547, 551 (1993) (manufacturers owe "a general duty to produce defect-free products"); *Gem Developers v. Hallcraft Homes of San Diego, Inc.*, 213 Cal.App.3d 419, 428 (1989) (same).

In fact, before the lower court did so, *no* court had interpreted section 1714 to impose a broader duty on product manufacturers. To the contrary, courts have recognized for 100 years that in cases involving personal injury caused by a product, the duty imposed by section 1714 is simply to supply a product that is not defective. *See Chavez*, 207 Cal.App.4th at 1314-15 (gun manufacturer subject to negligence liability for alleged

design defect); *Bettencourt v. Hennessy Indus., Inc.*, 205 Cal.App.4th 1103, 1118 (2012) (manufacturer subject to negligence liability for "design and warning defects"); *Evans v. Thomason*, 72 Cal.App.3d 978, 985 (1977) (landlords responsible for personal injury caused by a "defective" kitchen outlet); *Jaehne v. Pacific Tel. & Tel. Co.*, 105 Cal.App.2d 683, 688 (1951) ("One who undertakes to furnish an appliance for the use of others ordinarily assumes a duty to furnish a proper and reasonably safe appliance[.]"); *Fisher v. Pennington*, 116 Cal.App. 248, 251 (1931) (landlord responsible for personal injury caused by "the defects of the door"); *accord Garcia v. Becker Bros. Steel Co.*, 194 Cal.App.4th 474, 482-85 (2011) (defendant not subject to negligence liability for allegedly defective equipment it did not manufacturer or design).

In short, because a manufacturer's negligence liability for personal injury caused by a product always has depended on proof of a defect, and because Plaintiffs have offered no justification warranting an exception to that entrenched principle, the Court of Appeal should not have relied on section 1714 to find a broader duty to commercialize an alternative to a product that no one claims is defective.

C. The Court of Appeal's Expanded Duty Is at Odds with the Basic Premise of Products Liability Law.

Moreover, the duty recognized by the Court of Appeal cannot be reconciled with the basic premise underlying the law of products liability.

A manufacturer does not become subject to products liability unless and until it places a defective product *onto the market*. *See, e.g.*, *O'Neil*, 53 Cal.4th at 348 ("Regardless of a defendant's position in the chain of distribution, 'the basis for his liability remains that he has marketed or distributed a defective product,' and that product caused the plaintiff's injury.") (quoting *Daly*, 20 Cal.3d at 739); *Merrill*, 26 Cal.4th at 479 (a manufacturer is subject to negligence liability for "the design of a product 'placed on the market'") (quoting *Pike*, 2 Cal.3d at 470)). Indeed, the only basis for imposing *any* liability against product manufacturers is that public policy demands a remedy for harm caused by "defective products that reach the market." *Escola*, 24 Cal.2d at 462 (Traynor, J., concurring).

The expanded duty recognized by the Court of Appeal turns this basic principle on its head. Because Plaintiffs have renounced any claim that TDF is defective, it follows that they do not seek recovery for any harm caused by a defective product that Gilead *placed onto the market*. Instead, under Plaintiffs' reformulated theory of liability, Gilead is responsible for not

preventing their harm due to its "delay [in] marketing" TAF. *Gilead*, 98 Cal.App.5th at 941. Moreover, based on how Plaintiffs characterize their claim, the end date on Gilead's liability is when Gilead ultimately brought TAF "to market." *Id.* at 933.

This is the exact *opposite* of how the law of products liability always has functioned. Courts do not and should not impose liability for actions taken with respect to products that have not reached the marketplace. A rule that allows that outcome is at war with the very premise of products liability law. By using section 1714 to push the law of products liability beyond its historical boundary, the Court of Appeal failed to recognize that an expanded duty of care must be "consonant with" the common law in effect at the time. *Li*, 13 Cal.3d at 822.

V. A DUTY TO DEVELOP AND COMMERCIALIZE AN ALTERNATIVE TO A NON-DEFECTIVE PRODUCT WOULD HARM CONSUMERS AND MANUFACTURERS ACROSS ALL INDUSTRIES.

The duty recognized by the Court of Appeal and urged by Plaintiffs would damage more than just legal doctrine. It is bound to disrupt the product-development process in ways that are harmful to consumers and manufacturers alike.

Designing a product is not easy. Manufacturers must consider and balance a host of competing considerations when making design decisions. These considerations include budgetary constraints, consumer safety, product functionality, market

demand, aesthetics, and pricing, to name but a few. Given the "'relative complexity of design decisions and the trade-offs that are frequently required in the adoption of alternative designs,'" manufacturers invariably must make tough choices when balancing these competing considerations. *Kim*, 6 Cal.5th at 39 (quoting *Barker*, 20 Cal.3d at 418).

The inevitability of these trade-offs is why the Court of Appeal's decision below is so dangerous. If juries can penalize manufacturers for "delay in commercializing" alternatives to non-defective products, *Gilead*, 98 Cal.App.5th at 938, then manufacturers *will* change their behavior. That is what tort liability does—it "induce[s] behavioral changes." *Kuciemba*, 14 Cal.5th at 1026. The Court of Appeal suggests that manufacturers need only exercise "reasonable care" when "making decisions" about the commercialization of their products. *Gilead*, 98 Cal.App.5th at 922. But that is not useful guidance; it just creates more uncertainty about what obligations manufacturers may owe to future classes of plaintiffs when making those decisions.

The result of this confusion is unlikely to be "safer products," as the Court of Appeal assumed. *Id.* at 944. Instead, the expanded duty recognized by the court is far more likely to stifle innovation, reduce choice, increase prices, compromise safety, and subject manufacturers across all industries to

limitless liability for just about any decision made in the product-development process.

These outcomes do not bode well for consumers or manufacturers—or California's $3.1 trillion economy, which is the fifth largest of any country in the world, and the largest of any of the 50 states. *See* Forbes, *California*, *available at* https://www.forbes.com/places/ca/ (last visited Nov. 3, 2024); Bureau of Economic Analysis, *Gross Domestic Product by State and Personal Income by State, 2d Quarter 2024* at Table 1, *available at* https://www.bea.gov/sites/default/files/2024-09/stgdppi2q24.pdf (last visited Nov. 3, 2024). To maintain an appropriate balance between consumer safety and access to innovative products, this Court should reject the Court of Appeal's expanded duty.

A. The Court of Appeal's Novel Duty Would Chill Innovation and Reduce Consumer Choice.

Before the Court of Appeal decided *Gilead*, no court in the country held that a manufacturer has a duty to develop and commercialize a product. Instead, under our system of free enterprise, manufacturers had the freedom of choice to make products, not make products, go into different lines of business, or go out of business if their owners so desired. If manufacturers decided to make products, the law required only that they

produce reasonably safe ones—meaning products that are free of defects in their design, manufacture, and warnings.

Gilead changed all that. Now, even when their products are free of defects and thus reasonably safe, manufacturers can be coerced by the threat of litigation into making and supplying alternatively designed products just so consumers can have more choices. That defies common sense. Market forces of supply and demand have guided manufacturers' business decisions since our nation's founding. Those market forces have prompted manufacturers to produce an abundance of safe and innovative products that have made all our lives better. Courts should not seek to replace those market forces by imposing a novel duty that effectively conscripts manufacturers into making new products for the sake of consumer choice.

Further, if allowed to stand, that novel duty will have the opposite effect: it will stymie, not propel, innovation and will thereby reduce consumer choice. To comply with this duty, manufacturers will have to comb through the development history of their existing non-defective products to identify any design alternatives that might improve safety for any user under any foreseeable circumstance of use—no matter the nature of the risk posed or how remote it may be. To avoid liability, manufacturers then will have to devote their finite research and development budgets to bringing those alternative products to

market, regardless of the risks that the new products may pose to other consumers under other circumstances or the costs of commercializing them.

While manufacturers are busy making incremental improvements to existing products just to benefit certain users under certain circumstances, many will lack adequate resources to accomplish that task while, at the same time, pursuing development of truly groundbreaking products that satisfy unmet needs. And those manufacturers that do have sufficient resources to proceed on both tracks may decide the prospect of liability posed by the Court of Appeal's novel duty is not worth the risk.

Given the trade-offs inherent in the design process, a successful product usually is preceded by numerous ideas and prototypes that failed for one reason or another. If manufacturers pursuing pathbreaking products can be subject to liability for failing to commercialize those discarded ideas and prototypes, they may decide to divert their research and development dollars to other uses, calculating that the possibility of future profits in untested markets does not outweigh the certainty of costly litigation over delayed commercialization of incremental design alternatives. *See, e.g.*, *Brown*, 44 Cal.3d at 1063-65 (recognizing that the threat of liability can deter research and encourage market withdrawal).

In short, although safety obviously is a primary consideration when designing any product, the *Gilead* court's outsized focus on marginal safety gains for some consumers at the expense of all other considerations does not promote society's interest in innovation. *See, e.g.*, RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2, Comment ("The emphasis is on creating incentives for manufacturers to achieve optimal levels of safety in designing and marketing products. Society does not benefit from products that are excessively safe . . . any more than it benefits from products that are too risky."). And with less innovation, consumers will have fewer choices in the long run.

B. The Court of Appeal's Novel Duty Would Increase Prices and Threaten Consumer Safety.

Stymied innovation and reduced consumer choice are not the only adverse consequences that would ensue from adoption of the *Gilead* court's reasoning. There are others.

If the court's novel duty is allowed to take root, consumers are bound to pay higher prices. Indeed, manufacturers faced with expensive litigation over delayed-commercialization claims and the prospect for large judgments will pass those costs along to the consumer in the form of higher prices. That outcome—which this Court recognized was "far from theoretical" in the pharmaceutical context, *Brown*, 44 Cal.3d at 1064—is unavoidable. *See, e.g.*, Goldberg & Zipursky, *The Restatement*

(Third) and the Place of Duty in Negligence Law, 54 VAND. L. REV. 657, 719 (2001) (the cost of "liability and litigation" ultimately is "borne by consumers").

The Court of Appeal's novel duty also threatens to compromise consumer safety. By holding that a manufacturer can be subject to liability for delay in commercializing a new product that may be safer for some subset of users however small, the court created a perverse incentive to rush products to market that may pose safety risks to other, potentially larger subsets of users. Those risks may be the very reason that prompted a manufacturer to abandon the alternative design in the first place.

Of course, the risks posed by an alternative design may not be readily apparent during the development process. Sometimes, substantial testing and evaluation is necessary to identify potential risks. By authorizing the imposition of liability for delay in commercializing a new product, the Court of Appeal's decision may encourage some manufacturers to rush new products to market when a more deliberative approach involving additional pre-market testing and evaluation would have been prudent. That will harm consumers, not help them.

In the prescription drug context, the FDA provides a backstop to ensure no medication reaches the market unless it is judged to be reasonably safe. But most industries do not operate

under this same level of regulatory scrutiny. Thus, courts should foster rules of liability that encourage manufacturers across all industries to do the pre-market evaluation necessary to produce reasonably safe products. *See, e.g.*, *Price v. Shell Oil Co.*, 2 Cal.3d 245, 258 (1970) (the "basic purpose" of products liability is "to protect" the consumer). A rule of liability that prioritizes speed to market in lieu of overall consumer safety and other design considerations is antithetical to sound public policy.

C. The Court of Appeal's Novel Duty Would Weaponize Routine Product Development Decisions.

In addition to less innovation, reduced choice, higher prices, and compromised safety, the Court of Appeal's decision threatens to impose boundless liability on manufacturers across all industries. Although the court acknowledged that a duty "'to pursue *ever-better* new products or improvements to existing products' would be unworkable," *Gilead*, 98 Cal.App.5th at 921, the effect of the court's reasoning is to impose that precise duty. Armed with *Gilead*, creative lawyers now can weaponize virtually every major decision a manufacturer makes in the product-development process.

When to bring a new product to market. Among the most obvious targets of an enterprising lawyer will be a manufacturer's decision not to commercialize (or not to commercialize quickly enough) an alternative design that the

manufacturer knows could avert injury to some consumers under certain circumstances. A manufacturer's liability in that regard is virtually endless, because *Gilead* provides no workable standard for ascertaining *when* a manufacturer knows a design alternative may be safer for some consumers, or *how* much delay in commercializing that alternative is too much.

The Court of Appeal allowed a delay-in-commercialization claim to proceed against Gilead based solely on results from a single, 14-day Phase I/II study involving just 30 patients that showed TDF and TAF had a "similar" safety profile. (Opening Br. at 14-15.) If that is enough to support such a claim in the pharmaceutical context—it shouldn't be (Opening Br. at 60-64)—the quantum of evidence required in other contexts is guaranteed to be all but nil.

This Court has long recognized that products should achieve "reasonable and practical safety under a multitude of varying conditions." *Barker*, 20 Cal.3d at 434. By allowing juries to impose liability for decisions about commercialization of an alternative design that may benefit only a small subset of consumers by reducing an already remote risk, *Gilead* incentivizes manufacturers to rush *all* new products to market regardless of whether the risks or benefits of an alternative design, when considered in their totality, outweigh those of an

existing non-defective product. That makes no sense under *Barker* or this Court's other design-defect precedents.

Selecting what features to offer. When deciding what features to include on a product, a manufacturer must balance consumer safety against many other considerations, including but not limited to product functionality, consumer demand, and cost. Anyone who has been in the market for a new car knows this. Many automakers today offer an amazing array of features, but not all consumers want or can afford them. Automakers take these factors into consideration as part of their "decisionmaking process" when designing and marketing their automobiles. *Kim*, 6 Cal.5th at 39. Following *Gilead*, however, automakers are bound to fret over whether they will be sued for making the wrong decision about whether to include an optional feature on their vehicles.

For example, developments in holographic technology have led some automakers to include heads-up displays ("HUDs") in some of their cars. *See* Meier, *Which Cars Have Head-Up Displays?* (Apr. 30, 2024), *available at* www.cars.com/articles/which-cars-have-head-up-displays-434824/?msockid=1e4e1db4f9165e2245cf4c34916b3e (last visited Nov. 3, 2024). An HUD allows the display of information such as speed and navigation directions in the driver's line of sight above the dashboard. *See id.* Not all automakers offer a HUD as an option on every model

car, however. *See id.* While many manufacturers now offer the technology on at least some of their vehicles, it typically is available only on higher trim levels or as an optional feature. *See id.*

Under *Gilead*, a driver who sustains injury in an accident involving a vehicle that lacked an HUD could sue the manufacturer for not including this known technology in all its vehicles. So long as the driver could establish that inclusion of this emerging technology would have prevented the driver's particular accident, the manufacturer would be on the hook for damages even if it concluded (appropriately) that most of its target customers did not want it, or that its inclusion would have priced them out of the market.

Or consider the example of semi-autonomous driving technology, which is rapidly developing. A driver who is injured while using this technology may claim that the automaker failed to include an additional feature in the vehicle's operating system that would better alert drivers who are dozing off or not watching the road. Before *Gilead*, the automaker's negligence liability under a design-defect theory would turn on the reasonableness of its risk-benefit balancing. But after *Gilead*, that balancing becomes immaterial. So long as the additional feature would have been safer for the driver who sues, it makes no difference whether the manufacturer struck a reasonable balance between

safety, functionality, cost, and market demand when it designed its vehicle. By subjecting automakers to what is in effect absolute liability, *Gilead* thus could have "a substantial impact on the emerging market for automated driving technologies." Geistfeld, *A Roadmap for Autonomous Vehicles: State Tort Liability, Automobile Insurance, and Federal Safety Regulation*, 105 CALIF. L. REV. 1611, 1616 (2017).

Prescription drug manufacturers and automakers are not the only ones who risk being overcome by the wake of *Gilead*. Manufacturers across all industries will be at risk of juries second-guessing whether they struck the appropriate balance between safety, functionality, consumer demand, cost, and the other competing considerations that any company must consider when developing a new product. To be sure, manufacturers legitimately invite judicial scrutiny when they produce products that are not reasonably safe because they contain a design defect. But basic notions of fair play dictate that courts should not empower juries to penalize manufacturers for business judgments that result in reasonably safe products that lack any defect.

Moreover, although *Gilead* involves a manufacturer that allegedly delayed commercialization of a purportedly safer product that it invented, the new duty recognized by the Court of Appeal will not be confined to that specific context. Since the

new liability test in *Gilead* turns on the reasonableness of a manufacturer's conduct in delaying commercialization of a known safer alternative design, common sense dictates that plaintiffs' counsel will seek to extend that test to situations where a manufacturer delays commercialization of a known safer alternative that *someone else* invented. Thus, in a post-*Gilead* world, any manufacturer should expect to be sued for failing to equip its product (or failing to equip it quickly enough) with some new feature developed by a different entity. That makes the boundless duty in *Gilead* even more unworkable.

Whether a feature is standard or optional. Because *Gilead* at its core is about providing consumers with a choice between non-defective products and alternatively designed ones, even manufacturers who offer a particular feature as an option are subject to liability under *Gilead* for striking the wrong balance between functionality and safety—at least in cases where the actual user played no role in choosing between competing designs.

Take the scissor lift example from *Camacho*. *See supra* Part III.A. Scissor lifts are ubiquitous on construction sites across the United States. Contractors frequently rent them from equipment rental companies to facilitate their employees' work. Some manufacturers might have built their lifts with a steel chain as a standard feature to close the entrance while offering a

self-closing gate as an alternative design. Although both features provide reasonable safety according to the California Division of Occupational Safety and Health (the applicable state regulator), *see* 8 Cal. Code Regs. § 3642(a), manufacturers might have offered the chain as a standard feature and the gate as an option because they knew that construction workers often prefer the chain over the gate, which can interfere with loading large items onto a lift.

Under the reasoning of *Gilead*, a scissor lift manufacturer could be penalized for making that choice—no matter how sensible it was—if a single construction worker could have avoided injury had the lift that his employer rented included a gate instead of a chain. In that circumstance, an ambitious lawyer might argue that the worker's denial of a choice between the non-defective chain design and a purportedly safer alternative gate design is on a par with Plaintiffs' asserted lack of a choice between TDF and TAF. Based on that analogy, *Gilead* would allow the injured plaintiff to recover regardless of how reasonable the manufacturer's risk-benefit balancing was.

Pre-market testing. Following *Gilead*, the manufacturer of a non-defective product also is subject to attack for not conducting sufficient pre-market testing, which might have revealed the possibility of a safer design alternative for some consumers. *See Gilead*, 98 Cal.App.5th at 937 (offering "no

opinion about whether plaintiffs should be permitted to argue constructive knowledge on remand"). That was not the case before *Gilead*.

As noted, the court in *Valentine* held that a duty to test and inspect "has no significance" apart from a product's design, manufacture, and warnings. 68 Cal.App.4th at 1485. But now, plaintiffs' lawyers no doubt will try to circumvent *Valentine* by relying on *Gilead*. They will argue that, following *Gilead*, the manufacturer of a product that is not defective in its design, manufacture, or warnings nevertheless can be held liable on a negligent-failure-to-test theory if that testing would have revealed a safer way to build the product for some consumers. Notably, Plaintiffs do not argue that manufacturers who have only constructive knowledge of a safer alternative design should be exempted from a duty not to delay commercializing that design. (Answering Br. at 42.)

Gilead also creates an inverse—and perverse—incentive for manufacturers to do less rather than more pre-market testing. Indeed, the decision creates the risk of liability for decisions made in the early stages of product development when manufacturers necessarily have incomplete knowledge. If manufacturers can be liable for failing to pursue an alternative design that may be better for some consumers, without regard to the cost of that design or the risks it may pose to other

consumers, manufacturers will be disincentivized to conduct the very testing that might reveal the potential for such design alternatives. That runs counter to sound public policy. *See, e.g.*, *Campbell*, 32 Cal.3d at 121 (a rule of liability that "provide[s] a disincentive to improve the safety features of a product" would "interfere with one of the major policy goals" of tort liability).

Post-market investigation. *Gilead* also creates a perverse incentive for manufacturers to do less post-market investigation. When they learn their products have been involved in accidents, many manufacturers seek to uncover as many details about the accidents as possible. They do this not just to prepare for potential litigation but also to assess whether improvements to the design of their products may be warranted. If a manufacturer were to learn through the course of such an investigation that an atypical accident could have been averted through a feasible design alternative, the manufacturer becomes subject to liability under *Gilead* for delaying commercialization of that alternative design—even if the alternative design would have made no difference in a typical accident and regardless of the cost of implementing it. To avoid that outcome, some manufacturers may decide they are better off the less they know. While that might help them avoid a firing squad under *Gilead*, the greater public good will not be served if manufacturers conduct fewer post-market investigations. This Court's existing

precedents, which condition a manufacturer's negligence liability on proof of a product defect, provide a much better incentive for responsible behavior than *Gilead*.

VI. CONCLUSION

The Court should reverse for the reasons stated.

Dated: November 4, 2024 Respectfully submitted,

TUCKER ELLIS LLP

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CERTIFICATE OF COMPLIANCE

Pursuant to Rule 8.504(d) of the California Rules of Court, I hereby certify that this brief contains 13,990 words, including footnotes. In making this certification, I have relied on the word count of the computer program used to prepare the brief.

By: /s/ Peter L. Choate
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CERTIFICATE OF SERVICE

I am employed with the law firm of Tucker Ellis LLP, whose address is 515 South Flower Street, 42nd Floor, Los Angeles, California 90071-2223. I am over the age of eighteen years, and am not a party to the within action.

On November 4, 2024, I served the following: **APPLICATION OF INTERNATIONAL ASSOCIATION OF DEFENSE COUNSEL FOR LEAVE TO FILE AMICUS BRIEF AND AMICUS BRIEF IN SUPPORT OF PETITIONER GILEAD SCIENCES, INC.** on the interested parties (see attached service list) in this action by:

X **BY MAIL**: By placing a true copy thereof enclosed in a sealed envelope(s) addressed as above, and placing each for collection and mailing on that date following ordinary business practices. I am readily familiar with this business's practice for collecting and processing correspondence for mailing. On the same day that correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the U.S. Postal Service in Los Angeles, California, in a sealed envelope with postage fully prepaid.

X **BY TRUEFILING**: By transmitting a true copy via this Court's TrueFiling System.

X **(STATE):** I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

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

/s/ Sofia Escalante
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