

No. 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.

After 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. Chang

**APPLICATION TO FILE AMICI CURIAE BRIEF AND
[PROPOSED] AMICI CURIAE BRIEF OF NATIONAL
ASSOCIATION OF MANUFACTURERS ET AL. IN
SUPPORT OF PETITIONER GILEAD SCIENCES, INC.**

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APPLICATION TO FILE AMICI CURIAE BRIEF

Under rule 8.520(f) of the California Rules of Court, the National Association of Manufacturers, the Alliance for Automotive Innovation, the American Tort Reform Association, the American Coatings Association, the American Chemistry Council, the Medical Device Manufacturers Association, and the Consumer Technology Association request permission to file the attached brief.¹

- **The National Association of Manufacturers** is the largest manufacturing association in the United States, representing small and large manufacturers in all 50 states and in every industrial sector. Manufacturing employs 13 million men and women, contributes about \$2.91 trillion to the United States economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda

¹ No party or counsel for any party in this case authored the proposed brief in whole or in part or made a monetary contribution intended to fund the preparation or submission of the proposed brief. No person or entity other than amici or their counsel made a monetary contribution intended to fund the preparation or submission of the proposed brief.

that helps manufacturers compete in the global economy and create jobs across the United States.

- **The Alliance for Automotive Innovation** is the leading advocacy group for the auto industry, representing 45 automobile manufacturers and value chain partners who together produce approximately 95 percent of all light-duty vehicles sold in the United States. The Alliance is directly involved in regulatory and policy matters affecting the light-duty vehicle market across the country. Members include motor vehicle manufacturers, original equipment suppliers, and technology and other automotive-related companies.
- **The American Tort Reform Association** is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation.
- **The American Coatings Association** is a voluntary, nonprofit trade association representing more than 170 manufacturers of paints and coatings, raw materials suppliers, distributors, and technical professionals. As the preeminent organization representing the coatings industry in the United States, a principal role of ACA is to serve as

an advocate for its membership on legislative, regulatory, and judicial issues at all levels. In addition, ACA undertakes programs and services that support the paint and coatings industries' commitment to environmental protection, sustainability, product stewardship, health and safety, corporate responsibility, and the advancement of science and technology. Collectively, ACA represents companies with greater than 90% of the country's annual production of paints and coatings, which are an essential component to virtually every product manufactured in the United States.

- **The American Chemistry Council** represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier, and safer. ACC is committed to improved environmental, health, and safety performance through common sense advocacy designed to address major public policy issues, and health and environmental research and product testing.
- **The Medical Device Manufacturers Association** is a national trade association that provides educational and advocacy assistance to approximately 300 innovative and entrepreneurial medical technology companies. MDMA's

mission is to promote public health and improve patient care through the advocacy of innovative, research-driven medical device technology.

- **The Consumer Technology Association** represents the \$488 billion U.S. consumer technology industry, which supports more than 18 million U.S. jobs. CTA's membership is over 1100 American companies—80% of which are small businesses and startups. CTA also owns and produces CES®, the world's most powerful technology event.

Amici together represent the interests of tens of thousands of American businesses, both large and small, that have an interest in stability and predictability in the law governing their operations. But the novel duty proposed by plaintiffs and endorsed by the Court of Appeal in this case—to immediately commercialize any product that is arguably safer than an existing product—threatens to upend long-settled products-liability law and invite needless litigation over products that have no defect and that were responsibly designed, manufactured, and sold to the public.

Accordingly, amici request leave to file the attached brief, in which they argue that existing tort law already adequately guides corporate decision-making and that plaintiffs' proposed duty would harm the courts, manufacturers, and consumers.

Specifically, the new duty would: (1) burden the courts and manufacturers with a large volume of cases that would be difficult to resolve on the pleadings; (2) shift responsibility for determining the scope of manufacturers' duty from courts to juries, leading to arbitrary and unpredictable results; (3) result in price increases as manufacturers try to account for the costs of litigating claims like plaintiffs' negligence claim here; and (4) discourage manufacturers from pursuing safety-related innovation.

Amici curiae respectfully request that the Court accept the enclosed brief for filing and consideration.

November 4, 2024

Respectfully submitted,
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AMICI CURIAE BRIEF

INTRODUCTION

Tort law already extensively regulates manufacturers, requiring them to design and make reasonably safe products and to provide adequate warnings about them. Current products-liability law is generally stable and predictable, giving manufacturers fair notice of when they might be held liable for their products. Manufacturers can plan accordingly, allocating their limited resources according to well-established legal standards.

Affirming the decision below and creating a new duty to immediately commercialize supposedly safer products would destabilize the law, create needless uncertainty for manufacturers, and diminish consumer choice and welfare in four ways.

First, the new duty recognized by the Court of Appeal would needlessly burden the judiciary with meritless claims about products that are not defective. Plaintiffs could single out any new product—or a product that could have been developed—that is arguably safer than its predecessor, at least for some subset of consumers, and accuse its maker of not commercializing it quickly enough. With courts required to take the allegations in

the complaint as true, even fanciful cases could survive a demurrer—and tax the resources of the courts.

Second, the new duty would undermine the predictability in the law on which manufacturers rely by making juries, not judges, responsible for deciding when manufacturers have a duty to commercialize a new product. If juries were to decide in every case whether the defendant had sufficiently developed a product to trigger a duty to commercialize it, there would be no rhyme or reason to their verdicts and no judicial precedent that could guide manufacturers. Manufacturers would not know what the law required of them until after the fact—and possibly after a costly verdict.

Third, ad hoc and inconsistent jury verdicts would force manufacturers to raise prices in an effort to cover the potential costs of litigating cases and paying judgments. Those costs are built into the prices of products, spreading the risk of injury across the entire customer base. The price increases that would result from the radical duty endorsed by the Court of Appeal would harm all consumers, especially those who are at risk of being priced out of the market altogether.

Fourth, the new duty would dampen manufacturers' incentive to create safer products. Making every safety innovation a potential basis for a lawsuit would discourage research and development into new products and features. If

manufacturers developed new safety technology, they would potentially face liability no matter when and how they chose to commercialize it. Move too fast, without ironing out all the kinks, and risk liability for a defect. Move too slowly, perhaps by conducting further product testing, and risk liability for not rolling out the new product sooner. Faced with that dilemma, many manufacturers may instead opt to avoid innovating altogether.

The Court should reverse and reject the duty proposed by plaintiffs and adopted by the Court of Appeal.

ARGUMENT

Plaintiffs assert that existing law does not provide consumers sufficient protection and urge the Court to adopt the novel duty, recognized by the Court of Appeal, to commercialize a supposedly safer product. That proposed duty would not just be inconsistent with decades of decisional law from courts in California and across the country. (See Op. Br. at pp. 23-44.) It would also immediately create four practical problems that counsel against radically expanding California tort law as plaintiffs request.

I. The novel duty recognized by the Court of Appeal would flood the judiciary and burden manufacturers with a large number of speculative lawsuits.

Under current law, conceding that a product is not defective ends a products-liability case. (See Op. Br. at pp. 23-

31.) But under the Court of Appeal's decision, whether a product is defective would become immaterial. So long as a plaintiff could allege that the defendant knew of a safer alternative, trial courts applying California's liberal pleading standard would have to accept that allegation as true and allow cases to proceed past a demurrer. (See, e.g., *Evans v. City of Berkeley* (2006) 38 Cal.4th 1, 6.) Speculating in a complaint that there is some discarded prototype of a safer product, or some blueprint gathering dust in a drawer, might be enough.

Plaintiffs will have little difficulty pleading as much. Innovation is an iterative, dynamic process, and behind every successful product is a mountain of failures. Nine out of ten drug candidates that reach the clinical stage (already a tiny fraction of total candidates) amount to nothing, and a successful drug generally takes at least a decade—plus at least a billion dollars—to develop. (Sun, *Why 90% of clinical drug development fails and how to improve it?* (Feb. 11, 2022) Acta Pharm. Sin B <<https://tinyurl.com/42asnn4t>>.) Extensive testing happens in just about every other business, too. Thomas Edison ran 2,774 experiments before he hit on a winning light-bulb filament. (Israel, *Edison: A Life of Invention* (John Wiley & Sons 1998) p. 201.) And James Dyson tested 5,126 vacuum prototypes before selling his famous cyclonic vacuum. (Gallo, *How James Dyson's*

Thousands of Failures Can Help You Tell a Captivating Founder Origin Story (Sept. 9, 2021) Inc. <<https://tinyurl.com/2bey6pkm>>.)

If cases premised on the novel duty recognized by the Court of Appeal could generally not be resolved until summary judgment, the burdens of litigation—the financial costs and the distraction of key personnel—would be immense. Plaintiffs could threaten in every case to conduct an expensive fishing expedition through the defendant’s documents and to depose its employees. In some cases, the collection of a large enough number of plaintiffs might have an in terrorem effect on the defendants and force settlements, even if the claims had no merit. (See, e.g., *De Asencio v. Tyson Foods, Inc.* (3d Cir. 2003) 342 F.3d 301, 310 [“The aggregation of claims . . . profoundly affects the substantive rights of the parties to the litigation. Notably, aggregation affects the dynamics for discovery, trial, negotiation and settlement, and can bring hydraulic pressure to bear on defendants.”].) And with or without such settlements, “[t]he burden on the courts posed by a flood of complex cases that cannot be resolved in the early stages of litigation would be daunting.” (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1030.)

II. The Court of Appeal’s decision would undermine the predictability of products-liability law.

Traditionally, courts decide whether a defendant has a duty to the plaintiff, and juries decide whether, as a factual matter,

the defendant has discharged that duty. (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 772.) This Court has made clear that the question whether a defendant has a duty to the plaintiff is a quintessentially legal question fit for resolution by courts on the pleadings, at summary judgment, or through a nonsuit motion. (See, e.g., *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 363-364; *Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 477.) But the Court of Appeal's decision would place in juries' hands the legal question whether the defendant had sufficiently developed an alternative product and knew enough about its potentially superior safety profile that the defendant had a duty to bring it to market. (See, e.g., Ans. Br. at pp. 9, 31-32.)

That shift would be seismic. It would run counter to a long line of cases emphasizing the distinct responsibilities of courts and juries. "The controlling distinction between the power of the court and that of the jury is that the former is the power to determine the law and the latter to determine the facts." (*Dimick v. Schiedt* (1935) 293 U.S. 474, 486; see also, e.g., *Sparf v. United States* (1895) 156 U.S. 51, 88 ["while to facts answer juries, to the law answers the court"].) Applying that principle, courts have refused to commit the interpretation of statutes or other legal rules to the ad hoc discretion of juries. (E.g., *Life Techs. Corp. v. Promega Corp.* (2017) 580 U.S. 140, 147-148; *DiFiore v. American Airlines, Inc.* (1st Cir. 2011) 646 F.3d 81, 88.)

There is good reason to maintain this strict division of labor between courts and juries. Putting juries in charge not just of finding facts, but of *making the law*, is a recipe for chaos. If juries were to decide on a case-by-case basis whether a defendant had a duty to commercialize a product, they would inevitably reach inconsistent and unpredictable results. (See, e.g., *Los Angeles Farming & Milling Co. v. Thompson* (1897) 117 Cal. 594, 601 [no judgment may rest on “the arbitrary discretion of the jury”].) They would not reliably and predictably account for the countless considerations potentially bearing on whether and when a company chooses to bring a new product to market—including the company’s financial health, the cost of developing the product, the availability of materials, the cost of distributing the product, and whether there is sufficient demand for the product at a price that would allow the manufacturer to turn a profit. The result of any jury trial that turns on the Court of Appeal’s new standard would be arbitrary, the one-off result of the inscrutable balancing of an unknown set of factors. Manufacturers would be left unable to predict when they might have a duty to make a thought experiment or a prototype a commercial reality; they would know only the omnipresent threat that plaintiffs’ theory could result in unexpected and untold liability. In short, plaintiffs would replace a relatively stable and well-established legal regime with one that is anything but.

This world imagined by plaintiffs—one in which juries retroactively create the law based on the specific facts of each case—also presents serious due-process concerns. Due process requires that manufacturers be able to know the law *before* they act. (See, e.g., *Smith v. Goguen* (1974) 415 U.S. 566, 572-576; *Mattison v. Dallas Carrier Corp.* (4th Cir. 1991) 947 F.2d 95, 101-102.) If it is impossible for them to know it, then they cannot be held liable for violating it. (See, e.g., *Papachristou v. City of Jacksonville* (1972) 405 U.S. 156, 170-171; *In re Sheena K.* (2007) 40 Cal.4th 875, 891-892.) Recognizing the duty endorsed by the court below would invite needless—and endless—forays into this constitutional thicket.

Under the current legal regime, by contrast, questions of duty are purely legal and decided by courts according to “a defined ‘set of rules which, in most instances, makes it possible to reach a correct determination beforehand’” about the risk of liability. (*Ornelas v. United States* (1996) 517 U.S. 690, 697.) By retaining exclusive authority to make law and permitting “[i]ndependent appellate review of legal issues,” courts advance “the dual goals of doctrinal coherence and economy of judicial administration.” (*Salve Regina Coll. v. Russell* (1991) 499 U.S. 225, 231.) Juries, by contrast, have almost unreviewable discretion—and have long been criticized for producing “random,

lottery-like results.” (Breyer, *Breaking the Vicious Circle: Toward Effective Risk Regulation* (1993) p. 59.)

Plaintiffs might respond to this concern about shifting law-giving responsibility to juries by saying that it is not unusual for courts to set out a duty in general terms and for a jury to find the facts that give rise to that duty. On that theory, the court remains the master of the law, the jury master of the facts. But that separation would not be so clear in practice; neither plaintiffs nor the court below have ever articulated any guidelines that might channel the jury’s discretion. As a result, even if a court were technically the one pronouncing that there is a duty to commercialize a product whenever a defendant knew that product might be safer for some subset of its customers, it would fall to juries to give that vague pronouncement any content—to create and apply their own standards in each case. If anyone should be creating those standards, it is politically accountable legislatures and regulators, who already extensively supervise manufacturers, especially in the pharmaceutical industry. It would be a radical and damaging change to follow the Court of Appeal’s lead in “put[ting] the timing of corporate decisions about product development into the hands of lay juries.” (Priest, *California’s Negligence Tort Empowers Juries, Hurts Innovation* (Feb. 14, 2024) Bloomberg News <<https://tinyurl.com/2z9vwskd>>.)

In short, the new duty recognized by the Court of Appeal promises to transfer responsibility over a crucial legal determination to juries, which would inevitably produce doctrinal incoherence and deep confusion among market participants about what the law requires.

III. The new duty endorsed by the Court of Appeal would result in price increases as manufacturers tried to estimate the magnitude of their potential liability.

Current law imagines a forward-looking bargain between the consumer and the manufacturer, with perhaps a distributor and a retailer in between. Under that bargain, the consumer pays a competitive price in exchange for a nondefective product. That competitive price reflects more than just the direct costs of making the product, like the materials and the labor. It also reflects various indirect costs, including what the manufacturer will spend if the product does not work (warranty claims) or causes injury (personal-injury claims). (See, e.g., Schwartz, *Proposals for Products Liability Reform: A Theoretical Synthesis* (1988) 97 Yale L.J. 353, 362 [“A firm that compensates consumers for the harms its product causes will reflect the expected compensation cost in the purchase price. An element of the price thus is an insurance premium”]; Priest, *A Theory of the Consumer Product Warranty* (1981) 90 Yale L.J. 1297, 1308 [manufacturers “collect[] a premium in the sale price from a broad set of

consumers” to cover expected warranty claims].) In other words, the risk of product defects (that is, the cost of litigating and resolving claims stemming from those defects) is baked into the price of the product. (See, e.g., Calabresi, *Some Thoughts on Risk Distribution & The Law of Torts* (1961) 70 Yale L.J. 499, 530-531.)

Whether the risks of injury or litigation are large or small, manufacturers must account for them in deciding whether and at what price to offer a product to the market. In a very real sense, manufacturers are selling not just one physical product, but a product and a bundle of intangible rights, especially a warranty (against product defects) and what amounts to an insurance policy (against the risk of personal injury). (See, e.g., Abraham & Liebman, *Private Insurance, Social Insurance, and Tort Reform: Toward a New Vision of Compensation for Illness and Injury*, 93 Colum. L.Rev. 75, 88 (1993) [“Tort liability is also a forced-insurance arrangement, under which potential victims are required to insure themselves against the risk of suffering injury from . . . the sale of a product.”].) And it is impossible to sell insurance without having a good sense of the probability of a covered event and the cost that such an event might impose. (See, e.g., *Proctor v. State Farm Mut. Auto. Ins. Co.* (D.C. Cir. 1982) 675 F.2d 308, 323 & fn. 30.)

Pricing products to account for potential liability does not just protect manufacturers. It also helps consumers by ensuring that any companies that make defective products have the resources to compensate victims and purchase liability insurance. Pricing products to reflect their risks thus helps accomplish the “paramount policy” of products-liability law: “the protection of otherwise defenseless victims of manufacturing defects and the spreading throughout society of the cost of compensating them.” (*Ray v. Alad Corp.* (1977) 19 Cal.3d 22, 31.)

Adopting a duty to innovate would result in unpredictable outcomes and new and prolonged litigation, both of which will force manufacturers to increase prices. It would make the result of any case unpredictable and potentially penalize manufacturers for making choices that, in hindsight, arguably did not maximize consumer safety for some subset of consumers or even just one particular plaintiff. But plaintiffs and the Court of Appeal have not accounted for what that new regime would mean for manufacturers, which are unable to assess the likelihood of claims based on products that have yet to be fully developed or dangers that have yet to be understood. As a result, adopting a duty to innovate would compel manufacturers to brace for arbitrary future risks by increasing their prices to cover unexpected future costs. Those price increases would harm

consumers, especially those who would be priced out of the market.

IV. The Court of Appeal’s proposed duty would slow the pace of innovation and undermine safety in the name of promoting it.

Should a duty to innovate become law, manufacturers would be put to a difficult choice: They could either rush new products to market (and risk traditional suits over defects), or they could take their time (and risk suits, like this one, premised on the “delay” in bringing supposedly safer products to market).

If investing in innovation created the risk of lawsuits, manufacturers would have the incentive to invest less. The only surefire way to avoid liability would be to stop investing in innovation altogether. That disincentive would have the biggest effect on existing businesses, both because they have more to lose and because the release of any new product might immediately prompt comparisons to existing products—and questions about precisely when the new idea first became commercially practicable. Innovation would shift to newer businesses—many of which would lack the resources to pay significant judgments for any harms caused by their products, undermining the risk-spreading function of products-liability law.

The inevitable decline in investment and innovation from established players, and the shift in innovation to riskier ventures, would harm consumers, limiting their choices and

depriving them of important technological advances, including new safety features.

To see how these problems might play out, consider the car industry. Carmakers are continually innovating to make their products safer. If plaintiffs had their way, those innovations could give rise to legal liability. Whenever carmakers rolled out new safety technology—for example, a new lane-keeping system to prevent drivers from drifting off the road or a new braking system to shorten stopping distances and prevent crashes—they could be sued for not doing it sooner, or for doing it only for some models and not others. The theory would be much the same as plaintiffs’ theory in this case. Plaintiffs claim that Gilead deliberately withheld a safer product to make more money. (Ans. Br. at pp. 9, 40-41.) Carmakers could be accused of doing the same thing by making new safety technology available only in flagship models—and only much later including those same technologies in less expensive models. If that sort of market segmentation were a new form of negligence, manufacturers might make *only* the premium product with all the latest features—which would price many consumers out of the market—or avoid innovation altogether—which would prevent the development of important new safety features.

Cars are an obvious example, but there are countless others. A medical-device manufacturer could be sued on the

theory that a new drug-eluting stent that was long under development proved to be more effective at reducing the risk of blocked arteries than an earlier bare-metal model. A construction-equipment manufacturer could be sued for not rushing into production a complex sensor system preventing nail guns or saws from operating when they might injure fingers. And on and on.

The law should not discourage innovation, especially when it comes to safety. This Court should instead account for a reality that the Court of Appeal seems to have overlooked—that there are always tradeoffs in running a business. Every company, no matter how well capitalized and successful, has limited resources, and it must use its business judgment to allocate them. It must make choices. Some might disagree with those choices—might think that the company should have invested more in this or that product or segment of the market—but that is a decision that the courts (and governments more generally) traditionally have no say in. “[J]udges make for poor ‘central planners’ and should never aspire to the role.” (*NCAA v. Alston* (2021) 594 U.S. 69, 102-103.) Bearing that principle in mind, this Court should reinforce the traditional and administrable rule that manufacturers’ choices result in liability only when they result in a defective product.

CONCLUSION

Plaintiffs invite this Court to abolish a well-established and predictable legal regime with one that would be novel, arbitrary, and costly to courts, businesses, and consumers. The Court should avoid those problems by holding that there is no general duty to innovate or to immediately commercialize any supposedly safer product. The Court should reverse.

November 4, 2024

Respectfully submitted,

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Chemistry Council, Medical Device
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CERTIFICATION OF WORD COUNT

Under rule 8.204(c)(1) of the California Rules of Court, I certify that this application and brief contain 4,152 words, excluding the tables and this certificate, according to the word count generated by the computer program used to produce this document.

Dated: November 4, 2024

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PROOF OF SERVICE

I certify that on November 4, 2024, I electronically served this application and the accompanying brief on the parties (listed on the attached service list) through TrueFiling.

I also arranged for a copy of the application and the brief to be mailed to the trial court at the following address:

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

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