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March 12, 2024

The Honorable Chief Justice Patricia Guerrero
and Honorable Associate Justices
Supreme Court of California
350 McAllister Street
San Francisco, CA 94102

Re: *Gilead Tenofovir Cases*, No. S283862

To Chief Justice Guerrero and Associate Justices:

We write on behalf of the National Association of Manufacturers, the Alliance for Automotive Innovation, the American Tort Reform Association, the Personal Care Products Council, the American Coatings Association, and the American Chemistry Council to urge this Court to grant the petition for review filed by Gilead Sciences, Inc.

A. Introduction

In the decision below, the Court of Appeal became the first court in the country to endorse the theory that even if a product is not defectively designed or manufactured, and even if its warning labels are accurate and its marketing unobjectionable, its manufacturer may nevertheless be held liable for not selling a different product altogether. That decision conflicts with longstanding law making clear that a manufacturer's duties to the retail buyer of its products flow from, and are bounded by, those specific products. There has never been, until now, a duty to develop and sell a potentially better or safer product. So long as a product is not defective and is lawfully advertised and sold, that product's fate should be determined by the market, not by the courts.

Although the Court of Appeal embraced a completely novel method of holding manufacturers liable for selling non-defective products, it repeatedly suggested that its decision would not unsettle the law and unleash a flood of similar claims. These amici have serious doubts about that prediction. Nothing in the decision below applies exclusively to the pharmaceutical context, nor would it be difficult for other plaintiffs to copy the theory endorsed by the court below. Innovation is a necessity in every business. But now, discarded ideas

and prototypes, rather than being stepping stones on the path to success, could become the basis of lawsuits. And manufacturer defendants would have difficulty defeating even meritless cases on the pleadings, given California's liberal pleading standards.

In departing sharply from traditional products-liability law, the decision below has stirred up considerable concern about the scope of manufacturers' liability among these amici and the wide range of American businesses they represent. And these amici are not alone. Commentators across the country have sounded the alarm about the decision. For example:

- Yale Law Professor George Priest has said the Court of Appeal's decision marks "a radical change in the tort of negligence," "puts the timing of corporate decisions about product development into the hands of lay juries," and "deters innovation." (Priest, *California's Negligence Tort Empowers Juries, Hurts Innovation* (Feb. 14, 2024) Bloomberg News <https://tinyurl.com/2z9vwskd>.)

- NYU Law Professor Richard Epstein has explained that the Court of Appeal "manufacture[d] legal duties at total variance with common expectations and uniform historical practice," and that the court's decision will "reduce medical innovation, yet another instance of the iron law of unintended consequences." (Epstein, *How legal adventurism stifles medical innovation* (Feb. 16, 2024) O.C. Register <https://tinyurl.com/4f7tuv94>.)

- *The Wall Street Journal* explained that under the Court of Appeal's decision, "once a company starts tinkering with a new and potentially improved product, it could be legally obligated to bring it to market, no matter the commercial or technological barriers"—a rule that "will create a disincentive to innovate." (Editorial Board, *California Invents a Crazy New Tort* (Jan. 14, 2024) Wall Street Journal <https://tinyurl.com/y424v6ne>.)

This Court should grant review to clarify that scope and to bring California law back in line with the general and sound rule that a manufacturer can be held liable only for the products it actually made and sold, not products it *could have* made and sold.

B. Interest of these amici

Six amici urge this Court to grant review and reverse:

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 $2.85 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 that helps manufacturers compete in the global economy and create jobs across the United States.

2. **The Alliance for Automotive Innovation** is the leading advocacy group for the auto industry, representing 35 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.

3. **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.

4. **The Personal Care Products Council** is the leading national trade association representing cosmetics and personal care products companies. PCPC's membership represents more than 90% of the U.S. beauty industry. These members manufacture, distribute and supply the vast majority of personal care products sold in the U.S. and are global leaders in their field. PCPC is an important voice on legal, regulatory, legislative, scientific, and international issues regarding personal care products.

5. **The American Coatings Association** is a voluntary, nonprofit trade association representing some 250 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.

6. **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.

These amici together represent the interests of tens of thousands of American businesses both large and small. All those businesses have an interest in stability and predictability in the law governing their operations. But the Court of Appeal's decision in this case threatens to shake up long-settled products-liability law and invite needless litigation over products that were responsibly designed, manufactured, and sold to the public.

C. This Court should grant review.

It is essential for manufacturers to understand the potential scope of their liability *before* they sell products in this country's largest market, California. For decades, manufacturers have operated with confidence that selling a product that was not defectively designed or manufactured, and that was the subject of appropriate warnings, cannot result in any liability. The decision below has shaken that confidence, opening manufacturers of all kinds—not just

pharmaceutical companies—to a new theory of liability. This Court should grant review and reject that theory, thereby preventing the needless and unprecedented expansion of negligence liability that the decision below threatens to cause.

1. The Court of Appeal adopted a novel and incorrect theory of negligence.

The court concluded that Gilead might be liable for negligence even though its drugs were not defectively designed or manufactured and even though it appropriately warned patients about the drugs' risks. No other court in the country has ever endorsed that theory. To the contrary, as Gilead explains (Pet. at pp. 24-28), courts have consistently held that without some defect in design, manufacture, or warning, there can be no liability.

In fact, California courts have rejected theories like the one adopted by the court below. Consider, for example, *Valentine v. Baxter Healthcare Corp.* (1999) 68 Cal.App.4th 1467. There, the plaintiffs sought to hold the defendant liable for personal injuries caused by silicone breast implants. (*Id.* at p. 1474.) Their theory was that the defendant was negligent not just in designing, manufacturing, and warning about the implants, but also in failing to adequately test and inspect them. (*Ibid.*) The Court of Appeal rejected that theory, holding that negligence in testing or inspection cannot be an independent basis for products liability. The court explained that after the jury "exonerated [the defendant] of liability for manufacture, design, and warning, nothing remain[ed] upon which to hang the testing and inspection duties." (*Id.* at p. 1485.) Unless the manufacturer defendant makes a "product that is defective in design, manufacture, or warning, no injury can result. If the manufacturer designs the product safely, manufactures the product safely, and provides an adequate warning of dangers inherent in the use of the product, then a failure to test the product cannot, standing alone, cause any injury." (*Id.* at p. 1486.) The court thus rejected the notion that there should be "liability for breach of an independent duty to conduct long-term testing." (*Ibid.*)

The Court of Appeal reached a similar result in *Lambert v. General Motors* (1998) 67 Cal.App.4th 1179. There, even though the jury found that the design of the 1985 Chevy Blazer was not defective, it also found that General Motors was negligent in designing the Blazer. (*Id.* at p. 1182.) The Court of Appeal reversed the verdict, explaining that the plaintiff's case turned on a defective design and that he could not rescue it by turning to a theory of

"negligent design." (*Id.* at pp. 1184-1186 [collecting cases].) "If the design of the Blazer was not defective, General Motors could not be deemed negligent." (*Id.* at p. 1186.)

And, as Gilead points out (Pet. at pp. 26-27), this Court rejected a similar effort to rebrand a design-defect argument in *Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465. The plaintiffs there insisted they were suing over not a "defective product," but "negligent conduct." (*Id.* at p. 480.) It was nevertheless clear that they were suing over a supposed product defect, which state law in that case forbade. (*Id.* at p. 481.)

Here, by contrast, the Court of Appeal embraced the plaintiffs' effort to rebrand their claims. The plaintiffs *concede* that the products at issue were not defectively designed or manufactured, and that they received adequate warnings about the dangers. They nevertheless contend that Gilead breached a duty to them that is independent of the duties to design and manufacture a non-defective drug and to make appropriate warnings. That must mean manufacturers have some other, antecedent duty that runs to the ultimate buyers of their products—a duty that does not depend on the products themselves, even though those products are the only connection between the manufacturers and the buyers. And that duty, the Court of Appeal held, was to continue developing and to sell a *different* product.

Until now, no other court has recognized such a duty, and for good reason. No business has a duty to commercialize any product. If a business wishes to sell a product that could be improved in one way or another, it may do so, provided the product is not defective and is the subject of appropriate warnings. That decision may ultimately go unrewarded in the marketplace. A competitor might develop, patent, and sell a better product. But, until now, no principle of law or judicial decision required any business to sell the best possible product. This Court should grant review to make clear that only market forces—not tort law—govern business decisions to develop and sell (or not develop and sell) new, non-defective products.

2. The decision below has no limiting principle and creates needless uncertainty for all manufacturers.

Although the decision below addresses general principles of negligence law, the Court of Appeal repeatedly insists that the decision is narrow. It claims that the new theory it endorsed will apply only in the narrow circumstances

where a manufacturer has already invented a safer product and withheld it from the market—and therefore will not "result in a flood of litigation." (Opn. at pp. 10, 32, 52.) That prediction is dubious for two reasons.

First, the Court of Appeal's rationale is not limited to the facts of this case. The negligence theory that the court accepted could be repurposed against *any* manufacturer, not just a drug maker. (See Pet. at pp. 7-8, 21; Priest, *supra*.) The upshot of the Court of Appeal's decision is that the second *any* manufacturer comes up with an idea that somebody might later claim could have saved lives or presented fewer risks, it could have a duty to bring that idea to market. The staggering breadth of that rule is why these amici, which represent interests far broader than the pharmaceutical sector, are concerned about this case.

Second, it will not be hard for enterprising plaintiffs' lawyers to plead a claim under this new theory of negligence. There would be no shortage of potential targets, and California's liberal pleading standards would make it difficult to win quick victories even against meritless suits.

Gilead is not the only potential target for the plaintiffs' new theory of negligence. It is not the only manufacturer that tests a great many ideas before bringing one to market. Other drug makers do the same. They have to: Nine out of ten 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.) 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>.) There is innovation even in fast food: Taco Bell's "innovation scientists test roughly seventy" new products annually, and "to come up with those seventy, they consider thousands of ideas." (Hitchens, *Taco Bell's Innovation Kitchen, the Front Line in the Stunt-Food Wars* (Apr. 17, 2023) New Yorker <https://tinyurl.com/5ep9pcda>.) Innovation is crucial in just about every business, and behind every great product is a mountain of discarded ideas and prototypes.

The decision below will deter manufacturers from exploring such new ideas and prototypes, particularly those that might affect product safety. The prospect of offering products safer than the competition's provides a powerful incentive for companies to engage in the expensive and resource-intensive process of product innovation. But because of the decision below, that incentive will now be tempered by the threat of liability for every new design that a company investigates but does not ultimately choose to commercialize. In other words, the Court of Appeal's decision would undermine safety in the name of promoting it.

And it will be difficult to defeat claims brought under the theory endorsed below without substantial litigation costs. With California courts bound to accept pleadings as true and unable to police complaints for plausibility, a plaintiff need only plead that a defendant developed two products, knew one was safer, and sold the less safe one anyway. Those claims, even if fanciful, would have at least nuisance value—or, if the number of plaintiffs is large enough, might have an in terrorem effect on the defendant and force a settlement.

Another reason that even extremely weak claims would create undue settlement pressure is all the uncertainty about what the Court of Appeal's new standard means in practice. Here are just a few of the questions it leaves unanswered:

- When is a possibly safer product sufficiently developed to trigger a duty to market it to consumers?
- What evidence would be sufficient to demonstrate that the defendant knew the alternative product was safer?
- Do tradeoffs matter? What if the product the defendant actually sold is superior to purportedly safer alternatives on many other dimensions, such as efficacy and cost?

Given all the uncertainty inherent in this new negligence theory, manufacturers are left with no clear guidance on how to avoid liability, other than to avoid investing in innovation altogether.

If the Court of Appeal's decision teaches any lessons, they appear to be socially damaging ones. Manufacturers seem to have a choice between rushing products to market to avoid a negligence claim—risking liability for traditionally

recognized defects along the way—and avoiding innovation altogether. What they cannot do, at least without the threat of liability, is explore competing alternatives and responsibly allocate their capital to the ideas that promise to deliver sound, non-defective products and an appropriate return on investment.

In short, the Court of Appeal's claim that its decision is narrow is cold comfort not just to Gilead, but to every other business that might be sued under the novel theory validated in this case. In its effort to explain why that theory will rarely apply, the Court of Appeal drew up a blueprint for other plaintiffs to follow—one that could mire other manufacturers in years of litigation for no good reason.

D. Conclusion

The Court should grant review of Gilead's petition to uphold the fundamental rule that a manufacturer's duty to retail buyers of its products begins and ends with the products it actually sells, not a product it might have sold.

Sincerely,

Theane Evangelis

PROOF OF SERVICE

I, Daniel R. Adler, declare as follows:

I am employed in the County of Los Angeles, State of California, I am over the age of eighteen years, and I am not a party to this action. My business address is 333 South Grand Avenue, Los Angeles, CA 90071. On March 12, 2024, I served the following document:

LETTER FROM AMICI CURIAE IN SUPPORT OF GILEAD SCIENCES, INC.'S PETITION FOR REVIEW

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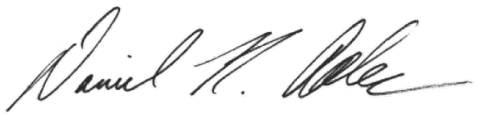
☑ **(STATE)** I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed on March 12, 2024.



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