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March 4, 2024

Via TrueFiling
Chief Justice Patricia Guerrero and Associate Justices
Supreme Court of California
350 McAllister Street
San Francisco, CA 94102-4797

Re: *Gilead Tenofovir Cases*, No. S283862, Amicus Letter of Washington Legal Foundation, Supporting Review

Honorable Justices:

Washington Legal Foundation submits this letter supporting Gilead Sciences, Inc.'s Petition for Review. Gilead's petition raises an important legal issue, acknowledged by the trial court as "novel," which merits the Court's review. Plaintiffs allege injury from a product but allege no product defect. In denying Gilead's summary judgment motion, the trial court approved an unprecedented liability theory: a manufacturer may be held liable in tort for not selling a different, marginally safer product.

The Court of Appeal affirmed in relevant part. It held that when a manufacturer has invented "what it knows is a safer, and at least equally effective, alternative" to an existing product it already sells, it "has a duty of reasonable care" to users of the current product when deciding on the commercialization of the alternative product. That expansive liability theory would wreak havoc on product manufacturing and product litigation throughout the State, destabilizing innovation. The Court should grant review.

Interest of Amicus Curiae

WLF is a nonprofit, public-interest law firm and policy center with supporters nationwide, including many in California. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as an amicus curiae to oppose novel state-law tort duties that second-guess the safety of federally regulated products. (See, *e.g.*, *Burningham v. Wright Med. Tech., Inc.* (Utah 2019) 448 P.3d 1283; *McNair v. Johnson & Johnson* (W.Va. 2018) 818 S.E.2d 852).) Such suits undermine the very goals of public health and safety that tort law is intended to further. WLF's Legal Studies division also regularly publishes articles by outside

experts on state-law approaches to product liability. (See, *e.g.*, John J. Park, Jr., *Law Rejecting "Innovator Liability" Theory Restores Civil Justice Sanity to Alabama*, WLF Legal Opinion Letter (June 19, 2015).)

The Court Should Grant Gilead's Petition Because the Court of Appeal's Novel Liability Theory Would Undermine California Product Liability Law.

Plaintiffs seek damages for taking tenofovir disoproxil fumarate (TDF) drugs but "concede that they are not asserting that the TDF drugs are defective." Thus, Plaintiffs do not allege that anything is wrong with the design, manufacture, or labeling of TDF drugs. The FDA has approved them as safe and effective when used as directed, and they have helped save and enhance the lives of countless people living with HIV/AIDS.

Under longstanding California law governing product-based injuries, a concession that the product at issue is not defective should end the litigation. Product manufacturers are responsible for selling a product that is neither defective nor unreasonably dangerous. Creating a new duty to bring a different product to market has no precedent and, as framed by the Court of Appeal, would be unbounded and unprincipled. While the existence of a safer alternative design is already a consideration in product defect cases, it can create liability only in specific situations under product liability law and does not create stand-alone liability.

Before TDF became available, HIV patients had to take multiple medicines at inconvenient schedules (sometimes requiring them to interrupt their sleep). Many patients found it impossible to maintain the proper dosage of medicine given this erratic schedule. FDA responded by encouraging the development of a single, once-a-day tablet therapy for treating HIV. Gilead answered that call with TDF. Gilead should not now face liability for doing so. A manufacturer's legal obligation is to sell a non-defective product, and when it has done so, it has exercised reasonable care in the product's design and has legally satisfied its duty to the purchaser and user of that product. (See *Milwaukee Elec. Tool Corp. v. Superior Court* (1993) 15 Cal.App.4th 547, 551 [California imposes "a general duty to produce defect-free products"]; *Williams v. Beechnut Nutrition Corp.* (1986) 185 Cal.App.3d 135, 141 ["A manufacturer/seller of a product is under a duty to exercise reasonable care in its design so that it can be safely used as intended by its buyer/consumer"].)

To be sure, Plaintiffs do not argue, under *Barker v. Lull Eng'g Co.* (1978) 20 Cal.3d 413, that Gilead should be liable for not implementing a "reasonable alternative design" of the same product. Nor do they argue that Gilead was negligent in designing TDF. Indeed, their claim has nothing to do with TDF—the drug Plaintiffs allege caused their injury. Rather, Plaintiffs contend that Gilead should be

liable for not developing earlier and selling more quickly entirely different products made with the ingredient TAF.

No court has *ever* imposed a duty on a manufacturer to develop and market a different product just because a plaintiff alleges that the other product might not have caused the injury alleged in the case. (See, *e.g.*, *Prentis v. Yale Mfg. Co.* (Mich. 1984) 365 N.W.2d 176, 181-82 ["in every other state" and in "every jurisdiction . . . [t]he plaintiff must, in every case . . . show that the product was defective"]; *Slisze v. Stanley-Bostitch* (Utah 1999) 979 P.2d 317, 320 ["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, or a duty to inform the consumer of the availability of the safer model." (cited by *Brown v. Sears, Roebuck Co.* (10th Cir. 2003) 328 F.3d 1274, 1283].) Because this theory of negligence eviscerates decades of California precedent governing product-based injuries, it warrants the Court's review.

Eliminating Defect from Product-Based Claims Would Open the Door to Unprincipled Liability and Undermine Product Innovation.

The Court should also grant the petition because the Court of Appeal's new liability theory could have widespread implications for many other useful, beneficial products sold in the State. It presumes that manufacturers should no longer be judged based on whether their products are defective, but on whether they could have brought different products to market. Innovation requires exploring multiple options when researching and developing new products. Many considerations go into deciding whether, when, and how to bring a new product to market. Innovative companies thus face endless choices in product development—the age-old Betamax-versus-VHS question. Choosing one product over the other must not be turned into a legal wrong, particularly when the product chosen has proven to be beneficial and is not defective.

The Court of Appeal's theory clashes with how technology is developed. For example, when auto manufacturers began making passive restraint technology, the U.S. Department of Transportation *encouraged* them to experiment with different options, including airbags and automated seatbelts. (See *Geier v. American Honda Motor Co., (*2000) 529 U.S. 861.) The regulators recognized that doing so gave the auto industry the ability to experiment, assess results, and maximize benefits. (See *id.* at 878-79 [favorably quoting DOT's explanation that "a mix of [passive restraint] devices would help develop data on [their] comparative effectiveness"].) Because there was nothing inherently defective about automated seatbelts, manufacturers who sold vehicles with non-defective automated seatbelts could not be found liable retroactively simply because airbags proved to be more effective in most collisions.

The same is true today with electric vehicle technology. Many manufacturers developed lithium-ion rather than solid-state battery technology for their cars. Although lithium-ion batteries recharge quickly and are effective at holding more power in smaller spaces, they also pose a greater fire risk. (See Pranshu Verma, *Inside the Race for a Car Batter that Charges Fast – and Won't Catch Fire,* Wash. Post. (May 18, 2022).) Some manufacturers are investing in solid-state battery technology for their electric vehicles because those batteries may be safer. Auto manufacturers who developed and sold lithium-ion batteries should not one day be subject to liability for selling lithium-ion batteries that are not defective on the theory that they should have sold vehicles with solid-state batteries sooner.

Entrepreneurial plaintiffs' lawyers no doubt will seek to leverage this new liability regime in countless circumstances. Consider the masks Americans have been wearing in response to the COVID-19 pandemic. Manufacturers developed varied masks, from cloth masks to disposable surgical masks to N95 respirators. It is now known that N95 respirators provide the highest level of protection. (See CDC, Types of Masks and Respirators (Jan. 28, 2022), https://perma.cc/U4Q3-PJPA) That does not mean that manufacturers of non-defective surgical and cloth masks can or should be liable—retroactively or today—for the spread of COVID-19 among individuals wearing those face coverings.

The Court of Appeal's new theory would have a disastrous effect on innovation and manufacturing outside the drug and device space. Basing liability on knowledge and financial considerations alone would open the door to untold liability. Like any business, manufacturers must consider profitability when deciding which products to make. Particularly in heavily regulated markets, a manufacturer must also consider many nuanced and interrelated factors when allocating finite resources. Liability for product harms must therefore remain focused on the product they made—not speculation over whether some other product might have been better for some people in some cases.

The Court Should Grant the Petition to Ensure This Novel Liability Theory Does Not Drive Improper Liability Here or in Other Cases.

Review is warranted here given the potential magnitude of this ruling. In the JCCP in which the trial court's order was entered, there are over 24,000 plaintiffs with claims that hinge on whether California law will allow this "novel" liability theory. So long as this new theory of liability remains viable, it creates a window of opportunity for creative, speculative, and abusive lawsuits against the manufacturers of many beneficial, non-defective products. Of course, imposing novel and unpredictable liability on prescription drug manufacturers harms consumers as well as manufacturers. It can "discourage the development and availability of life-sustaining and lifesaving drugs, thereby defeating a strong public interest." (*Carlin*

v. Superior Court (1996) 13 Cal.4th 1104, 1126-27.) Now is not the time to experiment with well-settled tort principles. Rather, it is time for this Court to intervene and defend the rule of law.

This Court's review is thus needed to "help assure that the powerful engine of tort liability, which can generate strong financial incentives to reduce, or to eliminate, production, points toward the right substances and does not destroy the wrong ones." (*Gen. Elec. Co. v. Joiner* (1997) 522 U.S. 136, 148-49 (Breyer, J. concurring); see also *Tamraz v. Lincoln Elec. Co.* (6th Cir. 2010) 620 F.3d 665, 678 [explaining that "allowing the law to get ahead of science" would "stifle innovation unnecessarily"].)

Conclusion

For these reasons, this Court should grant Gilead's petition and overturn the ruling below.

Respectfully submitted,

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John M. Masslon II
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PROOF OF SERVICE

DISTRICT OF COLUMBIA)
) SS
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I am employed in Washington, D.C. I am over the age of 18 years and not a party to this action. My business address is 2009 Massachusetts Avenue NW, Washington, D.C. 20036.

On March 4, 2024, I served the **Amicus Letter of Washington Legal Foundation Supporting Petition for Review** on all interested parties here as follows:

☒ (VIA E-SERVICE) I transmitted the document by electronic service to all interested parties via the Court's Electronic Filing System operated by ImageSoft TrueFiling (TRUEFILING).

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

Executed on March 4, 2024 at Washington, D.C.

/s/ Cory L. Andrews
CORY L. ANDREWS