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July 7, 2022

Honorable Jim Humes, Administrative Presiding Justice,
and Associate Justices of the First District Court of Appeal
350 McAllister Street
San Francisco, CA 94102-7421

Re: *Gilead Sciences, Inc. v. Sup. Court*, Court of Appeal No. A165558, Div. 4
Amicus Letter of Washington Legal Foundation
Supporting Petition for Writ of Mandate

To the Honorable Court:

Washington Legal Foundation submits this letter in support of Gilead Sciences, Inc.'s Petition for Writ of Mandate or Other Appropriate Relief.[1] Gilead's petition raises an important issue, acknowledged by the lower court as "novel," which merits the Court's immediate attention. Plaintiffs allege injury from a product but do not allege a product defect. In denying Gilead's summary judgment motion, the trial court authorized an unprecedented liability theory: a manufacturer may be held liable in tort for not developing and selling a different product.

The trial court's new liability rule rewrites California's longstanding law over product-based injuries. Besides removing the defect linchpin, it allows Plaintiffs to assert a negligence claim having nothing to do with the product they bought or used. Such an expansive liability theory would no doubt have recurring effects on product litigation throughout the state and destabilize product innovation. The Court should grant Gilead's petition.

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 amicus curiae to

[1] Amicus letters are procedurally proper. The Advisory Committee comment to Rule 8.487 states that courts may permit such letters in support of writ petitions, and the courts have routinely accepted them. (See, *e.g.*, *Regents of Univ. of Cal. v. Superior Court* (2013) 220 Cal.App.4th 549, 557-558; *L.A. Cnty. Bd. of Supervisors v. Superior Court* (2015) 235 Cal.App.4th 114, *rev'd on another ground,* (2016) 2 Cal.5th 282).)

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 Trial Court Approved a "Novel" Liability Theory that Would Undermine California Law.

In denying Gilead's motion for summary judgment, the trial court acknowledged that Plaintiffs advanced a "novel" theory of liability. As the court explained, Plaintiffs are seeking damages for taking tenofovir disoproxil fumarate (TDF) drugs but "concede that they are not asserting that the TDF drugs are defective." Thus, Plaintiffs are not alleging anything is wrong with the design, manufacture, marketing, 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 tort law governing product-based injuries, a concession that the product at issue is not defective should end the litigation. 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"].)

The trial court conceded this jurisprudence: "a product defect seems to necessarily be part and parcel of a negligent design claim" and that courts would require a defect "even under a negligence theory." Yet it "nonetheless" inexplicably concluded that it would allow Plaintiffs' claims to proceed under the theory that Gilead "should have more quickly developed and obtained approval for TAF [(tenofovir alafenamide)]," a completely different drug than TDF.

To be clear, 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. Instead, Plaintiffs contend that Gilead should be liable for not earlier developing and selling an entirely different product, 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, 181-182 ["in every other state" and in "every jurisdiction . . . [t]he plaintiff must, in every case . . . show that the product was defective"].) Because this theory of negligence eviscerates decades of California precedent over 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 this 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. Innovative companies 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 not defective.

The trial court'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., Inc.* (2000) 529 U.S. 861.) The regulators recognized that doing so gave 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"].) There was nothing inherently defective about the automated seatbelts. Thus, manufacturers who used non-defective automated seatbelts could not be subject to liability retroactively because airbags proved to be more effective in many collisions.

The same is true today with electric vehicle technology. Many manufacturers developed lithium-ion instead of solid-state battery technology for their cars because lithium-ion batteries recharge quickly and are effective at holding more power in smaller spaces. But 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 developed 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://bit.ly/3bEUYHV) 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.

Particularly in heavily regulated markets, such as prescription drugs, there are many nuanced and interrelated factors a manufacturer must consider when choosing which products to make. 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 Writ to Ensure This Novel Liability Theory Does Not Drive Improper Liability Here or in Other Cases.

Writ relief 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, making a post-trial appeal untimely and inadequate. (See *H. D. Arnaiz, Ltd. v. Cty. of San Joaquin* (2002) 96 Cal. App. 4th 1357, 1367 ["[D]elay and expense of trial are a valid consideration in deciding whether to grant writ review"].)

So long as this new theory of liability appears viable, it creates a window of opportunity for creative, speculative, and abusive lawsuits against other manufacturers of 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.

Conclusion

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

Respectfully submitted,

Cory L. Andrews
GENERAL COUNSEL & VICE
PRESIDENT OF LITIGATION

John M. Masslon II
SENIOR LITIGATION COUNSEL

PROOF OF SERVICE

STATE OF CALIFORNIA)
) SS
COUNTY OF LOS ANGELES)

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 July 7, 2022, I served the **Amicus Letter of Washington Legal Foundation Supporting Writ Petition for Review** on all interested parties in this action as follows:

☒ (VIA E-SERVICE) I caused the above-referenced document to be transmitted 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 July 7, 2022 at Washington, D.C.

/s/ Cory L. Andrews
CORY L. ANDREWS