March 4, 2024

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

Re: *Gilead Sciences, Inc. v. Superior Court of the City and County of San Francisco* (*Gilead Tenofovir Cases*), No. S283862

Dear Chief Justice Guerrero
& Associate Justices:

In accordance with California Rule of Court 8.500(g), I am writing on behalf of the Atlantic Legal Foundation to urge the Court to grant the Petition For Review filed by Gilead Sciences, Inc. on February 21, 2024.

Interest of the *Amicus Curiae* [1]

Established in 1977, the Atlantic Legal Foundation (ALF) is a national, nonprofit, nonpartisan, public interest law firm. ALF's mission is to advance the rule of law and civil justice by advocating for individual liberty, free enterprise, property rights, limited and responsible government, sound science in judicial and regulatory proceedings, and effective education, including parental rights and school choice. With the

[1] No party or counsel for a party authored or paid for this amicus letter in whole or part.

benefit of guidance from the distinguished legal scholars, corporate legal officers, private practitioners, business executives, and prominent scientists who serve on its Board of Directors and Advisory Council, ALF pursues its mission by participating as *amicus curiae* in carefully selected appeals before the Supreme Court, federal courts of appeals, and state appellate courts. *See* atlanticlegal.org.

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The issue in this case is whether, as the Court of Appeal held, a pharmaceutical manufacturer that developed and commercialized an FDA-approved, life-saving drug that is *not* alleged to be defective breaches a duty of care to a subset of consumers by halting development and commercialization of what the company allegedly knows is a safer, alternate drug. This important question, which has far-reaching ramifications for the pharmaceutical industry and the public, squarely aligns with two of ALF's primary missions: advocating for sound science and for free enterprise.

ALF long has been one of the nation's foremost proponents of judicial respect for sound science. The novel theory of product liability endorsed by the Court of Appeal—a pharmaceutical company's breach of what can be construed as a state-law duty to continuously innovate, expeditiously develop, and promptly commercialize any new drug appearing to pose a lower risk of adverse effects than the company's existing drugs—conflicts with sound science. This new tort is incompatible with the lengthy, multi-stage, scientific process by which a potential and ultimately successful new drug is identified, exhaustively researched and tested in the laboratory and in people, and subjected to rigorous FDA evaluation prior to being made available to the public. Holding a pharmaceutical company liable for exercising sound business judgment also interferes with free enterprise by constraining innovative companies' ability to make their own, carefully considered, research and development (R&D) and marketplace decisions.

Granting review and reversing the Court of Appeal not only would inure to the benefit of pharmaceutical and other types of innovative companies, but also would foster the public interest, which benefits from

thoroughly researched and tested, federally approved, safe and effective products.

DISCUSSION

1. The Court of Appeal indicated in its widely publicized, certified-for-publication Opinion that Petitioner Gilead Sciences, Inc. "developed and sold one of the first medications to treat HIV/AIDS"—TDF, which the Food and Drug Administration (FDA) approved in 2001, even though "its use carried a risk of skeletal and kidney damage." Op. at 1 (filed Jan. 9, 2024). Although "[t]he 24,000 plaintiffs in this coordinated proceeding allege that they suffered these and other adverse effects . . . they do not assert any claim seeking to prove that TDF is defective." *Id.* at 1-2. Instead, the plaintiffs allege that "[w]hile Gilead was developing TDF, it discovered a similar, but chemically distinct, potential drug," TAF; that "Gilead's early testing indicated TAF could be as effective as TDF at treating HIV/AIDS, while carrying a lower risk of adverse effects"; that "Gilead elected to defer development of TAF because it was concerned that the immediate development of TAF would reduce its financial return from TDF"; and that "[y]ears later, Gilead resumed the development of TAF and obtained FDA approval for its sale in 2015." *Id.* at 2. The plaintiffs "characterize their claim as one for ordinary negligence, contending that Gilead's decision to defer development of TAF to maximize its profits breached its duty of reasonable care to users of TDF." *Id.*

The Court of Appeal "conclude[d] that the legal duty of a manufacturer to exercise reasonable care can, in appropriate circumstances, *extend beyond the duty not to market a defective product*." *Id.* at 3 (emphasis added). The court rejected Gilead's contention that "when an FDA-approved prescription drug is accompanied by an adequate warning of its side effects, and is not shown to be defective in design or manufacture, the manufacturer does not owe users of the current drug a duty of reasonable care in its decisions about commercializing any alternative drug the manufacturer might invent." *Id.* at 39. Instead, the court held that "a drug manufacturer, having invented what it knows is a safer, and at least equally effective, alternative to a prescription drug that it is currently selling and that is not shown to be defective, has a duty of

reasonable care to users of the current drug when making decisions about the commercialization of the alternative drug." *Id.* at 11.

This unprecedented duty not only destroys the traditional, well-defined boundaries of product liability, but also clashes with sound science and free enterprise. The Court should grant the Petition For Review and hold that a pharmaceutical company cannot be held liable for postponing, or even terminating, development and/or commercialization of a prescription drug that consumers (here in hindsight) allege is safer than the *non-defective*, efficacious, FDA-approved drug that they have been using.

2. Developing and commercializing a new prescription drug—including obtaining FDA approval—is an extraordinarily costly, time-consuming, and commercially risky process. The duty of care invented by the Court of Appeal fails to take into account the formidable, and often insurmountable, financial, scientific, regulatory, and commercial hurdles that a new drug—even one that shows promise during early testing—must overcome before it can be made available to the public.

The FDA's website provides an overview of the five, universally accepted stages of new drug development:

- Discovery and Development
- Preclinical Research
- Clinical Research
- FDA Review
- FDA Post-Market Safety Monitoring

FDA, The Drug Development Process (Jan. 4, 2018).[2]

Since human health and safety are at stake, each of these successive and arduous stages of new drug development involves rigorous scientific research or testing and/or intensive evaluation of scientific data. "[D]rug discovery and development is unlike any other type of development or innovation process . . . [it] carries far greater uncertainty, and the

[2] http://tinyurl.com/mr4brsmp.

outcome is rarely assured." PharmaCentral, Drug Discovery and Development: A Step-By-Step Guide (Oct. 22, 2021).[3]

During Stage 1 (Discovery and Development), "thousands of compounds may be candidates for potential development," but "[a]fter early testing . . . only a small number of compounds look promising and call for further study." FDA, *supra.* During Stage 2 (Preclinical Testing), a candidate drug's toxicity is determined, and on that basis, "researchers . . . decide whether the drug should be tested in people." *Id.* Following human trials conducted during Stage 3 (Clinical Research), only 33% of new drug candidates move on to Stage 4 (FDA Review), *id.*, and of those, "[o]nly 12% . . . eventually receive [FDA] approval." Pharmaceutical Research and Manufacturers of America (PhRMA), Research & Development Policy Framework (Jan. 22, 2024);[4] *see also* Biotechnology Innovation Organization (BIO), Clinical Development Success Rates and Contributing Factors 2011-2020 (Feb. 2021).[5]

"On average, it takes 10-15 years and costs $2.6 billion to develop one new medicine, including the cost of the many failures." PhRMA, *supra.* During 2022 alone, PhRMA member companies invested more than $100 billion in R&D for new treatments and cures. *Id.* Given the enormous investment of scientific and financial resources involved in developing a "winner," pharmaceutical companies need to earn an acceptable return to continue engaging in new drug R&D.

3. The Court of Appeal essentially held that an innovative pharmaceutical company like Gilead can be penalized in the form of massive tort liability to tens of thousands (and potentially millions) of consumers for making strategic business decisions about the direction and timing of its new drug R&D. Unless reversed by this Court, the threat of such liability in California (and potentially additional States) will be a significant disincentive for engaging in innovative activity, which is how major pharmaceutical companies compete with each other

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[3] http://tinyurl.com/4yc8868a.

[4] http://tinyurl.com/435zak2m.

[5] Available at http://tinyurl.com/2u6w9d4x.

while serving the public. At the very least, pharmaceutical companies will be reluctant to make their products available for sale in California.

"Pharmaceutical companies undertake research for commercial reasons and their overarching objective is a return on capital invested." PharmaCentral, *supra.* "[T]he research a company pursues has to be in line with its commercial goals." *Id.* A common-law jury should not be permitted to second-guess sophisticated corporate decisions on whether, or when, to invest astronomical amounts of money in attempting to develop a new drug (through the scientifically exhaustive, multi-stage, self-selecting process summarized above), and/or to commercialize the product.

Contrary to the plaintiffs' contention, and apparently the Court of Appeal's rationale, an innovative pharmaceutical company (or any other company) does not engage in tortious conduct merely because it seeks to legitimately "maximize its profits" for the benefit of its shareholders. Op. at 2. Indeed, companies owe a duty to their shareholders to allocate their resources prudently in order to maintain or increase profitability.

The plaintiffs here have the benefit of hindsight since Gilead ultimately decided to, and was able to, successfully develop and commercialize TAF as an alternative to TDF. But if allowed to stand, the unprecedented duty of care created by the Court of Appeal—a duty that the court acknowledged is "*beyond* the duty not to market a defective product," *id.* at 3 (emphasis added)—could be construed or enlarged by other courts in California and elsewhere to apply to a pharmaceutical company's decisions to postpone, suspend, or terminate R&D on potential new drugs. If broadly interpreted, this extraordinary duty to innovate and commercialize could be applied not only (as the Court of Appeal did here) to potential substitutes for the company's existing products, but also to entirely new types of products. Imposing liability for such decisions, which typically are both scientifically and commercially based, would be an even greater disincentive for engaging in innovative activity. Chilling innovation not only would deprive the public of beneficial new products that a company chooses to research and develop, but also could destabilize the economy, weaken national security, and result in other detrimental effects.

In addition to prescription drugs, there are many other types of innovative products whose safety is evaluated and regulated by government agencies, for example, automobiles, medical devices, and pesticides. It is not difficult to imagine the personal injury bar transposing the Court of Appeal's radical extension of product liability to such other categories of products, indeed, to *any* type of product for which R&D might lead to an allegedly safer alternative. *See* Editorial, *California Invents a Crazy New Tort*, Wall St. J., Jan. 14, 2024. This is all the more reason why the Court should grant review.

CONCLUSION

The Court should grant the Petition For Review and reverse the Court of Appeal.

Respectfully submitted,

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