S283862

In the

Supreme Court

of the

State of California

GILEAD LIFE SCIENCES, INC.,

Petitioner,

v.

SUPERIOR COURT OF THE CITY AND COUNTY OF SAN FRANCISCO,

Respondent,

PLAINTIFFS IN JCCP NO. 5043,

Real Parties in Interest.

CALIFORNIA COURT OF APPEAL · FIRST APPELLATE DISTRICT · NO. A165558
SUPERIOR COURT OF SAN FRANCISCO · HON. ANDREW Y.S. CHENG · NO. CJC-19-005043

APPLICATION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF;
***AMICUS CURIAE* BRIEF of ATLANTIC LEGAL FOUNDATION IN SUPPORT OF PETITIONER GILEAD SCIENCES, INC.**

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APPLICATION FOR LEAVE TO FILE *AMICUS CURIAE* BRIEF

In accordance with Rule 8.520(f) of the California Rules of Court, the Atlantic Legal Foundation respectfully requests permission to file the accompanying *amicus curiae* brief in support of Petitioner Gilead Sciences, Inc.

1. Established in 1977, the Atlantic Legal Foundation (ALF) is a national, nonprofit, public interest law firm. Its 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 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.

2. ALF has a particular interest in this appeal because the questions presented squarely align with two of ALF's primary

missions: advocating for free enterprise and for sound science in judicial and regulatory proceedings.

3. The Court of Appeal held that innovative pharmaceutical manufacturers that research and develop life-saving drugs have a duty to "develop and commercialize an alternative product that it knows to be safer for some subset of consumers—and to do so without delay," Petitioner's Opening Brief at 33. ALF believes that its amicus brief will assist the Court because it discusses why this unprecedented theory of liability *clashes* with sound science as well as free enterprise. More specifically, ALF's brief describes why the duty imposed by the Court of Appeal is incompatible with the long, multi-stage, scientific process by which a potential and ultimately successful new drug is identified, exhaustively researched and tested in the laboratory and in humans, and subjected to rigorous Food and Drug Administration (FDA) evaluation prior to being made available to the public. ALF's amicus brief also explains that unless rejected by this Court, the expansive tort duty at issue in this appeal will stifle new product innovation to the public's detriment.

4. No party or party counsel authored the proposed amicus brief in whole or part, and no party, party counsel, or other person

or entity made a monetary contribution intended to fund the preparation or submission of the brief, other than the *amicus curiae*, its members, or its counsel in the pending appeal.

For these reasons, ALF respectfully requests the Court to accept and file the accompanying amicus brief.

Respectfully submitted,

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ARGUMENT

A. Exposing a pharmaceutical manufacturer to tort liability for halting development of a potential new drug at an early stage of testing conflicts with the scientific method

1. Petitioner Gilead Science's opening brief recounts in detail how it (i) developed TDF, a groundbreaking, life-saving, single-pill HIV medicine with rare side effects (bone-density loss and reduced kidney function) in only a tiny percentage of patients (Petitioner's Opening Brief ("POB") at 11-13); (ii) began a preliminary investigation of TAF as a possible backup candidate during the unpredictable human trials of TDF (*id.* at 13-15); (iii) halted the investigation of TAF based on preliminary results suggesting a safety profile similar to, or worse than, TDF (*id.* at 9; 13-16); and (iv) much later restarted research & development of TAF as a possible lower-dose, alternative HIV medicine for an aging population whose lives had been significantly prolonged by TDF (*id.* at 16-17).

2. The Plaintiffs have tried to circumvent well-established product liability principles in this product liability litigation. The Court of Appeal's opinion confirms, for example, that "plaintiffs do not seek to prove that TDF-containing medications are defective." Opinion ("Op.") at 7. Instead, Plaintiffs' supposedly "ordinary"

negligence claim is that because of Gilead's alleged decision to "postpone" development of TAF, they "'were deprived of the *choice* between TDF and TAF.'" *Id.* at 2, 7; *see also* POB at 17 ("Plaintiffs assert an unprecedented duty: that Gilead should have brought TAF to market earlier to give them an alternative choice to TDF.").

Contrary to bedrock principles of product liability law, the Court of Appeal held "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." Op. at 3 (emphasis added); *see also id.* at 17. 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 of Appeal 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." Op. at 11.

The court "analyze[d] plaintiffs' claims as premised on *actual knowledge*" that "TAF was safer than TDF." *Id.* at 11 n.5 (emphasis added). Gilead explains that "[t]he court drew the 'actual knowledge' predicate from Plaintiffs' allegations, not from proof in the summary-judgment record, as required." POB at 20; *see also id.* at 60 (explaining that extensive human testing is required before a manufacturer can know whether a candidate drug is safer than, and effective as, an existing FDA-approved drug). Further, Gilead emphasizes that based on early testing, TAF "showed safety profiles *similar* to that of [TDF]—not, as Plaintiffs assert, that TAF was safer." *Id.* at 15 (internal quotation marks omitted).

3. The Court of Appeal observed that "a decision to delay commercialization of a new drug, when it is made earlier in the development process, may be more complicated and challenging for a jury to evaluate, and more susceptible to hindsight bias." Op. at 57. *This statement does not go far enough*: The court should have held that a jury *never* should be called upon to "evaluate," *i.e.*, second-guess, based on hindsight, any such science-based

commercialization decision for the purpose of imposing tort liability upon a pharmaceutical manufacturer.

Holding a pharmaceutical manufacturer liable for halting development and commercialization of an alternative new drug (or any new drug) where, as here, only preliminary testing has been conducted, not only would be unprecedented, but also contrary to sound science and the scientific method. Indeed, Gilead indicates that in deciding to halt development of TAF, it "*relied on the science*—most notably, years of data in the real world from tens of thousands of people that had proved TDF to be safe, effective, and well-tolerated, while [limited human trials] had not shown TAF to be safer or meaningfully more effective than TDF." POB at 16 (emphasis added).

4. Scientific knowledge is not static, including in connection with research & development of a new drug. Instead, "[s]cientific conclusions are subject to perpetual revision." *Daubert v. Merrell Dow Pharm., Inc.* (1993) 509 U.S. 579, 597. "[A]rguably, there are no certainties in science . . . ." *Id.* at 590. "Indeed, scientists do not assert what they know is immutably 'true' . . . ." *Id.* (quoting brief submitted by ALF on behalf of *amici curiae* Nobel laureate Nicolaas Bloembergen *et al.*).

"[I]n order to qualify as 'scientific knowledge,' an inference or assertion must be derived by the scientific method," *id.*—the universally accepted process of continually and progressively postulating, testing, and disproving hypotheses.

> Sound science implies that a set of data, facts, or conclusions of a scientific nature are supported by studies that follow the high standards of the scientific method. These standards describe important investigational attributes and practices such as the formulation of a readily testable hypothesis; the use of systematic and well-documented experimental or analytical methods (e.g., adequate sample sizes, appropriate control experiments); the application of appropriate data analysis tools (e.g., statistics and mathematical models) to the data; and the articulation of conclusions that address the hypothesis and are supported by the results.

Soc'y of Env't Tox. and Chem. (SETAC), Technical Issue Paper, Sound Science 1 (1999).[1] In other words, "science is an honorably self-correcting process." H. Holden Thorp, *Public debate is good for science*, Science, Jan. 15, 2021, at 213.[2]

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[1] Available at http://tinyurl.com/y7ejy9ty.

[2] Available at http://tinyurl.com/yw9th8pa.

5. The discovery and development of new life-saving drugs is a long, arduous, extraordinarily costly and financially risky, multi-stage scientific process that follows the scientific method. Only a tiny fraction of potential products (including backups to other potential products) survive extensive preclinical laboratory research, human clinical testing, and FDA regulatory review and approval. "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, Research & Development Policy Framework.[3]

FDA's website provides an overview of the five well-established stages of new drug development in the United States:

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

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

[3] https://tinyurl.com/2p8ns6dp (last visited Oct. 14, 2024).

[4] https://tinyurl.com/mrya4fye.

Since human health and safety are at stake, each of these successive 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 outcome is rarely assured." PharmaCentral, Drug Discovery and Development: A Step-By-Step Guide (Oct. 2021).[5]

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*. When a compound moves to Stage 2 (Preclinical Research), the candidate's toxicity is determined, and on that basis, "researchers . . . decide whether the drug should be tested in people." *Id.* Following multi-phase human trials conducted during Stage 3 (Clinical Research), only 33% of new drug candidates move on to Stage 4 (FDA Review). *Id.* "Only 12% of new molecular entities that enter

[5] Available at https://tinyurl.com/y8hy5mzj.

clinical trials eventually receive [FDA] approval." PhRMA, *supra*; *see also* Biotechnology Innovation Organization (BIO), Clinical Development Success Rates and Contributing Factors 2011-2020 (Feb. 2021); POB at 61.[6]

6. Attaching liability at an early stage of new drug development based on a pharmaceutical manufacturer's supposed "actual knowledge" that a candidate drug is safer than an existing drug is contrary to the fundamental nature of continually evolving scientific knowledge and incompatible with the multi-stage scientific method by which potential new drugs are explored, tested, submitted for FDA review and approval, and eventually made available to the public.

The Court of Appeal's imposition of a duty upon a pharmaceutical manufacturer to have developed and commercialized a now-available safe and effective alternative drug *sooner* than it actually did is predicated on the benefit of hindsight. Pharmaceutical manufacturers, however, do not have foresight about whether a potential new drug will survive the extensive

[6] https://tinyurl.com/2as33v8y.

research & development process. As discussed above, new drug development is a well-established scientific process inherently wrought with uncertainty from the test tube phase though and including FDA's determination about whether to approve a new drug as safe and effective. The minuscule percentage of potential new drugs that survive the entire process explains why such uncertainty is a fact of life in the pharmaceutical industry.

B. The radical new tort duty imposed by the Court of Appeal is contrary to the public interest

Unless reversed, the extraordinary new duty invented by the Court of Appeal—a duty to develop and commercialize alternative drugs supposedly "actually known" at an early stage of scientific testing to be safer than existing drugs—could be broadly construed to apply to pharmaceutical companies' decisions to postpone, suspend, or terminate research & development of *any type* of potential new drug. This duty not only is irreconcilable with sound science and the scientific method, but also would suppress vital innovative activity in the pharmaceutical industry, and thus, would harm the public interest.

In *Brown v. Superior Court* (1988) 44 Cal.3d 1049, this Court, rejecting imposition of strict liability for prescription drugs,

explained that "the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use." *Id.* at 1063. More specifically,

> [i]f drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments. Further, the additional expense of insuring against such liability — assuming insurance would be available — and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it the most. . . .
>
> The possibility that the cost of insurance and of defending against lawsuits will diminish the availability and increase the price of pharmaceuticals is far from theoretical.

Id. at 1063-64.

The Court of Appeal summarily rejected *Brown*'s admonition against liability theories that chill innovative activity in the pharmaceutical industry. Op. at 49-50. There is no principled reason, however, why *Brown*'s teaching should be inapplicable to the Court of Appeal's expansive theory of liability—in the Court of

Appeal's words, a "manufacturer's duty of reasonable care [that] can extend more broadly than the duty to make a non-defective product." *Id.* at 17. As this Court explained in *Brown*, 44 Cal.3d at 1065, "[t]he imposition of a harsher test for liability would not further the public interest in the development and availability of these important products."

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 drastic extension of liability to such other categories of products, indeed, to *any* type of product for which research & development might lead to an allegedly safer alternative. *See* Editorial, *California Invents a Crazy New Tort*, Wall St. J., Jan. 14, 2024. Chilling innovation by an onslaught of "failure to develop and commercialize" litigation, or even just the threat of such litigation, not only would deprive the public of beneficial new products that a company chooses to research & develop, but also could destabilize the economy, weaken national security, and result in additional detrimental effects.

CONCLUSION

The Court of Appeal should be reversed.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

In accordance with Rule 8.204(c)(1) of the California Rules of Court, the foregoing *amicus curiae* brief is proportionally spaced and contains 2,024 words according to the word processing program used to prepare it.

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