International
Center for
Law & Economics

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

MARCH 9, 2024

FILED & SERVED VIA TRUEFILING

RE: *Gilead Tenofovir Cases*, Docket No. S283862, Amicus Letter of the International Center for Law & Economics

Dear Justice Guerrero and Associate Justices,

In accordance with California Rule of Court 8.500(g), we are writing to urge the Court to grant the Petition for Review filed by Petitioner Gilead Sciences, Inc. ("Petitioner" or "Gilead") on February 21, 2024, in the above-captioned matter.

We agree with Petitioner that the Court of Appeal's finding of a duty of reasonable care in this case "is such a seismic change in the law and so fundamentally wrong, with such grave consequences, that this Court's review is imperative." (Pet. 6.) The unprecedented duty of care put forward by the Court of Appeal—requiring prescription drug manufacturers to exercise reasonable care toward users of a *current* drug when deciding when to bring a *new* drug to market (Op. 11)—would have far-reaching, harmful implications for innovation that the Court of Appeal failed properly to weigh.

If upheld, this new duty of care would significantly disincentivize pharmaceutical innovation by allowing juries to second-guess complex scientific and business decisions about which potential drugs to prioritize and when to bring them to market. The threat of massive liability simply for not developing a drug sooner would make companies reluctant to invest the immense resources needed to bring new treatments to patients. Perversely, this would deprive the public of lifesaving and less costly new medicines. And the prospective harm from the Court of Appeal's decision is not limited only to the pharmaceutical industry.

We urge the Court to grant the Petition for Review and to hold that innovative firms do not owe the users of current products a "duty to innovate" or a "duty to market"—that is, that firms cannot be held liable to users of a current product for development or commercialization decisions on the basis that those decisions could have facilitated the introduction of a less harmful, alternative product.

Interest of Amicus Curiae

The International Center for Law & Economics ("ICLE") is a nonprofit, non-partisan global research and policy center aimed at building the intellectual foundations for sensible, economically grounded policy. ICLE promotes the use of law and economics methodologies and economic learning to inform policy debates. It also has longstanding expertise in evaluating law and policy relating to innovation and the legal environment facing commercial activity. In this letter, we wish to briefly highlight some of the crucial considerations concerning the effect on innovation incentives that we believe would arise from the Court of Appeal's ruling in this case.[1]

The Court of Appeal's Duty of Care Standard Would Impose Liability Without Requiring Actual "Harm"

The Court of Appeal's ruling marks an unwarranted departure from decades of products-liability law requiring plaintiffs to prove that the product that injured them was defective. Expanding liability to products *never even sold* is an unprecedented, unprincipled, and dangerous approach to product liability. Plaintiffs' lawyers may seek to apply this new theory to many other beneficial products, arguing manufacturers should have sold a superior alternative sooner. This would wreak havoc on innovation across industries.

California Civil Code § 1714 does not impose liability for "fail[ing] to take positive steps to benefit others," (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 215), and Plaintiffs did not press a theory that the medicine they received was defective. Moreover, the product included all the warnings required by federal and state law. Thus, Plaintiffs' case—as accepted by the Court of Appeal—is that they consumed a product authorized by the FDA, that they were fully aware of its potential side effects, but *maybe* they would have had fewer side effects had Gilead made the decision to accelerate (against some indefinite baseline) the development of an alternative medicine. To call this a speculative harm is an understatement, and to dismiss Gilead's conduct as unreasonable because motivated by a crass profit motive, (Op. at 32), elides many complicated facts that belie such a facile assertion.

A focus on the narrow question of profits for a particular drug misunderstands the inordinate complexity of pharmaceutical development and risks seriously impeding the rate of drug development overall. Doing so

> [over-emphasizes] the recapture of "excess" profits on the relatively few highly profitable products without taking into account failures or limping successes experienced on the much larger number of other entries. If profits were held to "reasonable" levels on blockbuster drugs, aggregate profits would almost surely be insufficient to sustain a high rate of technological progress. . . . If in addition developing a blockbuster is riskier than augmenting the assortment of already known molecules, the rate at which important new drugs appear could be retarded significantly. Assuming that important new drugs yield substantial consumers' surplus untapped by their developers, consumers would lose along with the drug companies. Should a tradeoff be required between modestly excessive prices and profits versus retarded technical

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

> progress, it would be better to err on the side of excessive profits. (F. M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 97, 113 (1993)).

Indeed, Plaintiffs' claim on this ground is essentially self-refuting. If the "superior" product they claim was withheld for "profit" reasons was indeed superior, then Plaintiffs could have expected to make a superior return on that product. Thus, Plaintiffs claim they were allegedly "harmed" by not having access to a product that Petitioners were not yet ready to market, even though Petitioners had every incentive to release a potentially successful alternative as soon as possible, subject to a complex host of scientific and business considerations affecting the timing of that decision.

Related, the Court of Appeal's decision rests on the unfounded assumption that Petitioner "knew" TAF was safer than TDF after completing Phase I trials. This ignores the realities of the drug development process and the inherent uncertainty of obtaining FDA approval, even after promising early results. Passing Phase I trials, which typically involve a small number of healthy volunteers, is a far cry from having a marketable drug. According to the Biotechnology Innovation Organization, only 7.9% of drugs that enter Phase I trials ultimately obtain FDA approval.[2] (Biotechnology Innovation Organization, *Clinical Development Success Rates and Contributing Factors 2011-2020,* Fig. 8b (2021), *available at* https://perma.cc/D7EY-P22Q.) Even after Phase II trials, which assess efficacy and side effects in a larger patient population, the success rate is only about 15.1%. (*Id.*) Thus, at the time Gilead decided to pause TAF development, it faced significant uncertainty about whether TAF would ever reach the market, let alone ultimately prove safer than TDF.

Moreover, the clock on Petitioner's patent exclusivity for TAF was ticking throughout the development process. Had Petitioner "known" that TAF was a safer and more effective drug, it would have had every incentive to bring it to market as soon as possible to maximize the period of patent protection and the potential to recoup its investment. The fact that Petitioner instead chose to focus on TDF strongly suggests that it did not have the level of certainty the Court of Appeal attributed to it.

Although conventional wisdom has often held otherwise, economists generally dispute the notion that companies have an incentive to unilaterally suppress innovation for economic gain.

> While rumors long have circulated about the suppression of a new technology capable of enabling automobiles to average 100 miles per gallon or some new device capable of generating electric power at a fraction of its current cost, it is rare to uncover cases where a worthwhile technology has been suppressed altogether. (John J. Flynn, *Antitrust Policy, Innovation Efficiencies, and the Suppression of Technology*, 66 ANTITRUST L.J. 487, 490 (1998)).

Calling such claims "folklore," the economists Armen Alchian and William Allen note that, "if such a [technology] did exist, it could be made and sold at a price reflecting the value of [the new technology], a net profit to the owner." (ARMEN A. ALCHIAN & WILLIAM R. ALLEN, EXCHANGE & PRODUCTION: COMPETITION, COORDINATION, & CONTROL (1983), at 292). Indeed, "even a monopolist typically will have an incentive to adopt an unambiguously superior technology." (Joel M. Cohen and Arthur J. Burke, *An Overview of the Antitrust Analysis of Suppression of Technology*, 66

[2] It is important to note that this number varies with the kind of medicine involved, but across all categories of medicines there is a high likelihood of failure subsequent to Phase I trials.

ANTITRUST L.J. 421, 429 n. 28 (1998)). While nominal suppression of technology can occur for a multitude of commercial and technological reasons, there is scant evidence that doing so coincides with harm to consumers, except where doing so affirmatively interferes with market competition under the antitrust laws—a claim not advanced here.

One reason the tort system is inapt for second-guessing commercial development and marketing decisions is that those decisions may be made for myriad reasons that do not map onto the specific safety concern of a products-liability action. For example, in the 1930s, AT&T abandoned the commercial development of magnetic recording "for ideological reasons. . . . Management feared that availability of recording devices would make customers less willing to use the telephone system and so undermine the concept of universal service." (Mark Clark, *Suppressing Innovation: Bell Laboratories and Magnetic Recording*, 34 TECH. & CULTURE 516, 520-24 (1993)). One could easily imagine arguments that coupling telephones and recording devices would promote safety. But the determination of whether safety or universal service (and the avoidance of privacy invasion) was a "better" basis for deciding whether to pursue the innovation is not within the ambit of tort law (nor the capability of a products-liability jury). And yet, it would necessarily become so if the Court of Appeal's decision were to stand.

A Proper Assessment of Public Policy Would Cut Strongly Against Adoption of the Court of Appeal's Holding

The Court of Appeal notes that "a duty that placed manufacturers 'under an endless obligation to pursue ever-better new products or improvements to existing products' would be unworkable and unwarranted," (Op. 10), yet avers that "plaintiffs are not asking us to recognize such a duty" because "their negligence claim is premised on Gilead's *possession* of such an alternative in TAF; they complain of Gilead's knowing and intentionally *withholding* such a treatment...." (*Id*).

From an economic standpoint, this is a distinction without a difference.

Both a "duty to invent" and a "duty to market" what is already invented would increase the cost of bringing any innovative product to market by saddling the developer with an expected additional (and unavoidable) obligation as a function of introducing the initial product, differing only perhaps by degree. Indeed, a "duty to invent" could conceivably be *more* socially desirable because in that case a firm could at least avoid liability by undertaking the process of discovering new products (a socially beneficial activity), whereas the "duty to market" espoused by the Court of Appeal would create only the opposite incentive—the incentive never to gain knowledge of a superior product on the basis of which liability might attach.[3]

[3] To the extent the concern is with disclosure of information regarding a potentially better product, that is properly a function of the patent system, which requires public disclosure of new ideas in exchange for the receipt of a patent. (See *Brenner v. Manson*, 383 U.S. 519, 533 (1966) ("one of the purposes of the patent system is to encourage dissemination of information concerning discoveries and inventions.")). Of course, the patent system preserves innovation incentives despite the mandatory disclosure of information by conferring an exclusive right to the inventor to use the new knowledge. By contrast, using the tort system as an information-forcing device in this context would impose risks and costs on innovation without commensurate benefit, ensuring less, rather than more, innovation.

And public policy is relevant. This Court in *Brown v. Superior Court*, (44 Cal. 3d 1049 (1988)), worried explicitly about the "[p]ublic policy" implications of excessive liability rules for the provision of lifesaving drugs. (*Id.* at 1063-65). As the Court in *Brown* explained, drug manufacturers "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." (*Id.* at 1063). The Court of Appeal agreed, noting that "the court's decision [in *Brown*] was grounded in public policy concerns. Subjecting prescription drug manufacturers to strict liability for design defects, the court worried, might discourage drug development or inflate the cost of otherwise affordable drugs." (Op. 29).

In rejecting the relevance of the argument here, however, the Court of Appeal (very briefly) argued a) that *Brown* espoused only a policy against burdening pharmaceutical companies with a duty stemming from *unforeseeable* harms, (Op. 49-50), and b) that the relevant cost here might be "some failed or wasted efforts," but not a reduction in safety. (Op. 51).[4] Both of these claims are erroneous.

On the first, the legalistic distinction between foreseeable and unforeseeable harm was not, in fact, the determinative distinction in *Brown*. Rather, that distinction was relevant only because it maps onto the issue of incentives. In the face of unforeseeable, and thus unavoidable, harm, pharmaceutical companies would have severely diminished incentives to innovate. While foreseeable harms might also deter innovation by imposing some additional cost, these costs would be smaller, and avoidable or insurable, so that innovation could continue. To be sure, the Court wanted to ensure that the beneficial, risk-reduction effects of the tort system were not entirely removed from pharmaceutical companies. But that meant a policy decision that necessarily reduced the extent of tort-based risk optimization in favor of the manifest, countervailing benefit of relatively higher innovation incentives. That same calculus applies here, and it is this consideration, not the superficial question of foreseeability, that animated this Court in *Brown*.

On the second, the Court of Appeal inexplicably fails to acknowledge that the true cost of the imposition of excessive liability risk from a "duty to market" (or "duty to innovate") is not limited to the expenditure of wasted resources, but the *non*-expenditure of *any* resources. The court's contention appears to contemplate that such a duty would not remove a firm's incentive to innovate entirely, although it might deter it slightly by increasing its expected cost. But economic incentives operate *at the margin*. Even if there remains *some* profit incentive to continue to innovate, the imposition of liability risk simply for the act of doing so would necessarily reduce the amount of innovation (in some cases, and especially for some smaller companies less able to bear the additional cost, to the point of deterring innovation entirely). But even this reduction in incentive is a harm. The fact that some innovation may still occur despite the imposition of considerable liability risk is

[4] The Court of Appeal makes a related argument when it claims that "the duty does not require manufacturers to perfect their drugs, but simply to act with reasonable care for the users of the existing drug when the manufacturer has developed an alternative that it knows is safer and at least equally efficacious. Manufacturers already engage in this type of innovation in the ordinary course of their business, and most plaintiffs would likely face a difficult road in establishing a breach of the duty of reasonable care." (Op. at 52-3).

not a defense of the imposition of that risk; rather, it is a reason to question its desirability, exactly as this Court did in *Brown*.

The Court of Appeal's Decision Would Undermine Development of Lifesaving and Safer New Medicines

Innovation is a long-term, iterative process fraught with uncertainty. At the outset of research and development, it is impossible to know whether a potential new drug will ultimately prove superior to existing drugs. Most attempts at innovation fail to yield a marketable product, let alone one that is significantly safer or more effective than its predecessors. Deciding whether to pursue a particular line of research depends on weighing myriad factors, including the anticipated benefits of the new drug, the time and expense required to develop it, and its financial viability relative to existing products. Sometimes, potentially promising drug candidates are not pursued fully, even if theoretically "better" than existing drugs to some degree, because the expected benefits are not sufficient to justify the substantial costs and risks of development and commercialization.

If left to stand, the Court of Appeal's decision would mean that whenever this stage of development is reached for a drug that may offer any safety improvement, the manufacturer will face potential liability for failing to bring that drug to market, regardless of the costs and risks involved in its development or the extent of the potential benefit. Such a rule would have severe unintended consequences that would stifle innovation.

First, by exposing manufacturers to liability on the basis of early-stage research that has not yet established a drug candidate's safety and efficacy, the Court of Appeal's rule would deter manufacturers from pursuing innovations in the first place. Drug research involves constant iteration, with most efforts failing and the potential benefits of success highly uncertain until late in the process. If any improvement, no matter how small or tentative, could trigger liability for failing to develop the new drug, manufacturers will be deterred from trying to innovate at all.

Second, such a rule would force manufacturers to direct scarce resources to developing and commercializing drugs that offer only small or incremental benefits because failing to do so would invite litigation. This would necessarily divert funds away from research into other potential drugs that could yield greater advancements. Further, as each small improvement is made, it reduces the relative potential benefit from, and therefore the incentive to undertake, further improvements. Rather than promoting innovation, the Court of Appeal's decision would create incentives that favor small, incremental changes over larger, riskier leaps with the greatest potential to significantly advance patient welfare.

Third, and conversely, the Court of Appeal's decision would set an unrealistic and dangerous standard of perfection for drug development. Pharmaceutical companies should not be expected to bring only the "safest" version of a drug to market, as this would drastically increase the time and cost of drug development and deprive patients of access to beneficial treatments in the meantime.

Fourth, the threat of liability would lead to inefficient and costly distortions in how businesses organize their research and development efforts. To minimize the risk of liability, manufacturers may avoid integrating ongoing research into existing product lines, instead keeping

the processes separate unless and until a potential new technology is developed that offers benefits so substantial as to clearly warrant the costs and liability exposure of its development in the context of an existing drug line. Such an incentive would prevent potentially beneficial innovations from being pursued and would increase the costs of drug development.

Finally, the ruling would create perverse incentives that could actually discourage drug companies from developing and introducing safer alternative drugs. If bringing a safer drug to market later could be used as evidence that the first-generation drug was not safe enough, companies may choose not to invest in developing improved versions at all in order to avoid exposing themselves to liability. This would, of course, directly undermine the goal of increasing drug safety overall.

The Court of Appeal gave insufficient consideration to these severe policy consequences of the duty it recognized. A manufacturer's decision when to bring a potentially safer drug to market involves complex trade-offs that courts are ill-equipped to second-guess—particularly in the limited context of a products-liability determination.

Conclusion

The Court of Appeal's novel "duty to market" any known, less-harmful alternative to an existing product would deter innovation to the detriment of consumers. The Court of Appeal failed to consider how its decision would distort incentives in a way that harms the very patients the tort system is meant to protect. This Court should grant review to address these important legal and policy issues and to prevent this unprecedented expansion of tort liability from distorting manufacturers' incentives to develop new and better products.

Respectfully submitted,

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PROOF OF SERVICE

PORTLAND, OREGON) SS

I am employed in Portland, OR. I am over the age of 18 years and not a party to this action. My business address is 1104 NW 15th Avenue, Suite 300, Portland, OR 97209.

On March 9, 2024, I served the Amicus Letter of International Center for Law & Economics 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 9, 2024 at Portland, OR.

/s/ Kristian Stout

KRISTIAN STOUT