S283862

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

GILEAD SCIENCES, INC.,
Petitioner,

v.

SUPERIOR COURT OF THE STATE OF CALIFORNIA,
COUNTY OF SAN FRANCISCO,
Respondent,

GILEAD TENOFOVIR CASES,
Real Parties in Interest.

AFTER A DECISION BY THE CALIFORNIA COURT OF APPEAL
FIRST APPELLATE DISTRICT, DIV. 4, CASE NO. A165558
SAN FRANCISCO COUNTY SUPERIOR COURT CASE NO. CJC-19-005043
HON. ANDREW Y.S. CHENG, TRIAL JUDGE

PLAINTIFFS' COMBINED ANSWER TO AMICUS BRIEFS

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INTRODUCTION

Plaintiffs and Real Parties in Interest submit this combined Answer to the multiple amicus briefs filed in support of Defendant and Petitioner Gilead Sciences, Inc. ("Gilead").[1] Just as Gilead has done throughout this litigation, Gilead's Amici ("Amici"), a collection of well-funded interest groups representing the pharmaceutical industry in various capacities, focus on the supposed benevolence of pharmaceutical companies in the race to find life-saving medications to justify immunity from tort claims such as this one. For decades, pharmaceutical companies have relied on their unique role of supplying that which we need most—medications to treat society's most vulnerable—to justify incredible structural protections and benefits, including federal preemption, liability immunities, patent exclusivity, tax incentives and other subsidies.

According to Amici, none of this is enough. Amici argue that holding a pharmaceutical company to California's general negligence standard of care for its conduct in causing thousands to suffer needlessly would "chill innovation" (Chamber of Commerce at 6), halt research into alternative compounds (PhRMA at 38), and "rob the most vulnerable patient populations … of new medicines they desperately need." (CEG at 20.) According to one amicus, this case "risks bankrupting" Gilead—a

[1] The amicus briefs filed in support of Gilead were filed by: (1) Pacific Research Institute ("PRI"); (2) Atlantic Legal Foundation ("ALF"); (3) International Association of Defense Counsel ("IADC"); (4) Pharmaceutical Research and Manufacturers of America et. al ("PhRMA"); (5) Civil Justice Association of California et al. ("CJAC"); (6) Chamber of Commerce of the United States of America et. al ("Chamber of Commerce"); (7) International Center for Law & Economics ("ICLE"); (8) DRI–Center for Law and Public Policy et. al ("DRI"); (9) Viasat, Inc. et. al ("Viasat"); (10) Product Liability Advisory Council, Inc. ("PLAC"); (11) Archer Aviation Inc. et al ("Archer Aviation"); (12) National Association of Manufacturers et al. ("NAM"); and (13) Community Education Group et. al ("CEG").

company with a market capitalization of over $100 billion—and may cause the "imminent ruination" of the entire pharmaceutical industry. (PRI at 11, 13, 41.) At every step, Amici, who claim to be "laser focused on developing innovative medicines" (PhRMA at 2), justify the need for even more immunity than they currently possess on the basis that they save lives and alleviate human suffering. However, pharmaceutical companies are *not* our savior. The interest of Amici is not patient safety. Rather, it is money. Big Pharma is a prophet *of profit*.

While the manufacture of certain prescription drugs is laudable, pharmaceutical companies cannot rely on their unique role in supplying life-saving medications to secure extensive protections that no other industry enjoys and yet disavow any obligation to act reasonably in light of the severe risks to human life their products pose. Nothing justifies insulating drug companies from a duty to act reasonably in their business so as to prevent foreseeable harm. This is especially true where the very rationales touted by Amici are unsupported by the reality of today's market.

As the former editor-in-chief of the *New England Journal of Medicine* has explained, the pharmaceutical industry "discovers few genuinely innovative drugs, spends less than half as much on research and development … as on marketing and administration[,] and consistently has profit margins far above those of most other Fortune 500 industries." (Marcia Angell, THE TRUTH ABOUT THE DRUG COMPANIES: HOW THEY DECEIVE US AND WHAT TO DO ABOUT IT ix (2005) ("Angell").) The reality is that most "new drugs" on the market are "me-too drugs" that are merely "higher-priced versions of existing medicines," such as the "six statins … on the market to lower cholesterol, all variants of the first." (*Id*. at ix, xxiv.; see also Son Le & Neel U. Sukhatme, *Reaching for Mediocrity: Competition and Stagnation in Pharmaceutical Innovation* (2020) 64 Int'l Rev. L. & Econ. 1, 2 ("Le & Sukhatme") ["Despite the[] social costs, me-

too drugs continue to be commonly produced by pharmaceutical companies."].) And big pharmaceutical companies spent *$56 billion more* on stock buybacks and dividends from 2016 to 2020 than they spent on research and development. (Staff of H. Comm. on Oversight & Reform, 117th Cong., Drug Pricing Investigation Industry Spending on Buybacks, Dividends, and Executive Compensation 1 (Jul. 2021), https://perma.cc/B6CK-ZY63 ("Drug Pricing Investigation"); see also John Abramson, SICKENING: HOW BIG PHARMA BROKE AMERICAN HEALTH CARE AND HOW WE CAN REPAIR IT 105 (2022) ("Abramson") [explaining that a quarter of the largest drug companies "spend *ten times as much on sales and marketing*" as they do on research and development].) Further, although government researchers perform "much of the R&D that contributes to new pharmaceuticals," "pharmaceutical companies … rely heavily on a narrative of exclusive rights fueling innovation to justify strong patent protection and resulting high prices for the products they ultimately sell." (Lisa Vertinsky, *Pharmaceutical (Re)Capture* (2021) 20 Yale J. Health Pol'y, L. & Ethics 146, 173 ("Vertinsky"); see also Abramson, *supra*, at xv [noting that "[t]he foundational research that made the rapid development of [COVID-19] vaccines possible had been completed in 2016 by scientists" at the National Institutes of Health].)

Amici's alarmist claims about the chilling effects on research and development presented by tort liability as alleged here therefore rest on a patently false narrative about pharmaceutical companies and a misguided conception of their incentives for innovation. And Amici fail to rebut the substantial *innovation-generating* effects of disincentivizing drug manufacturers from strategically delaying the introduction of safer alternative drugs to game the patent system and maximize profits. (Cf. Amalea Smirniotopoulos, *Bad Medicine: Prescription Drugs, Preemption, and the Potential for a No-Fault Fix* (2011) 35 N.Y.U. Rev. L. & Soc.

Change 783, 813-819 ("Smirniotopoulos") [state tort law works together with federal regulation of pharmaceutical drugs to best protect the public].)

As detailed below, nothing argued by Amici supports Gilead's position that a manufacturer can *never* be liable in negligence to a consumer for physical injury caused by its product *unless* the product is defective. Amici criticize the Court of Appeal's opinion affirming that Gilead owed a duty of care to the 24,000 HIV-infected Plaintiffs in this case, all users of its drug TDF, when making decisions about commercializing an allegedly safer and equally effective drug (TAF), as being "radical" (ALF at 15), "absurd" (PLAC at 37), and "deeply unfair" (Chamber of Commerce at 6). Yet, it is Amici's position that is extreme.

California has long recognized the viability of ordinary negligence claims against product manufacturers separate and apart from strict product liability claims. Neither Gilead nor Amici cite a *single* California case holding that a manufacturer's duty of care to its consumers is categorically limited to producing a "defect"-free product. As aptly held by the Court of Appeal, "[t]he circumstances under which a manufacturer might appropriately be held liable for injury caused by its products are simply too varied to be so constrained. Under section 1714, harm resulting from a manufacturer's failure to exercise reasonable care may be compensable, *even if* the product causing the harm does not meet the legal definition of 'defective.'" (*Gilead Tenofovir Cases* (2024) 98 Cal.App.5th 911*,* 922 (*Gilead*).) Thus, the Court of Appeal held that a drug manufacturer's duty to the users of a drug it is currently selling can "extend beyond the duty not to market a defective product" and the policy factors set forth in *Rowland v. Christian* (1968) 69 Cal.2d 108 ("*Rowland*") do not justify "precluding negligence liability for prescription drugs without proof of a defect." (*Id*. at 917.) Nothing argued by Amici disrupts the sound analysis by the Court of Appeal.

Parroting Gilead's briefs, Amici argue that insulating manufacturers from any liability beyond the four corners of a product defect is necessary "*to strike the appropriate balance* between consumer safety and access to innovative products." (IADC at 19, italics added; Petitioner's Opening Brief (POB) at 29.) According to Amici, "[t]here is no need" to permit negligence liability under the facts alleged because "biopharma manufacturers are already strongly incentivized to bring innovative medicines to market in a safe and expedient manner." (PhRMA at 29; Chamber of Commerce at 21, 25 [arguing that there is little reason to acknowledge the "gratuitous tort liability" at issue here because Plaintiffs are already protected by "California product liability law."].)

But this case demonstrates that a manufacturer's incentive to release improved alternatives can be easily overridden when greater profits can be garnered by withholding drugs to manipulate market exclusivities. Liability for product defects alone would *not* protect Plaintiffs from the corporate greed incentivizing Gilead's alleged misconduct, which deprived thousands of consumers of an option that would have avoided severe physical injury. And given the near-blanket immunity pharmaceutical manufacturers already enjoy from allegedly defective drugs,[2] it appears that the "balance" Gilead and Amici seek is *impunity*. Such a rule would *not* be for the good of the public – but for the good of Gilead.

For many reasons, the Court of Appeal's opinion should be affirmed.

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[2] See Mary J. Davis, *Time for A Fresh Look at Strict Liability for Pharmaceuticals* (2019) 28 Cornell J.L. & Pub. Pol'y 399, 412 ["What is very different from other products liability contexts, however, is the dramatic impact on state tort liability from modern federal preemption doctrine in the area" of prescription drugs]; Anita Bernstein, *(Almost) No Bad Drugs: Near-Total Products Liability Immunity for Pharmaceuticals Explained* (2020) 77 Wash. & Lee L.Rev. 3, 32–37 [state law design and warning defect claims against drug companies are usually preempted].

ARGUMENT

I.

GILEAD'S AMICI FAIL TO ESTABLISH THAT THE DUTY IN THIS CASE STIFLES INNOVATION AND THREATENS CONSUMER SAFETY

Threaded throughout the briefs submitted by Amici is the mantra that tort liability destroys innovation and leaves consumers at risk. (See, e.g., PRI at 13, 46 [arguing that the duty here will "wreck[] the entire process of drug innovation" and be a "death sentence" for drug companies]; ALF at 17 [liability in this case "could destabilize the economy [and] weaken national security"]; see also Gilead Rep. at 8 [liability for the conduct alleged will "deter[] innovation, distort[] development priorities, decrease[] affordability, and reduce[] overall consumer safety."].)

This Court has consistently, and correctly, been skeptical of sweeping claims from drug companies that liability will stifle innovation. (See, e.g., *T.H. v. Novartis Pharmaceuticals Corp.* (2017) 4 Cal.5th 145, 173 (*T.H.*) [rejecting "contention that warning label liability would stifle innovation by substantially raising drug costs and chilling the development and marketing of new drugs" because the "logic buttressing this argument is far from self-evident"]; *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1112 (*Carlin*) [finding "no clear or sufficient basis for concluding that research and development will inevitably decrease" as a consequence of imposing strict liability for failure to warn]; *In re Cipro Cases I & II* (2015) 61 Cal.4th 116, 155 [rejecting claim that subjecting reverse payment patent settlements to antitrust scrutiny would "stifle innovation."].)[3] Here,

[3] The pharmaceutical industry has claimed "for at least 60 years" that "any manner of legal liability or oversight will chill innovation." (Justice Catalyst Br. at 9–14.) Most recently, an industry group stated that permitting the federal government to negotiate prices for some drugs

the pharmaceutical industry's defenders fail once again to substantiate their alleged harms to innovation. And they fail to disprove the *innovation-generating* effects of the duty at issue in this case, including the speedier delivery of improved medicines.

A. Amici Fail to Substantiate Their Alleged Harms to Innovation and Consumer Safety.

Amici tell an innovation[4] story that rests on an inconsistent and incomplete portrayal of manufacturer incentives. To start: PhRMA argues that the misconduct alleged in this case *never* happens because companies "have every incentive to develop and deliver safe new medicines as quickly as possible because of the 'first mover' dynamics in the pharmaceutical industry." (PhRMA at 31.) Yet if there is a strong "first mover advantage" to releasing safer and more effective products (*id*. at 20), it is not clear why recognizing a *duty* to avoid unreasonably withholding such products would prompt "many manufacturers … to avoid innovating altogether." (NAM at 13.) And it is simply not true that pharmaceutical manufacturers are always "eager" to get improved drugs "to market as quickly as possible." (ICLE at 13.) Regulatory exclusivities under the Food, Drug, and Cosmetic Act "create a perverse incentive to *delay introduction of pharmacologic improvements until right before the patents on the original drug expire*,

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covered under Medicare would "kill innovation," even though an "independent study by the Congressional Budget Office directly contradict[ed] [that assessment], finding there would likely only be 2 fewer drugs approved over a decade and 15 fewer drugs over the next 30 years." (Cynthia Ho & Liza Vertinsky, *"Innovation Bullying" in Drug Poli cy*, Health Affairs Forefront. June 16, 2021. https://www.healthaffairs.org/c ontent/forefront/innovation-bullying-drug-policy ("Ho & Vertinsky").)

[4] There is "little clarity or agreement on what constitutes pharmaceutical innovation," but "[m]any think 'innovative pharmaceutical' implies improved, increased value, or otherwise 'healthier' compared to the status quo." (Anjali D. Deshmukh, *Redefining Innovation for Pharmaceutical Innovation* (2024) 104 B.U. L. Rev. 577, 580, 584.)

delaying patient access to better therapies." (Sean Dickson and Amy Killelea, *Intentionally Delayed Pharmaceutical Innovation Under Perverse Incentives: Gilead's HIV Pipeline as a Case Study*. Health Affairs. June 16, 2021. https://perma.cc/NCE8-ZXXG ("Dickson and Killelea")); see also Robin Feldman and Evan Frondorf, *Drug Wars: A New Generation of Generic Pharmaceutical Delay* (2016) 53 Harv. J. on Legis. 499, 532 [noting that Actavis purportedly introduced its new Alzheimer's drug "three years after it was approved by the FDA" and "less than a year before the patents on [its original drug] would expire" to "thwart generic entry"]; Justice Catalyst Br. at 22–24.)

Further, empirical research shows that the incentive for "strategic delay" is strongest, as in the present case, when the introduction of the follow-on drug "*would cannibalize sales of the original drug* … an original product is *almost twice as likely* to have a line extension approved in the period leading up to expected generic entry than three or more years prior." (Annabelle C. Fowler, *Hurry Up or Wait? Strategic Delay in the Introduction of Pharmaceutical Line Extensions.* Harvard University. December 23, 2019. https://perma.cc/7EEC-CDHS, italics added*;* see also 1 Federal Trade Comm'n Staff, ANTICIPATING THE 21ST CENTURY: COMPETITION POLICY IN THE NEW HIGH-TECH, GLOBAL MARKETPLACE (1996) ch. 9, at 16 [relying on Kenneth "Arrow's theoretical model of a monopolist who would have the *incentive to eliminate, delay, or reduce an innovative effort* if it would otherwise lead to a product that could *cannibalize sales of the monopolist's current product*."] (italics added).)

Pharmaceutical innovation is *not* advanced by immunizing drug manufacturers from tort liability for strategically delaying the introduction of safer drugs to (1) maximize the effect of regulatory exclusivities and (2) minimize the cannibalization of existing drug sales.

Next, Amici speculate that the duty at issue in this case will incentivize pharmaceutical manufacturers to avoid research "that might lead them to acquire knowledge" about potentially safer or more effective alternatives to their existing drugs. (Archer Aviation at 10; see also Viasat at 14 ["pausing research is arguably the only way to avoid liability entirely."].) But this portrayal of manufacturer incentives is shallow and unidimensional. It ignores the extraordinary potential *rewards* for a manufacturer that invents a safer or more effective alternative to its existing product. In the pharmaceutical context, "blockbuster"[5] drugs such as Merck's Gardasil 9 HPV vaccine, Sanofi's Toujeo diabetes drug, and Novartis's Tasigna leukemia drug are safer and/or more effective versions of earlier drugs marketing by those companies. Drug companies can make billions of dollars by "extend[ing] the effective patent life" of their drug through research identifying small improvements to the drug. (W. Nicholson Price II, *The Cost of Novelty* (2020) 120 Colum. L. Rev. 769, 801.) And empirical research shows that "[i]nnovation is driven by competition, not deregulation." (Justice Catalyst Br. at 19–20.) Amici fail to establish that drug companies' strong financial incentive to research alternatives to their existing products will be affected by a duty to not unreasonably withhold safer and at least equally effective drugs.

Amici next assert that the threat of liability will push manufacturers to prioritize "incremental improvements to existing products" above "truly groundbreaking products that satisfy unmet needs." (IADC at 64; see also Archer Aviation at 11; Viasat at 5–6, 10.) This ignores the reality that drug companies are currently *not* prioritizing "groundbreaking" products. "[T]he majority of drugs marketed as new are actually new versions of old drugs,

[5] A "blockbuster" drug is a "drug with sales of over a billion dollars a year." (Angell, *supra*, at 10.)

and many new drugs are not improvements over existing drugs." (Ho & Vertinsky, *supra*; see also Robin Feldman, *Patent Term Extension and the Last Man Standing* (2023) 42 Yale L. & Pol'y Rev. 1, 4–5 ["78% of the drugs associated with new patents are not new drugs coming on the market; they are existing ones."].) And rather than addressing the needs of "underserved populations" (CEG at 24), "firms pursue low-risk strategies that can more easily yield commercial success," including "ever-greening (extending the monopoly period on a drug by artificially extending the life of a patent or other exclusivity), and developing the me-too drugs (drugs that are structurally related to a first-in-class compound and share the same therapeutic purposes, but with only minor differences in the pharmacological profile that provide, at best, incremental innovation)." (Mariana Mazzucato & Henry Lishi Li, *A Market Shaping Approach for the Biopharmaceutical Industry* (2021) 49 J.L. Med. & Ethics 39, 40.)

Even for those manufacturers that *are* developing "life-changing products," Amici fail to establish that the threat of tort liability in the narrow circumstances posited by this case outweighs the enormous potential rewards of such innovations. (Viasat at 9–10 [asserting, implausibly, that "Viasat could be forced [by this duty] to devote resources to tweaking its existing commercial modems rather than investing in new communications systems … it supplies to the United States military."].) As an independent analysis has found, "[f]or a product believed to have [blockbuster] profit potential, even a large proportionate reduction in the investment incentive [because of liability risk] is *unlikely to deter* a company from proceeding." (Steven Garber, RAND Institute for Civil Justice PRODUCT LIABILITY AND THE ECONOMICS OF PHARMACEUTICALS AND MEDICAL DEVICES (1993) 36, italics added.)

Amici's other claimed impacts on innovation are equally half-baked. IADC asserts that manufacturers fearing "liability for delay in

commercializing a new product that may be safer for some subset of users however small" will have a "perverse incentive to rush products to market that may pose safety risks to other, *potentially larger subsets* of users." (IADC at 66, italics added.) But a rational manufacturer, protected in negligence law by a reasonableness standard and motivated to minimize its *overall* potential liability, would not rush a new product to market despite the risks to a "larger" group of users because it may protect a "small" "subset of users." PhRMA argues that a pharmaceutical company might "wait to seek approval until all alternatives for a better candidate are exhausted" without even trying to reconcile that claim with its assertion there is a "significant first-mover advantage" to "bring[ing] promising drugs forward quickly." (PhRMA at 29, 38.) And Archer Aviation's claim that the cost of defending against claims will "reduc[e] the resources that are available to invest in developing innovative products" (Archer Aviation at 22–23) is an argument against product liability law altogether.

What is lacking from Amici's alarmism about innovation is empirical evidence that the threat of tort liability—which extends beyond the narrow duty affirmed in this case—has stifled pharmaceutical innovation. (See also Gilead Rep. at 39 [asking this Court to "presume" that "tort duties affect manufacturer behavior" "until and unless direct empirical evidence refutes it."].) This is yet another example of what scholars have described as "innovation bullying" by the pharmaceutical industry: "[c]laims of innovation harm … without any independent, substantiated evidence linking proposed measures to actual social welfare harm, let alone evidence of harm that would exceed the benefits associated with the proposed measure." (Ho & Vertinsky, *supra*.)

Critically, there is "little or no empirical support for [the] claim" that "liability for injuries will create risks that will chill pharmaceutical industry innovation." (Marc A. Rodwin, *Compensating Pharmaceutical Injuries in*

the Absence of Fault (2014) 69 Food & Drug L.J. 447, 456, fn. 41; see also Steven Garber, RAND Institute for Civil Justice, ECONOMIC EFFECTS OF PRODUCT LIABILITY AND OTHER LITIGATION INVOLVING THE SAFETY AND EFFECTIVENESS OF PHARMACEUTICALS (2013) 55–56, 58, 62 ["[T]here is no reliable empirical basis for estimating in dollar terms the social costs or benefits of liability-induced ... price increases, or effects on product safety, effectiveness, or innovation"]; *Lance v. Wyeth* (Pa. 2014) 85 A.3d 434, 456 (*Lance*) ["We do not discount the impact of litigation on the pharmaceutical industry, but we simply do not know enough about it to undertake any kind of reasoned comparison of the social policy effects of curtailing fault-based liability in Pennsylvania."] (italics added).) Amici fail to substantiate the innovation-limiting effects of the duty in this case.

B. Amici Fail to Disprove the Substantial Innovation-Generating Effects of the Duty in This Case, Including the Speedier Delivery of Improved Medicines.

Amici's bleak portrait of stifled innovation fails to account for the substantial *innovation-generating* effects of a manufacturer's duty to exercise reasonable care when making decisions about commercializing safer and at least equally effective alternatives to its existing product. Empirical research has shown that for most industries—including the pharmaceutical industry—increased liability costs have *increased* expenditures on research and development and "provide[d] incentives for product safety improvements." (W. Kip Viscusi & Michael J. Moore, *Product Liability, Research and Development, and Innovation* (1993) 101(1) J. Political Econ. 161, 164, 182, italics added ("Viscusi & Moore"); W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Links Between Product Liability and Innovation*, in THE LIABILITY MAZE: THE IMPACT OF LIABILITY LAW ON SAFETY AND INNOVATION (Peter W. Huber

& Robert E. Litan, eds., 1991) 81, 113 ["[F]or most industries [including the pharmaceutical industry] the costs of product liability provide *safety incentive effects that more than offset the product withdrawal effects*."] (italics added).) "We infer from these results that the *development of new, safer products is the primary outcome engendered by the recent growth in the cost of product liability* to firms." (Viscusi & Moore*, supra*, 101(1) J. Political Econ. at 182, italics added.) The duty in this case thus squarely incentivizes the development of new, safer products.

In the pharmaceutical industry, the duty affirmed in this case is *especially* likely to incentivize beneficial research and development. Rather than focusing their resources on developing improved drugs, many pharmaceutical companies are instead producing "me too" drugs without any demonstrated additional therapeutic benefit to "grab a share of an established, lucrative market." (Angell, *supra*, at xxiv, 81–82; see also Le & Sukhatme, *supra*, 64 Int'l Rev. L. & Econ. at 1 [explaining that "me-too" drugs are "often highly profitable despite providing minimal marginal social benefits.")[6] Rather than creating new drugs, companies manipulate the patent system to maximize the lifecycle of their existing drugs through "[a]nticompetitive practices such as creating patent thickets, product hopping, evergreening, and 'pay for delay' arrangements" with generic manufacturers. (Vertinsky, *supra*, 20 Yale J. Health Pol'y, L. & Ethics at

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[6] As Angell explains, drug companies "have to show the FDA only that new drugs are 'effective,' " not that "they are *more effective than (or even as effective as) what is already being used* for the same condition. … In fact, on the basis of placebo-controlled trials, *drugs can be approved that are actually worse than drugs already on the market*." (*Id*. at 75–76, italics added; see also Aaron S. Kesselheim et. al, *Pharmaceutical Policy in the United States in 2019: An Overview of the Landscape and Avenues for Improvement* (2019) 30 Stan. L. & Pol'y Rev. 421, 433 (Kesselheim) ["Over half of all pivotal trials test a new drug against placebo rather than an active comparator."].)

173.) And big pharmaceutical companies puff up their share prices through expending resources exceeding their research and development costs on share buybacks and dividends. (Drug Pricing Investigation, *supra*, at 1.) Liability here would realign drug company incentives toward innovation and away from gaming the patent system to maximize profits.

State tort liability also best serves the public by exposing valuable information about the safety of drugs, helping to educate the public about regulatory failure, revealing manufacturer misconduct that would otherwise go undisclosed, and permitting patients to be compensated for their injuries. (*Smirniotopoulos, supra,* 35 N.Y.U. Rev. L. & Soc. Change at 813-817.)

Amici repeatedly invoke *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063 (*Brown*), which declined to impose strict liability for design defects in prescription drugs because such liability might discourage drug development or otherwise limit access to pharmaceuticals. (ALF at 15–16; PLAC at 14.) *Brown's* analysis was specific to imposition of *strict products liability*. (*Brown*, *supra,* 44 Cal.3d at pp. 1061, 1065; see also *Carlin,* 13 Cal.4th at 1110-1112 & fn. 4 [*Brown* concerns *only* claims for strict products liability].) As detailed by the Court of Appeal, while *Brown* rejected application of strict product liability design defect for injuries caused by prescription drugs, *Brown* left other claims, such as negligence, intact. (*Gilead,* 98 Cal.App.5th at 943, citing *Brown,* 44 Cal.3d at 1069, fn. 12.) And as correctly held by the Court of Appeal, "while drug manufacturers have continued to resist the imposition of liability in other contexts by asserting that it would chill innovation, courts after *Brown* have declined to accept those assertions as unsupported by an evidentiary showing," and Gilead's argument here is "similarly unsupported." (*Gilead*, at 943, citing e.g., *Carlin, supra,* 13 Cal.4th at 1117; *T.H., supra,* 4 Cal.5th at 173; *Conte v. Wyeth, Inc*. (2008) 168 Cal.App.4th 89*,* 106 (*Conte*).)

Further, the rationale in *Brown*—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" (*Brown*, *supra*, 44 Cal.3d at 1063)—supports the recognition of liability here. The broader public interest in the availability of affordable and effective drugs is *frustrated* by immunizing drug manufacturers from negligence liability for deliberately delaying the introduction of superior drugs to maximize profits from their existing drugs. And this public interest is advanced by *encouraging* drug manufacturers to commercialize alternatives that are safer and at least equally effective. As *Brown* explicitly noted, while manufacturers may not face strict liability for design defects, they remain accountable "under general principles of negligence." (*Brown, supra,* 44 Cal.3d at 1069, fn. 12).

Negligence remains one of the few remaining avenues for plaintiffs to challenge unreasonable conduct of drug manufacturers that causes them harm. Indeed, tort liability in cases such as this one addresses a gap in the incentive structure of pharmaceutical manufacturers. In some cases, there is a "first mover advantage" to releasing a superior drug as soon as possible (PhRMA at 20); here, as alleged, there is an advantage to holding that drug back and shifting users to that drug shortly before the end of the first drug's patent lifecycle to maximize the regulatory exclusivity period and avoid cannibalizing the first drug's profits. Liability here properly aligns a drug company's profit motivations with society's interest in a greater supply of affordable and effective medicines.

II.

GILEAD'S AMICI'S "NO DEFECT, NO DUTY" RULE HAS NO FOUNDATION IN CALIFORNIA LAW AND HAS BEEN REJECTED IN MULTIPLE JURISDICTIONS

Amici join Gilead in confidently asserting that there is a *century-old* common-law rule, existing in *all* jurisdictions, that bars a manufacturer's liability in negligence for injuries caused by its product unless the plaintiff proves a manufacturing, design, or warning defect under the tests developed in strict liability law. (IADC at 18, 22; ICLE at 6; CJAC at 8; PLAC at 27.) As now explained, none of this is accurate.

A. Requirements of Strict Products Liability Do Not Apply to Limit Theories of Negligence Asserted Against Manufacturers Under California Law.

While Amici argue that a manufacturer can *never* be liable in negligence for injury to consumers caused by its product unless the plaintiff proves a product defect as defined under strict liability law (IADC at 21–22; CJAC at 15; Chamber of Commerce at 6), they do not identify a single California case *holding* that negligence liability cannot exist for conduct *independent* of design, manufacture, or warning. California courts have never held that the universe of manufacturer negligence liability is limited to the categories defined in strict liability law. (Cf. *Chico Bridge Co. v. Sacramento Transp. Co.* (1898) 123 Cal. 178, 182 [noting the "infinite" circumstances in which negligence liability may arise].)

1. Amici Fail to Recognize that Strict Liability and Negligence are Distinct Torts.

California courts have made it clear that the doctrine of strict product liability does not *restrict* theories of ordinary negligence brought against product manufacturers. (See *T.H., supra,* 4 Cal.5th at 163, 175-177 & fn. 4; *Conte, supra,* 168 Cal.App.4th at 108.) While a defect in the product is a

predicate to any claim for strict products liability, the same is not true for all negligence claims against a manufacturer. The doctrine of strict products liability was *not* intended to displace all other theories of recovery.

Over 100 years ago, in a concurring opinion in *Escola v. Coca Cola Bottling Co.* (1944) 24 Cal.2d 453, Justice Traynor first articulated the policies supporting strict product liability. (*Jimenez v. Superior Court* (2002) 29 Cal.4th 473, 477–78.) "Two decades later, in *Greenman v. Yuba Power Products, Inc.* (1963) 59 Cal.2d 57, [], this court embraced Justice Traynor's view, and California became the first state to allow recovery for strict products liability." (*Id*.) The doctrine sought to *expand* liability of manufacturers for injuries caused by their products to protect injured consumers "who are powerless to protect themselves." (*Greenman*, *supra*, 59 Cal.2d at 62.) Under no scenario was the doctrine of strict products liability intended to limit the rights of an individual to bring an ordinary claim for negligence against a manufacturer or otherwise restrict the scope of a manufacturer's *negligence* liability to manufacturing, design, or warning defects.

This Court has repeatedly explained that the *purpose* of the defect requirement in strict liability law is preventing strict liability from turning into absolute liability by limiting the bases for imposing strict liability on manufacturers to "three types of defects—manufacturing defects, design defects, and 'warning defects[.]' " (*Carlin*, *supra*, 13 Cal.4th at 1110; see *Daly v. General Motors Corp.* (1978) 20 Cal.3d 725, 733 (*Daly*) ["From its inception, … strict liability has never been, and is not now, absolute liability. … On the contrary, the plaintiff's injury must have been caused by a 'defect' in the product."]; *Cronin v. J.B.E. Olson Corp.* (1972) 8 Cal.3d 121, 133 [explaining that the defect requirement in strict liability law "serve[s] the beneficial purpose of preventing the seller from being treated as the insurer of its products."].) Negligence, on the other hand, has no need

for a defect requirement because it has different limiting principles "to maintain some fault-based boundaries against absolute manufacturer liability" (PLAC at 29), including the duty of care and breach requirements. And negligence, unlike strict liability, is flexible enough to capture wrongful conduct extending beyond manufacture, design, and warning. (See W. Page Keeton et al., *Prosser & Keeton on the Law of Torts* § 96, at 684 (5th ed. 1984) [noting that a manufacturer's "negligence may be found over an area quite as broad as his whole activity in preparing and selling the product" including inspection, testing, advertising and "the entire process of manufacture and sale"].)

Amici fail to recognize that the "defect requirement" serves as the limiting factor in strict liability cases and is entirely separate from claims based on negligence. (See *Williams v. J-M Manufacturing Company, Inc.* (2024) 102 Cal.App.5th 250, 263 ["[T]he element of duty in any negligence cause of action [does not] merge[] [and] is [not] coextensive with the defect element in a strict liability cause of action."].) These two actions—strict liability and negligence—are distinct torts with distinct purposes and distinct limiting principles. (IADC at 51; see *Daly*, *supra*, 20 Cal.3d at 733 ["In [strict liability's] evolution, the doctrinal encumbrances of contract and warranty, and *the traditional elements of negligence, were stripped from the remedy,* and a *new tort emerged* which extended liability for defective product design and manufacture beyond negligence but short of absolute liability."].)

This Court has repeatedly rejected attempts to conflate strict liability and negligence standards. (See, e.g., *Cronin*, *supra*, 8 Cal.3d at 133 [rejecting requirement that "design defect" requires proof that product was "unreasonably dangerous" because such a requirement "rings of negligence"]; *Anderson v. Owens-Corning Fiberglas Corp.* (1991) 53 Cal.3d 987, 1002 (*Anderson*) [noting that a manufacturing or design defect

is not "rooted in negligence" to the same extent as a warning defect because a manufacturing or design defect "can be evaluated without reference to the conduct of the manufacturer"]; *Himes v. Somatics, LLC* (2024) 16 Cal.5th 209, 222, 224 [a "manufacturer's failure to warn … results in a breach of its general duty of care to the patient under negligence principles *or* a breach of its obligation to market a product free from defects under strict liability principles."] (italics added); see also *Brown*, *supra*, 44 Cal.3d at 1069, fn. 12 [precluding drug manufacturer's strict liability for design defects but permitting liability under "general principles of negligence"].)

Like Gilead, Amici fail to address the multiple cases from this Court and the Courts of Appeal affirming findings of liability for negligence even though the plaintiff failed to prove (or sometimes even allege) that a product was "defective" as defined under strict liability law. (See Plaintiffs' Answer at 22 [collecting cases]; see also *Toole v. Richardson-Merrell Inc.* (1967) 251 Cal.App.2d 689, 703–04 [rebuttable presumption of negligence arose from violation of the federal reporting obligations for drug manufacturers; the "standard of conduct" enforced by negligence law may be defined by statute independent of any alleged defect in the product]; *Hasson v. Ford Motor Co.* (1977) 19 Cal.3d 530, 541, overruled on other grounds in *Soule v. General Motors* (1994) 8 Cal.4th 548, 574 (*Soule*) [concluding that a manufacturer's negligence was not precluded by a "no defect" finding].)

Consider *Mexicali Rose v. Superior Court* (1992) 1 Cal.4th 617, 621, 633 (*Mexicali Rose*), which held that a plaintiff may state a cause of action in negligence against a " 'manufacturer' of foodstuffs" for failing to exercise due care in the preparation of food when the "injury-producing substance is natural to the preparation of the food served" even though the food is not "defective" under strict liability's "reasonable expectation"

test.[7] *Mexicali Rose* is fatal to the "no defect, no duty" rule because it shows that negligence liability for injury caused by a product does not *depend* on proving "defectiveness" as defined under strict liability law.

IADC attempts to distinguish *Mexicali Rose* by arguing that "the Court simply adopted a rule under which a plaintiff could pursue both a strict liability claim and a negligence claim for 'foreign' defects in prepared food products, but could pursue only a negligence claim for 'natural' defects in such products." (IADC at 28.) But this distorts *Mexicali Rose*'s language *and* reasoning.

This Court did *not* distinguish between "natural defects" and "foreign defects"—or suggest that negligence claims depend on proof of "natural defects"—but rather distinguished between "injury-producing substances … natural to the preparation of the food served" and those "foreign to the food served." (*Mexicali Rose*, *supra*, 1 Cal.4th at 630–631.) This Court, appropriately, limited its use of the term "defective" to describe the prerequisite for *strict* liability. (See *id*. at 631 ["[I]f the substance is foreign to the food served, then a trier of fact *additionally must determine whether its presence … rendered the food … defective under the theor[y] of … strict liability*."] (italics added).) And this Court did not arbitrarily distinguish the theories of liability available for injury caused by naturally-occurring substances (negligence) and foreign substances (negligence and strict liability), but rather concluded that the "reasonable expectation"

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[7] IADC notes that the *Mexicali Rose* Court "expressly stated that its 'holding' was 'limited in application to commercial restaurant establishments' " (IADC at 28–29, quoting *Mexicali Rose*, *supra*, 1 Cal.4th at 619, fn. 1), but the Court of Appeal has found its "reasoning of even greater force where there has been a retail sale of meat to a consumer who herself has prepared the injurious food." (*Ford v. Miller Meat Co.* (1994) 28 Cal.App.4th 1196, 1199.) Amici offer no reason to limit *Mexicali Rose* to foodstuffs.

defectiveness test in strict liability law *cannot* be satisfied for naturally-occurring substances. (See *id*. at 633.) Thus, the Court recognized that the "legal concept of a 'defect' " in strict liability is *not* the "outer boundary" (IADC at 19) of a manufacturer's liability for injuries caused by its product.

Lunghi v. Clark Equipment Co. (1984) 153 Cal.App.3d 485 (*Lunghi*) and *Hernandez v. Badger Construction Equipment Co.* (1994) 28 Cal.App.4th 1791 (*Hernandez*) also illustrate that satisfying the "defect" requirement in strict liability is not always necessary to prove a negligence claim. In *Lunghi*, the Court held that there was no inconsistency between a finding that there was no defect in the design of a product and a finding that the manufacturer was negligent in failing to conduct an adequate retrofit campaign where "appellants presented *evidence on negligence quite apart from the design issue*." (*Lunghi*, *supra*, 153 Cal.App.3d at 494 (italics added).) And in *Hernandez*, the Court held that a finding that there was no design defect in a construction crane when it left the possession of the manufacturer without a particular safety device was not inconsistent with a finding that the manufacturer was nonetheless negligent because "[f]ailure to conduct an adequate retrofit campaign may constitute negligence *apart* from the issue of defective design." (*Hernandez*, *supra*, 28 Cal.App.4th at 1827–1828, italics added; see also *id*. at 1829 [noting defendant's acknowledgement that "a jury's special finding of no product defect is not necessarily inconsistent with a finding of negligence."].)

IADC argues that "the existence of a defect was *implicit* in the negligence claims asserted" in those cases because the "manufacturer defendants were subject to liability under a failure-to-warn theory and/or a failure-to-retrofit theory based on post-sale evidence[.]" (IADC at 27, 29.) But this "implicit" defect theory misses the point: The plaintiffs in *Lunghi* and *Hernandez* had viable negligence claims even though juries found that the products at issue were not defective under the strict liability theories

presented. It does not matter that Amici can reconceptualize the products at issue as somehow defective: The fact is that the juries in those cases *rejected* that conclusion. And the negligence claims were nevertheless allowed to proceed.[8]

Likewise misplaced is Amici's reliance on *Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, which concerned the application of a *legislatively created exception* to Civil Code section 1714 for design defect claims involving firearms. (IADC at 21-22; PLAC at 15, 30.) The issue before the Court was whether the plaintiff's allegations of negligence fell within the ambit of this statutory exception. (*Merrill, supra,* 26 Cal.4th at 478-482.) The Court concluded that the alleged negligent conduct was *predicated* on a theory of design defect and thus embraced by the statutory exception. (*Id*. at 480-481.) The analysis was entirely cabined to the allegations and *statutory exception* at issue.[9]

Nothing in *Merrill* supports Amici's position that a plaintiff must prove a defect in every claim for negligence against a manufacturer. (*Gilead, supra,* 98 Cal.App.5th at 929-930.)[10] As recognized by the Court

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[8] Indeed, Amici's position would mean that the reasonableness of a manufacturer's conduct under negligence law is tethered to the fluctuating meaning of the term "defective" under strict liability law. However, and as noted by this Court in *Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 427, "the term defect as utilized in the strict liability context is neither self-defining nor susceptible to a single definition applicable in all contexts."

[9] Notably, the California legislature *repealed Section 1714.4* shortly after and in direct response to the decision in *Merrill*. (See S.B. 682, 2001-2002 Reg. Sess. (Cal. 2002).)

[10] The few other cases cited by IADC are likewise beside the point as they involve negligence claims *premised* on a theory that the product is "defective" in its design, manufacturing, or warnings. (See IADC at 21–25; see, e.g., *Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110, 127 [holding that jury inconsistently found that defendant was not strictly liable for failure to warn but was liable for negligent failure to warn given that

of Appeal, the authority cited in *Merrill* also does not support the position that a plaintiff alleging negligence "must in every case prove a product defect." (*Id*. at 930.)

And to the extent Amici argue that Plaintiffs' negligence claim is a disguised "design defect" claim like the claim in *Merrill* (ICLE at 10–11; IADC at 30–31), such an argument is contradicted by *Gilead's* explicit recognition in its motion for summary judgment that "the focus of Plaintiffs' claim—the supposed duty that they claim was breached—is *not about the design of the TDF medications but rather about the other compound (TAF)*, which Plaintiffs argue Gilead should have more quickly developed and gotten to market … *Plaintiffs' claim is not that the TDF medications are 'negligently designed' or 'defective[] for purposes of establishing liability under a theory of negligence*.' *Merrill v. Navegar*, *Inc.*, 26 Cal. 4th 465, 478-79 (2001)." (1App.131–132, italics added.)

As Gilead aptly recognized and the Court of Appeal confirmed, Plaintiffs' claim challenged "conduct *independent* of TDF's design … Gilead's alleged recognition of TAF's superiority and its reasons for pausing development … [and] does not depend on an evaluation of the risks and benefits of TDF as an HIV/AIDS medication, as would be necessary in a claim for negligent design." (*Gilead*, *supra*, 98 Cal.App.5th at 933.) Plaintiffs do not allege that TDF was defectively designed and are not claiming that its risks outweigh its benefits; rather they allege that Gilead's *independent conduct* after TDF was released—strategically delaying the introduction of TAF until 2015 to maximize TAF's exclusivity and

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both theories were "*premised on a single alleged defect*."]; *Montez v. Ford Motor Co.* (1980) 101 Cal.App.3d 315, 319 [explaining that when "liability hinges on [a] manufacturing defect only," "liability ... in strict liability or in negligence [is] required to be congruent."].) Liability here *does not* depend on proof of a defect.

minimize the cannibalization of TDF's profits—harmed TDF's users by unreasonably depriving them of the choice of a safer alternative drug.

Because Plaintiffs allege negligent conduct *apart* from TDF's design, they need not establish that TDF is defective to have a viable negligence claim. (See *Gilead*, *supra*, 98 Cal.App.5th at 933 ["[P]laintiffs' claim is entirely consistent with a conclusion that the benefits of TDF use for hundreds of thousands of HIV/AIDS sufferers have vastly exceeded the harm from its side effects."].)

2. Further, Amici's "No Defect, No Duty" Rule Has No Historical Basis.

Amici assert that "[f]or nearly a century, California courts have adhered to a fundamental principle: a plaintiff alleging injury from a product must prove a defect in that product." (ICLE at 9; see also IADC at 26 [asserting that "defect" requirement in negligence law "*pre-dates* this Court's adoption of strict liability in *Greenman* []—by more than *three decades*"]; Gilead Rep. at 8 [accusing Plaintiffs of ignoring the "reams of history" supporting this requirement].) But this historical analysis of a common law privity rule obscures more than it reveals.

Amici is right that there was a common law rule preventing third parties not in privity from asserting negligence claims against manufacturers alleging personal injury from the use of manufactured articles unless (1) the article manufactured was inherently dangerous or (2) the article was reasonably certain to "bec[o]me, because of defective construction or assembling, an instrument *imminently dangerous* to human life or limb." (*Kalash v. Los Angeles Ladder Co.* (1934) 1 Cal.2d 229, 231, 233, italics added.) But there is no meaningful parallel between this privity exception, which limited the *products* that a manufacturer could be liable in negligence for based on the danger they posed and permitted claims for injury caused by non-defective but "inherently dangerous" products, and

the "defect" requirement in strict liability, which limits a manufacturer's liability to certain *categories* of defect: design, manufacturing, and warning. *None* of the venerable cases cited by Amici suggested that a manufacturer was *only* liable in negligence for *conduct* resulting in design, manufacture, or warning defects. Amici have thus failed to show that negligence law ever recognized a "defect" limitation that mirrors the limitation under strict liability law.

Furthermore, negligence's concern with privity is long past (see Prosser, *The Fall of the Citadel (Strict Liability to the Consumer)* (1966) 50 Minn. L. Rev. 791, 793, 817–820), so to the extent that negligence law *ever* recognized some kind of defect requirement, such requirement no longer delimits a manufacturer's duty of care.

Finally, even if there is a common law rule barring negligence liability without proof of a defect, this Court is required to depart from that rule if it conflicts with Section 1714 of the Civil Code. Section 1714, which was enacted in 1872 (long before *Kalash*), "establishes the law of this State respecting the subjects to which it relates, and its provisions are to be liberally construed with a view to effect its objects and to promote justice." (Civ Code., § 4.) This Court "begin[s] always with the command of Civil Code section 1714, subdivision (a)" in determining liability for negligence. (*Christensen v. Superior Court* (1991) 54 Cal.3d 868, 885.) Accordingly, this Court has declined to follow "rigid" common law classifications that were inconsistent with Section 1714's "basic policy." (*Rowland*, *supra*, 69 Cal.2d at 119.) And it has struck down "common law distinctions resulting in wholesale immunities … when such distinctions could not withstand critical scrutiny" under section 1714. (*Sprecher v. Adamson Companies* (1981) 30 Cal.3d 358, 363; see also *Bryant v. Pacific Elec. Ry. Co.* (1917) 174 Cal. 737, 742 [concluding, in announcing a rule regarding imputable negligence, that "no other rule is consistent with section 1714[.]"].)

Thus, despite Amici's efforts to rewrite history, the reality is that California has *never* conditioned a manufacturer's liability in negligence for harm caused by its product on proof that the product was defective. And even if such a rule existed at common law (it didn't), section 1714 controls. (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 214 (*USA Taekwondo*) [Section 1714 "establishes the *default rule* that each person has a duty 'to exercise, in his or her activities, reasonable care for the safety of others.'"].)

B. The Supposedly Universal "No Defect, No Duty" Rule Has Been Rejected in Multiple Jurisdictions.

Gilead's Amici echo Gilead's claim that "other jurisdictions universally require a defect." (Gilead Rep. at 22; see, e.g., IADC at 22.) But this is not true. At best, the cases they cite stand for the unremarkable proposition that where a plaintiff's claim *depends* on proving that a product is "defective" in its design, manufacturing, or warnings, the plaintiff cannot evade the need to prove a defect by reframing the claim in negligence.[11] Furthermore, Amici ignore the *multiple* cases from *multiple* jurisdictions recognizing that a plaintiff may state a claim for negligence alleging injuries caused by a manufactured product without proving that it is defective under strict liability law.

Toner v. Lederle Lab'ys (9th Cir. 1987) 828 F.2d 510, 513 (*Toner*), applying Idaho law, held that a drug manufacturer that marketed a vaccine that was found not to be defective under strict liability law could be held liable for *negligently failing to develop and market a safer alternative vaccine*. There, the plaintiff contended that the defendant failed to develop

[11] PLAC, for example, string-cites cases like *Hawkins v. Montgomery Industries Intern., Inc.* (Al. 1988) 536 So.2d 922, 927, which held that the absence of evidence that a product was defective foreclosed a negligence claim that was "*predicated upon the idea that the product was defective*." (PLAC at 27, fn. 7.)

and market an alternative vaccine that was not currently on the market that was apparently safer than the one given to him that caused paralysis. (*Ibid*.) The Ninth Circuit held, based on the Idaho Supreme Court's answers to certified questions (see *Toner v. Lederle Laboratories* (Idaho. 1987) 732 P.2d 297), that there was no inconsistency in the jury finding liability in negligence and no liability in strict liability:

> As the Idaho Supreme Court points out, the focus in negligence is on the manufacturer's conduct, while in strict liability it is on the product and the user's expectations. … *It is not enough for [the defendant] to argue that the jury's finding of negligence concludes that [the marketed vaccine] was defective, while its finding on strict liability states a contrary view.* The law and the instructions required the jury to examine the case from two different points of view. *It is reasonable to read the special verdicts as saying that [the defendant's] failure to develop the [alternative] vaccine was unreasonable conduct, although the danger posed by the product itself was not greater than an ordinary consumer would reasonably expect.*

(*Toner*, *supra*, 828 F.2d at 513, italics added.)[12]

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[12] Gilead dismisses *Toner* by arguing that the "Idaho Supreme Court has since disavowed" the view taken in that case by requiring a plaintiff bringing a negligence claim to prove a defect. (Gilead Rep. at 22.) Not true: *Toner* remains good law for the proposition that a plaintiff may prevail on a negligence claim without proving that the marketed product was defective under strict liability law if the claim is not predicated on proof of a defect. (See *Blomhorst v. Pierce Mfg., Inc.* (D. Idaho Mar. 28 2014) No. 4:10–cv–00573–REB, 2014 WL 1319717 at *11 ["As the decision in *Toner* describes, a plaintiff may prevail on their negligence claim, but not their strict liability claim, because the jury could reasonably have examined the case from two different points of view and reached its verdict based on the separate foci of the two causes of action."]; see also *Livingston v. Isuzu Motors, Ltd.* (D. Montana 1995) 910 F.Supp. 1473, 1487, 1489–1490 [relying on *Toner* to conclude, under Montana law, that there was no inconsistency in jury verdicts finding defendants negligent for their "design, testing or failure to warn" but not finding the product defective]; *Holley v. Gilead Sciences, Inc.* (N.D. Cal. Sep. 28, 2023) No. 18-cv-06972-

In *Lance*, *supra*, 85 A.3d at 436, 458–460, the Supreme Court of Pennsylvania allowed claims against a drug manufacturer to proceed on a negligent design theory alleging that the manufacturer improperly marketed and failed to recall a drug even though the drug was FDA-approved when the alleged harm occurred and there was no claim of inadequate warnings. The court agreed with the plaintiff "that *adherence to the three-prong manufacturing/design-defect/warnings overlay is more consistent with the strict-liability arena (where this Court has maintained that the focus is exclusively on the product) than it is to negligence (as to which the main focus is on conduct)* … In other words, in the negligence arena at least, the substantive allegations are more important than the labels." (*Id*. at 458.); see also *Phillips v. Cricket Lighters* (Pa. 2003) 841 A.2d 1000, 1008 [rejecting as "deeply flawed" the argument that the unavailability of a strict-liability claim premised on design-defect theory necessarily foreclosed a claim for negligent design].)

In *Connelly v. Hyundai Motor Corp.* (1st Cir. 2003) 351 F.3d 535, the First Circuit Court of Appeals held, applying New Hampshire law, that there was no inconsistency in a jury's finding that Hyundai was not liable for defectively designing an airbag but was liable for negligently testing or designing the airbag. The Court rejected Hyundai's claim that "the *existence of a defect is a determinative factor in both* negligent design and strict liability design defect claims[.]" (*Id*. at 538, italics added; see also *id*. at 542 ["[I]t appears from the verdicts that the jury understood that 'the focus of strict liability is on whether the design itself was unreasonably dangerous whereas in a negligence case the focus is on the conduct of the manufacturer.' "].)

JST, 2023 WL 6390598 at *6 [relying on *Toner* to reject "Gilead's argument to the extent it asserts it cannot be held liable for negligence if it is not liable under a strict-liability theory."].)

In *Wagner v. International Harvester Co.* (8th Cir. 1979) 611 F.2d 224, 228–229, the Eighth Circuit Court of Appeals, applying Minnesota law, held that a special verdict finding that the "design of [a tractor] was not defective insofar as it incorporated a left-foot decelerator" was not inconsistent with a concurrent verdict that the manufacturer was "negligent in [the] design, testing, or manufacture of the … tractor with reference to its stability [o]r the use of a left foot decelerator" since the wording of the concurrent verdict "directly suggest[ed] an alternative basis for the jury's initial finding of negligence."

In *Griggs v. BIC Corp.* (3rd Cir. 1992) 981 F.2d 1429, 1435, the Third Circuit Court of Appeals, also applying Pennsylvania law, explained that there is an important theoretical basis for distinguishing between negligence and strict liability law in the products liability context; namely, the underlying analysis necessary to reach each legal conclusion giving rise to liability are qualitatively different in that the *social policy determination as to product defect in strict liability is not the equivalent of a determination of duty in negligence law*. "Viewing the negligence claim as merely one step beyond strict liability … obscures the true difference between negligence and strict liability." (*Id*. at 1438.) As the Court explained:

> In strict liability, the focus is on a defect in the product, regardless of fault, and that defect is determined in relation to a particular subset of the general population: the intended user who puts the product to its intended use. In negligence, the focus is on the reasonableness of a defendant's conduct, and this reasonableness is determined in relation to a different subset of the general population, and one that is conceivably broader: anyone who foreseeably may be subject to an unreasonable risk of foreseeable harm.
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> … In strict liability, the plaintiff need not show fault, but only prove a product defect. A product cannot be defective when its design and performance meet all of the requirements of the

> intended user, regardless of the foreseeability of misuse by unintended users. In negligence, the plaintiff must prove fault of the manufacturer, which is an element not required in strict liability law. The scope of inquiry, however, expands because of the duty to unintended but foreseeable users. *Although the results may very well often be the same in strict liability and negligence under a given set of facts, the focus of each claim is different, and therefore proof of negligence may be possible without a finding of strict liability.*

(*Id*. at 1438–1439, italics added; see also *Talkington v. Atria Reclamelucifers Fabrieken BV* (4th Cir. 1998) 152 F.3d 254, 263–264 [applying South Carolina law, the Court held jury's verdict that the manufacturer was not strictly liable for the child's injuries because the lighter "was *not defective or unreasonably dangerous to the ordinary consumer* (an adult) for its intended use (lighting a cigarette)" was not inconsistent with the finding that the manufacturer "negligently failed to exercise due care towards the vulnerable child plaintiffs when it was reasonably foreseeable that serious harm could result from Cricket's failure to include child-resistant safety features on its lighter".].)

Finally, in *Fischer v. Cleveland Punch and Shear Works Co.* (Wi. 1979) 280 N.W.2d 280, 286, the Supreme Court of Wisconsin held that there was no inconsistency between a jury's finding that a machine was not "unreasonably dangerous" as required for strict liability but was negligently designed because of a "lack of ordinary care in the design of the product."

Amici rely on *Burton v. E.I. du Pont de Nemours & Co., Inc.* (7th Cir. 2021) 994 F.3d 791, 817 (*Burton*), which held, applying Wisconsin law, that the trial court "erroneously allowed the jury to find [a manufacturer] liable on the negligence claims without proof of a product defect." (PLAC at 32.) The Seventh Circuit Court of Appeals stressed, however, that there was "*no negligent act to speak of [in that case], apart*

from [the manufacturer's] sale of a potentially dangerous product." (*Burton*, *supra*, 994 F.3d at 819.) Here, by contrast, there *is* a "negligent act to speak of … apart from" the sale of TDF: Gilead strategically delaying the development of a safer alternative drug to maximize its profits.

Thus, Gilead and Amici's hyperbolic rhetoric that "[n]ever before has a court – in this State or anywhere else – held that a plaintiff can recover damages for injuries allegedly caused by a non-defective product" (Gilead Writ at 9; see also Gilead Rep. at 22; IADC at 22) is simply wrong. Gilead and Amici's position that manufacturers sit outside the law of negligence and are shielded from all liability, except to the extent that it is based on a defective product, does not withstand scrutiny.

III.

GILEAD'S AMICI MISCHARACTERIZE THE APPLICABLE FACTS, MISSTATE THE GOVERNING LAW, AND MISREPRESENT THE DUTY OF CARE RECOGNIZED BY THE COURT OF APPEAL

Amici's case-specific claims fare no better than their sweeping assertions about innovation and the common law. They mischaracterize the applicable facts by ignoring Gilead's presentation of its case below and disregarding the damning record evidence suggesting that Gilead strategically delayed TAF's introduction at the expense of TDF's users. They misstate the governing law by refusing to engage with the plainly applicable two-step framework under Civil Code section 1714 for evaluating duty claims. They misrepresent the duty of care affirmed by the Court of Appeal by exaggerating its scope and disregarding its limiting principles. And finally, they overstate the workability challenges of permitting negligence liability in a case that is no more complicated or susceptible to bias than other design defect cases.

A. Amici Mischaracterize the Applicable Facts.

On appeal from the denial of summary judgment, it is well-established that all facts and inferences must be viewed in the light most favorable to the non-moving party. (*Gund v. County of Trinity* (2020) 10 Cal.5th 503, 507, fn. 2.) Despite this clear standard, Amici essentially urge this Court to accept Gilead's version of the facts—and even Amici's unsupported assertions—while drawing inferences in Gilead's favor and disregarding any inferences supporting Plaintiffs. (See, e.g., PRI at 15, 33; see also Gilead Rep. at 8 [claiming Plaintiffs' case is "based on pure fiction"].) This approach not only conflicts with the settled standard for summary judgment review but also misrepresents how Gilead presented its case in both the trial court and the Court of Appeal.

As this Court has explained, when a defendant "assert[s] below that the purpose of their motion for summary judgment [is] to determine whether the [plaintiff] had stated a cause of action," it will "apply the rule applicable to demurrers and *accept the allegations of the complaint as true* … '[This Court's] primary task is to *determine whether the facts alleged provide the basis for a cause of action* against defendants under any theory.' " (*American Airlines, Inc. v. County of San Mateo* (1996) 12 Cal.4th 1110, 1117–1118 (*American Airlines*); see also *Prue v. Brady Co.* (2017) 242 Cal.App.4th 1367, 1378 ["Because the gist of [defendant's] motion was not the absence of disputed material facts but was instead whether [plaintiff's] complaint alleged sufficient facts to state a cause of action, its motion for summary judgment was, in effect, a motion for judgment on the pleadings."].)

Here, Gilead did *not* move for summary judgment on the ground that there was undisputed evidence disproving Plaintiffs' factual allegations but instead "asserted below" (*American Airlines*, *supra*,12 Cal.4th at 1118) that there is "*no cognizable claim* against Gilead for failing to develop and

obtain approval for TAF earlier than it did when, as here, Plaintiffs are not claiming that the accused TDF medications are defectively designed … *There is no such thing as a claim* to redress alleged injuries caused by a defendant's product without … proving a design defect." (1App.121, 131–132, italics added.)

As the trial court explained in denying the motion for summary judgment, "*Gilead does not dispute the existence of its duty of care …* To the extent Gilead believes that *there is no cognizable negligence claim because it does not owe a legal duty or the duty as framed by Plaintiffs*, *Gilead does not brief such an argument* as necessary to carry its initial burden … *Instead, Gilead argues, unsuccessfully, that California does not recognize non-defect claims of ordinary negligence against product manufacturers*." (10App.3247, italics added.)

In its writ petition to the Court of Appeal, Gilead noted that it "*assumes the truthfulness of [Plaintiffs'] account* and simply presents straightforward legal questions about the viability of Plaintiffs' claims under the law." (Gilead Writ at 11, italics added.) And Gilead asserted in its petition for rehearing in the Court of Appeal that it did not contest Plaintiffs' allegations of knowledge or motivation because they "were *not material to the legal issues* in the motion." (Gilead Pet. Rehearing at 16, italics added.) Given Gilead's framing of the issues below, Amici are wrong to suggest that the Court of Appeal "committed a serious procedural error by denying Gilead's summary judgment motion … without regard to the parties' voluminous evidentiary record." (IADC at 40.)[13]

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[13] Because of the way Gilead framed its motion for summary judgment, Plaintiffs had no need to present all of the evidence at their disposal regarding Gilead's knowledge and motivation. (Cf. Dickson and Killelea, *supra* [providing a detailed chronology of this case].) This Court should not permit Gilead to benefit from its narrow framing of the issue below by limiting Plaintiffs to the evidence in the summary judgment record.

And even if the evidence in the summary judgment record is relevant to determining whether Plaintiffs stated a cause of action for negligence, Gilead's Amici grossly misstate that evidence. PRI, for example, asserts that Gilead did not know "in 2004, nor indeed before 2013," that " 'TAF had less impact than TDF on renal function [and] bone metabolism' … TAF was both better and safer than TDF only by ignoring TAF's use limitations and known side effects." (PRI at 38–39.)

However, the evidence reveals that by the early 2000s, Gilead's studies revealed TAF's superior biochemical stability could achieve the same antiviral effect as TDF with only one-tenth (0.1) the amount of tenofovir. (5App.1662-1670,1716-1724). The difference in minimum dosing between TDF and TAF meant that the TAF reduced the amount of toxic tenofovir being filtered by the kidneys by roughly ninety percent (90%), which decreased the risks of renal, bone and tooth injuries in humans. (Id.) On November 28, 2001, three weeks after TDF was approved, Gilead filed an IND for TAF and began clinical testing. (6App.1882-1894.) Gilead's Phase I/II clinical trial of TAF began in mid-2002 and showed results consistent with the preclinical findings. (6App.1910-1911.) By September 27, 2002, Gilead had completed a head-to-head comparison of TAF and TDF in human beings (Study GS-120-1101), which showed that 50 mg. of TAF delivered higher tenofovir concentration in HIV infected cells than 300 mg. of TDF. (Id.) That data also showed that TAF was more stable than TDF and thus increased the cellular distribution of drug. (Id.) In fact, Gilead's head of R&D would later describe the preclinical tests as "spectacular" and the clinical results as "remarkable." (5App.1712-1715.) In December 2002, Gilead then decided to develop TAF, and within weeks it laid out a detailed plan to get FDA approval and sale by 2006. (6App.1971-1982.)

Nothing about TAF showed anything other than tremendous promise. However, after the 2002 Phase I/II trial was completed in early 2003, no further testing was undertaken or planned. As discovery revealed, in April to May 2003, Gilead decided to delay TAF's submission to 2015 based a series of business discussions and meetings that showed that delaying TAF from the originally planned launch date in 2006 until near the end of TDF's patent would result in a tremendous increase in Gilead's revenue and earnings. (6App.2086-2051; see also 2202-2209.) Evidence in the record shows:

On April 3, 2003, Gilead conducted a business review of TAF. (6App.1917-1931.) The review acknowledged that TAF was a novel second-generation prodrug of tenofovir with enhanced potency and superior efficacy to TDF (6App.1919-1920), but the committee also recognized that TAF would cannibalize Viread sales, estimating between 70-80% of Viread's sales at peak cannibalization (6App.1922).

The next day, April 4, 2003, Gilead had its corporate development do a separate analysis "outside the scope of the business review" that would "explore [TAF] potential as an IP extension for Viread." They directed the analyst to do a "quick and dirty model for [TAF] where [Gilead extends] the patent life from 2017 to 2020? We would take the existing development costs (in the latest assumptions documents) and move them forward such that we could get [TAF] on the market two years prior to 2017." (6App.2084.)

By April 14, 2003, the 'quick and dirty' analysis showed that if Gilead deferred TAF until the end of TDF patent life, it could reap billions more in profit and revenue than it could make if it got it to market as initially planned. (6App.2086-2150.)

Three days later, with the only change to Gilead's knowledge of TAF being the business consequences of developing it as planned, Gilead

shelved development. (7App.2153.) As the executive summary of the meeting notes:

> The recommendation of the Review Committee was to stop development due the likelihood that GS-7340 *would ultimately cannibalize Viread regardless of its efficacy and safety profile*. One reason for continuing/restarting development would be to obtain patent extension. Corporate development has agreed to compute the NPV [net present value] for this scenario. … [i]f the patent extension proves worthwhile, the development of TAF might resume. The program is to be revaluated in the Spring of 2004.

(7App.2153, italics added.)

On September 18, 2003, Corporate Development delivered its 'Financial Analysis of GS7340 as a Tenofovir Exclusivity Extension. (7App.2202-2209.) The analysis showed that by delaying TAF until 2015, and switching patients, Gilead stood to reap billions in revenue and profits. (7App.2209.) A year later, on October 21, 2004, Gilead announced that commercial development of TAF was ending. (7App.2278.)

These documents *alone* are sufficient to demonstrate, or in the very least raise a triable issue of fact, that Gilead did know in 2004 and well before 2013 (PRI at 38–39) that TAF was as effective and safer than TDF and that its decision to delay commercialization of TDF was to maximize profits. In fact, Gilead's senior executives further confirmed Gilead's belief in TAF's superiority, when in 2010 (the year in which the September 18, 2003 financial analysis indicated TAF should be restarted), Gilead's President and Chief Science Officer told Gilead's Board of Directors that TAF "an improved prodrug of tenofovir that could replace Viread with more selective exposure in infected cells resulting in at least equivalent efficacy and no side effects on renal function or bone mineral density." (8App.2627-2633, italics added.)

And while PRI asserts that Gilead "never sought to reap … supposed monopoly profits" from TAF's delayed introduction (PRI at 39), it ignores the evidence above demonstrating otherwise, including (1) the April 2003 email from Gilead's Manager of Corporate Development that described "developing [TAF] as a patent extension strategy" (6App.2087), (2) the September 18, 2003 "Financial Analysis of GS7340 [TAF] as a Tenofovir *Exclusivity Extension*" (7App.2202, 2204, italics added), and (3) Gilead's CEO's statement in 2011 that TAF was previously shelved for "business reasons," including that TAF's study results "suggest[ed] that [TDF] wasn't the safest thing on the market." (7App.2392–2393.)

Amici do not establish that the undisputed evidence in this case *negates* Plaintiffs' allegations and evidence regarding Gilead's knowledge and motivation. To the extent that there are disputes about Gilead's knowledge and motivation, these matters should be determined by a jury.

B. Amici Misstate the Governing Law.

Amici insist that Civil Code Section 1714's general duty of care does not apply to this case (PLAC at 30; IADC at 54; PRI at 17) and pay, at best, lip service to this Court's two-step *Rowland* analysis. (CJAC at 16–20.) Indeed, Gilead did not argue below, and does not argue now, that it owed *no duty* to Plaintiffs. (*Gilead,* 98 Cal.App.5th at 919-920; 1App:132; 10App:3246-3247.) There is no question that the duty to take ordinary care in one's activities under section 1714 applies to a manufacturer of prescription drugs and is owed to the users of such drugs. (See *Bettencourt v. Hennessy Indus., Inc.* (2012) 205 Cal.App.4th 1103, 1117-1119 ["Under established California law, a manufacturer … owes a duty of care to foreseeable users of its product."].) Further, and as held by the Court of Appeal, Gilead "created the risk of harm to plaintiffs by selling TDF, a drug with harmful side effects[.]" (*Gilead*, 98 Cal.App.5th at 935.) And Gilead made Plaintiffs' "position worse" (*USA Taekwondo, supra,* 11

Cal.5th at 214) by pausing—for nearly a decade—the development of an alternative drug without the same adverse effects. (1App:46.) As Gilead held the "exclusive rights to develop, manufacture, distribute and sell … tenofovir," its conduct deprived Plaintiffs of an essential choice in their battle with HIV/AIDS and needlessly "exposed [them] to a more toxic form of the drug[.]" (1App:45–46.) Because Gilead's "entire conduct created a risk of harm," section 1714's default rule of duty applies. (*Kuciemba v. Victory Woodworks, Inc.* (2023) 14 Cal.5th 993, 1017–1018.)

According to PRI, Section 1714 *does not apply at all* in product liability cases and limits its scope to negligent "contemporary activity or oversight of the activities at the time the injury occurs." (PRI at 16–17.) Yet it does not even attempt to connect these purported exclusions to the statutory text, which states broadly that *"[e]veryone is responsible*, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her *want of ordinary care or skill in the management of his or her property or person*[.]" (Civ. Code, § 1714, italics added.) And California cases do not support a carveout for product liability actions. As far back as *Dahms v. General Elevator Co.* (1932) 214 Cal. 733, 738–739, this Court suggested that Section 1714's duty to exercise ordinary care is the "true reason" that "an action sounding in negligence may be maintained by a stranger to a contract for the execution of a specific piece of work or the *sale of a manufactured article*, if the product of the stipulated work or the article sold was abnormally dangerous or noxious." (Italics added; see also *Merrill*, *supra*, 26 Cal.4th at 477 [explaining, in a product liability case involving a negligence claim, that the duty analysis "always [begins] with the command of ... section 1714, subdivision (a)[,]' " but concluding that the statutory exception in Civil Code section 1714.4 barred Plaintiffs' negligence claim].) Furthermore, PRI gives no reason for

product manufacturers, but not other defendants, to have this special exception from liability under Section 1714.

The Chamber of Commerce argues that the "Court of Appeal's theory … boils down to imposing liability on Gilead based on nonfeasance, where the law is 'reluctan[t] to impose liability.' (*Brown v. USA Taekwondo* (2021) 11 Cal.5th 204, 214.)" (Chamber of Commerce at 11.) However, and as this Court emphasized in *USA Taekwondo,* the distinction between "misfeasance" and "nonfeasance" is "imprecise and prone to misinterpretation." (*USA Taekwondo*, 11 Cal.5th at 215, fn. 6.) "'The proper question is not whether an actor's failure to exercise reasonable care entails the commission or omission of a specific act.' … Rather, it is 'whether the actor's *entire conduct created a risk of harm*.'" (*Ibid.,* italics added.) As just explained, Gilead's "entire conduct" created a risk of harm to Plaintiffs that gave rise to a general duty of care.

Section 1714 applies to this case, which means that Gilead needs to justify a categorical exception to its duty of care under *Rowland*. (See *Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 783 ["The question is not whether a new duty should be created, but whether an exception to Civil Code section 1714's duty of exercising ordinary care in one's activities … should be created."].) Yet Amici—with the exception of CJAC—*ignore* the *Rowland* factors altogether.

And CJAC adds little to Gilead's perfunctory *Rowland* analysis, arguing, for example, that "too many factors stood between Gilead's conduct and the plaintiffs' injury to conclude that injury was reasonably foreseeable. … Gilead would have to obtain FDA approval. It would need to have the resources available to produce the drug in quantity. Then, the plaintiffs would have had to determine in consultation with their doctors whether they should switch to the new drug." (CJAC at 16–17.) But as a federal appeals court has explained, "the fact that one can fashion a multi-

step description of the causal chain does not mean that the injurious conduct and the injury alleged are insufficiently connected." (*Estados Unidos Mexicanos v. Smith & Wesson Brands* (1st. Cir. 2024) 91 F.4th 511, 534.) Here, it was plainly foreseeable that (1) a big pharmaceutical company that had *already* obtained FDA approval of a tenofovir-based drug would likely secure approval of another tenofovir-based drug which was shown to be safer and equally effective in Phase I/II trials, (2) the company would have sufficient resources to produce that drug in quantity, and (3) users of the first drug would suffer injury by not being able to switch to the alternative. Amici get Gilead nowhere on the critical legal questions in this case.

C. Amici Misrepresent the Duty Owed by Gilead.

The Court of Appeal carefully circumscribed the duty at issue in this case. It 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." (*Gilead*, *supra*, 98 Cal.App.5th at 922.) It stressed that a manufacturer of an FDA-approved drug does not have a "legal duty to invent a safer alternative drug." (*Id*. at 921.) And it emphasized that Plaintiffs' negligence claim is "premised on Gilead's possession" of a safer alternative drug and its "knowing and intentional withholding of such a treatment following its invention." (*Ibid*.)

Amici distort the Court's opinion beyond recognition, tearing down a straw man. According to the Chamber of Commerce, manufacturers will be liable "whenever one product is brought to market before another." (Chamber of Commerce at 4; see also PRI at 10 [suggesting that this case seeks to hold manufacturers liable for developing drugs in the "wrong sequence"].) Not true: Per the Court of Appeal's reasoning, a manufacturer

of an existing drug is only liable if it possesses an alternative that is safer and at least equally effective and *then* makes unreasonable decisions about the commercialization of that alternative that causes harm to the drug's existing users. And improper *sequencing* is an Orwellian way to characterize the appalling misconduct alleged in *this* case: Gilead strategically delaying the introduction of a safer drug to game the patent system at the expense of users of its existing drug.

According to IADC, the Court of Appeal required all manufacturers to "develop and commercialize *without delay* an alternative to a nondefective product." (IADC at 18, italics added; see also NAM at 11 [alleging that Court created "a new duty to *immediately* commercialize supposedly safer products"].) But the duty recognized in this case does not require manufacturers to sell alternatives "without delay" but merely requires the manufacturer to act reasonably when making decisions about the commercialization of a safer alternative product that the manufacturer has already invented. The extent of any delay is simply a factor relevant to determining whether the manufacturer acted reasonably. At the breach stage, the manufacturer could show that the delayed release of an alternative was not unreasonable for reasons including (1) the need for further safety and effectiveness testing, (2) the need to prioritize alternative products with greater benefits to consumers, and (3) the lack of demand for the alternative product.

According to multiple Amici, the Court of Appeal imposed a "limitless duty" applicable to *all* manufacturers. (See, e.g., IADC at 18; Viasat at 7; Archer Aviation at 19; see also Gilead Rep. at 7.) This reveals yet another misunderstanding of the legal framework for determining a duty question under California law. The Court of Appeal, appropriately, considered the duty question in this case in its factual context and in light of Plaintiffs' allegations. (See *Verdugo v. Target Corp.* (2014) 59 Cal.4th 312,

336 [limiting the duty question to the *specific* failure alleged by the plaintiff, namely, "Target's failure to acquire and make available in its department store an AED for use in a medical emergency."].)

After determining that Gilead's alleged conduct increased the risk of harm to Plaintiffs, the Court considered whether an exception to its general duty of care under Section 1714 was justified under the *Rowland* factors, focusing on the specific regulatory environment (pharmaceuticals), specific exclusivity rules for new drugs that may incentivize strategic delay (patent protections and regulatory exclusivities), and specific alleged misconduct (intentionally withholding TAF to maximize profits).

The Court of Appeal's approach is aligned with this Court's recognition that "there is an important distinction between prescription drugs and other products" such that the same principles of liability do not always apply. (*Brown*, *supra*, 44 Cal.3d at 1063.)[14] A manufacturer's duty to commercialize safer alternatives in a different setting, and any possible *Rowland* exception, must be resolved in its particular context.

D. Amici Wrongly Suggest that the Duty Affirmed by the Court of Appeal is Unworkable.

Amici claim that the duty in this case is unworkable because "(1) evaluating product-development issues like the kind at issue here is outside the core competencies of courts and juries and (2) this evaluation will itself be tainted by significant inherent bias," including "hindsight bias" and

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[14] As explained above, here, unlike in *Brown*, the distinction between prescription drugs and other products *supports* hold drug companies liable for deliberately withholding the introduction of lifesaving alternatives to their existing drugs. (Cf. Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment k*, 42 Wash. & Lee L. Rev. 1139, 1144–1145 (1985) [explaining that pharmaceutical manufacturers have the "most serious and intense obligation that one can find in the entire body of negligence law" because the "circumstances in which [they] must deal directly involve severe risks to human life."].)

"context bias." (Archer Aviation at 24; see also Chamber of Commerce at 16 [suggesting that this duty "would effectively allow juries to establish business policy."]

Both objections are baseless. Juries are *already* required to evaluate complex product-development decisions in design defect cases. (See *Barker*, *supra*, 20 Cal.3d at 418, 431 [noting that juries are called upon to determine whether a design is safe enough given "the *relative complexity of design decisions* and *the trade-offs that are frequently required* in the adoption of alternative designs" in light of factors including the "mechanical feasibility of a safer alternative design" and "the financial cost of an improved design"]; *Kim v. Toyota Corp.* (2018) 6 Cal.5th 21, 28 [jury heard evidence about "Toyota's decision to make VSC optional equipment on the 2005 Toyota Tundra," including evidence of "market research" into consumer preferences and Toyota's competitive positioning]); *Soule*, *supra*, 8 Cal.4th at 563 [emphasizing that a "complex weighing of risks, benefits, and practical alternatives is 'implicit' in so many design-defect determinations"]; *Demara v. The Raymond Corp.* (2017) 13 Cal.App.5th 545, 563 [noting that "technical issues of feasibility, cost, practicality, risk, and benefit" are "impossible to avoid" under the risk-benefit test for design defects] (quoting *Barker, supra*, 20 Cal.3d at 431, 433).) And juries evaluate the propriety of business resource allocations in other contexts, including claims asserting breaches of fiduciary duties through improper income distributions. (See, e.g., *Siry Investment, L.P., v. Farkhondehpour* (2022) 13 Cal.5th 333, 339–340.)[15] Further, concerns about "hindsight

[15] Bizarrely, Amici argue that the duty in this case is virtually indistinguishable from the inquiry in a product liability case (IADC at 33–40), while simultaneously arguing that it is unworkable for a jury to make a reasonableness determination in this case.

bias" and "context bias" exist in *all* product liability actions, yet juries are still empowered to make these determinations.

Beyond this, Amici fail to justify Gilead's purportedly "narrower" position that a drug company cannot have sufficient knowledge to trigger this duty without having completed a Phase III trial into the alternative drug *and* head-to-head comparisons with the existing drug following FDA approval. (See ICLE at 26 [asserting that sufficient knowledge about the "efficacy and safety of a drug candidate" is only attainable "after FDA approval, once there have been large-scale head-to-head comparative studies."].) PhRMA contends that "even Phase III trials generally do not permit the kind of comparative assessment that the Court of Appeal said should be the foundation of tort liability. Most Phase III trials are placebo-controlled trials, meaning the treatment is being compared to a sugar pill or similar inactive administration." (PhRMA at 26.) But this proves too much: Gilead's fallback position would essentially immunize a manufacturer from liability unless the manufacturer *gratuitously* ran (and published the results of) a head-to-head trial between its earlier and newer drugs. This Court should reject any *Rowland* exception that would eviscerate the duty of care that exists in this case.

Furthermore, PhRMA fails to establish that "in no world and under no circumstances" could a company "know" that a medicine like TAF "will prove out to be equally effective as or have a better safety profile than a marketed product like TDF that has gone through the entire development process." (PhRMA at 18–19.) To start: The FDA has created multiple pathways for drug approvals *before* Phase III trials are conducted, including the "Fast Track pathway (1988) [that] allows approval based on *one Phase II trial that produces sufficient safety and efficacy data*" and "the Accelerated Approval pathway (1992) [that] allows approval [before Phase III trials] based on surrogate measures that are only 'reasonably likely' to

predict patient benefit." (Kesselheim, *supra*, 30 Stan. L. & Pol'y Rev. at 438, italics added; see also *id*. at 433 [noting that "nearly half of all pivotal trials rely upon surrogate measures or biomarkers (markers of disease such as changes in laboratory tests or radiology reports) as endpoints, as opposed to clinical outcomes (such as end-organ damage, mortality, or changes in symptoms)."].) Amici's position would thus foreclose a manufacturer's liability for negligently withholding a safer and more effective drug even if the FDA had sufficient information to approve the alternative.

Lastly, Amici, like Gilead (Rep. at 34), rely on generalized statistics regarding the unknowability of the likely prospects of an alternative drug that do not address drugs developed by the *same* company that received FDA approval for a *related* molecule. The record does not permit this Court to make the sweeping assessment that a drug company that secures approval for a drug, *cannot* know (for the purposes of negligence liability) that a related compound is safer and at least equally effective following a Phase II trial.

CONCLUSION

For the foregoing reasons, Amici fail to establish that liability in this case would stifle innovation, frustrate California law nor warrant a categorical exception for public policy reasons. The Court of Appeal's opinion affirming the trial court's order denying summary judgment of Plaintiffs' negligence claim should be affirmed.

Dated: January 27, 2025

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CERTIFICATE OF WORD COUNT

This brief contains 13,966 words per a computer generated word count.

s/ Holly N. Boyer
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PROOF OF SERVICE

I am employed in the County of Los Angeles, State of California. I am over the age of 18 and not a party to the within action; my business address is 600 S. Lake Avenue, Suite 408, Pasadena, CA 91106.

On the date set forth below, I served the foregoing document(s) described as follows: **PLAINTIFFS' COMBINED ANSWER TO AMICUS BRIEFS**, on the interested parties in this action by placing ___ the original/ X a true copy thereof enclosed in a sealed envelope(s) addressed as follows:

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☒ BY ELECTRONIC SERVICE VIA TRUEFILING Based on a court order, I caused the above-entitled document(s) to be served through TrueFiling at https://www.truefiling.com addressed to all parties appearing on the electronic service list for the above-entitled case. The service transmission was reported as complete and a copy of the TrueFiling Filing Receipt Page/Confirmation will be filed, deposited, or maintained with the original document(s) in this office.

☒ STATE I declare under penalty of perjury that the foregoing is true and correct.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct and that this declaration was executed on January 27, 2025 at Honolulu, Hawaii.

s/ Kelsey Wong
Kelsey Wong

SERVICE LIST

Gilead Sciences, Inc. v. The Superior Court of California, County of San Francisco
(S283862 | A165558 | CJC-19-005043)

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