A165558

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

FIRST APPELLATE DISTRICT, DIVISION FOUR

GILEAD SCIENCES, INC.,
Petitioner,
v.
SUPERIOR COURT OF THE STATE OF CALIFORNIA, COUNTY OF SAN FRANCISCO,
Respondent,
and
GILEAD TENOFOVIR CASES,
Real Parties in Interest.

SUPERIOR COURT OF CALIFORNIA, SAN FRANCISCO COUNTY
HON ANDREW Y.S. CHENG | CASE NO. CJC-19-005043

APPLICATION OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, CALIFORNIA CHAMBER OF COMMERCE, THE ALLIANCE FOR AUTOMOTIVE INNOVATION, AND WASHINGTON LEGAL FOUNDATION FOR LEAVE TO FILE SUPPLEMENTAL AMICI CURIAE BRIEF IN RESPONSE TO THE COURT'S SEPTEMBER 7, 2023 ORDER AND IN SUPPORT OF PETITIONER GILEAD SCIENCES, INC.; PROPOSED SUPPLEMENTAL AMICI CURIAE BRIEF

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BACKGROUND

Pursuant to California Rules of Court, rule 8.487 subd. (e), and this Court's Order of September 7, 2023 requesting supplemental briefing, Amici Curiae the Chamber of Commerce of

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the United States of America ("U.S. Chamber"), the California Chamber of Commerce ("CalChamber"), the Alliance for Automotive Innovation ("Auto Innovators"), and the Washington Legal Foundation ("WLF") hereby request leave to file the attached supplemental amici curiae brief in support of Petitioner Gilead Sciences, Inc. ("Gilead" or "Petitioner").

Good cause exists to grant Amici Curiae's application. The U.S. Chamber, CalChamber, Auto Innovators, and WLF participated in this appeal as amici curiae during the initial round of merits briefing. The aim of this supplemental brief is to provide additional guidance on questions for which the Court has ordered supplemental briefing. While the Court's September 7 Order did not explicitly invite further briefing by amici curiae, supplemental briefing will aid the Court and demonstrate why—as a matter of law and policy—it should reject Plaintiffs' theory of liability, which seeks to impose a duty on Gilead for "*not developing TAF early enough*." (See R. at 132 [ll. 11-12], italics added.)

Among the five questions posed by the Court, Amici Curiae focus specifically on Questions 1(b) and 4.

First, pursuant to Question 1(b), Amici Curiae seek to clarify the proper test for a "defective" drug under *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1056 and illustrate how California's existing products liability standards are clear and sufficient to address the Plaintiffs' theory of liability.

Second, responding to Question 4, Amici Curiae address the core policy dilemmas implicated by Plaintiffs' unprecedented negligence theory—that is, the amorphous duty standard that

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Plaintiffs seek to impose outside the traditional contours of products liability jurisprudence.

This application and the proposed supplemental brief by Amici Curiae have been filed on September 28, 2023—the due date for all the parties' supplemental briefs, per the Court's September 7 Order. (See Cal. Rules of Ct., rule 8.487, subd. (e)(2), (3).)

STATEMENT OF INTEREST

The Chamber of Commerce of the United States of America ("U.S. Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the U.S. Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the U.S. Chamber regularly files amicus briefs in cases, like this one, that raise issues of concern to the nation's business community. Many of the U.S. Chamber's members are companies and professional organizations that seek to enforce their rights in the courts. Indeed, the U.S. Chamber routinely files amicus briefs in cases pending before California courts, including cases involving pharmaceutical and labor and employment matters.

The California Chamber of Commerce ("CalChamber") is a non-profit business association with approximately 14,000 members, both individual and corporate, representing 25% of the state's private sector and virtually every economic interest in the

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state of California. While CalChamber represents several of the largest corporations in California, 70% of its members have 100 or fewer employees. CalChamber acts on behalf of the business community to improve the state's economic and jobs climate by representing business on a broad range of legislative, regulatory and legal issues.

Formed in 2020, the Alliance for Automotive Innovation ("Auto Innovators") is a respected, collective organization representing the voice of the automotive industry. Focused on creating a safe and transformative path for sustainable industry growth, Auto Innovators represents the manufacturers producing nearly 98 percent of cars and light trucks sold in the U.S. The organization is directly involved in regulatory and policy matters affecting the light-duty vehicle market across the country. Members include motor vehicle manufacturers, original equipment suppliers, as well as technology and other automotive-related companies.

The Washington Legal Foundation ("WLF") is a nonprofit, public-interest law firm and policy center with supporters nationwide, including many in California. WLF promotes free enterprise, individual rights, limited government, and the rule of law. It often appears as amicus curiae to oppose novel state-law tort duties that second-guess the safety of federally regulated products. (*See, e.g.*, *Burningham v. Wright Med. Tech., Inc.* (Utah 2019) 448 P.3d 1283; *McNair v. Johnson & Johnson* (W.Va. 2018) 818 S.E.2d 852.) Such suits undermine the very goals of public health and safety that tort law is intended to further. WLF's Legal

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Studies division also regularly publishes articles by outside experts on state-law approaches to product liability. (*See*, *e.g.*, John J. Park, Jr., *Law Rejecting "Innovator Liability" Theory Restores Civil Justice Sanity to Alabama*, WLF Legal Opinion Letter (June 19, 2015).)

Pursuant to California Rules of Court, rules 8.487 subd. (e)(5), and 8.200 subd. (c)(3), the Amici declare that no party or counsel for a party in the pending case authored the proposed supplemental amici brief in whole or in part or made a monetary contribution intended to fund the preparation or submission of this proposed brief. Furthermore, no person or entity other than amici, their members, or their counsel made a monetary contribution intended to fund the preparation or submission of the proposed brief.

Respectfully submitted,

Dated: September 28, 2023 DLA PIPER LLP (US)

By: _____

Justin R. Sarno
Ben C. Fabens-Lassen

Attorneys for Amici Curiae,
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INTRODUCTION

Plaintiffs' negligence cause of action is a misguided effort to evade the existing, clear, and workable framework of California products liability law. Despite Plaintiffs' conflicting representations and dizzying amalgamations of overlapping legal principles, no bright-line rule or articulation of a "duty" is required, because Plaintiffs' novel negligence theory fails as a matter of law.

This lawsuit hinges on the flawed allegation that Gilead should have brought its TAF product to market sooner, because TAF was a safer and "newer" product that could serve as an alternative to TDF—a product Plaintiffs concede is "not defective." In short, Plaintiffs ascribe fault to Gilead for delaying the introduction of an alleged feasible alternative medication. But, under California law, the existence of a feasible alternative design is a relevant *factor* in the risk-benefit calculus to prove a design defect. It cannot, and should not, independently authorize a negligence cause of action.

As a matter of law and policy, Plaintiffs' unprecedented negligence theory is as dangerous as it is unsupported. Were a product manufacturer to be held liable in general negligence for failing to introduce an innovative product to market sooner—a product that the business had no obligation to design, develop, or release in the first place—then California's well-established products liability principles for protecting consumers would be eviscerated. In its place would be an unprecedented, elastic

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standard, authorizing negligence liability to be imposed whenever a business fails to expeditiously release a new product.

This cannot be the path forward. If adopted, such a standard would thwart innovation and deter businesses from introducing new products altogether. The marketplace of innovation would be replaced by a paralyzing fear that any business-related justification for delaying a product's release will be transformed into an unstructured predicate for tort liability.

Accordingly, this Court must reject Plaintiffs' liability theory and grant the relief requested in Gilead's petition.

ARGUMENT

A. The availability of a "safer alternative design" is a *factor* in the risk-benefit test under products liability law, not an independent and discrete theory of negligence.

Question 1(b) of this Court's September 7, 2023 Order asks the parties to state the proper test for a "defective drug" under *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1056. Amici address this question to help demonstrate why Plaintiffs' negligence claim is dangerously wrong headed, and why this Court should reverse the trial court's grant of summary judgment.

Defining the "defectiveness" of a drug under California law requires a holistic analysis of numerous factors. Indeed, "the term defect as utilized in the strict liability context is neither self-defining nor susceptible [of] a single definition applicable in all contexts." (*Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413,

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427.) In an effort to bypass this analysis, Plaintiffs concede that TDF was non-defective, but they concurrently represent that the question of TDF's defectiveness is immaterial. However, as shown below, Plaintiffs are making a products liability claim. *Brown* and its progeny illustrate the reasons why.

Even before *Brown* was decided, the California Supreme Court recognized the unique balancing that courts must undertake to define a product "defect." In *Daly v. General Motors Corp.* (1978) 20 Cal.3d 725, the Court explained that because "finished products must incorporate and balance safety, utility, competitive merit, and practicality under a multitude of intended and foreseeable uses," courts must "'weigh' competing considerations in an overall product design" to decide "whether the deign was 'defective.'" (*Id.* at p. 746.)

In *Brown*, the Court reaffirmed this approach when it contrasted strict liability standards with principles of general negligence. "Strict liability differs from negligence in that it eliminates the necessity for the injured party to prove that the manufacturer of the product which caused injury was negligent." (*Brown*, *supra*, 44 Cal.3d at p. 1056.) Strict liability focuses "not on the conduct of the manufacturer but on the product itself, and holds the manufacturer liable if the product was defective." (*Id.*; see also *Greenman v. Yuba Power Prods., Inc.* (1963) 59 Cal.2d 57, 62.)

Section 402A of the Restatement (Second) of Torts articulated the "strict liability doctrine," which California and "almost all" other states ultimately adopted. (*Brown*, *supra*, 44

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Cal.3d at p. 1056.) Following the publication of section 402A, the California Supreme Court in *Barker* offered some practical guideposts for defining a "design defect." (*Id.* at p. 1057.) Namely, *Barker* identified three types of defects: (1) *manufacturing defects*—where a flaw in the manufacturing process results in a product that differs from the manufacturer's intended result; (2) *design defects*—where products are "perfectly" manufactured but are unsafe because of the absence of a safety device; and (3) *marketing defects*—where a product is dangerous because it lacks adequate warnings or instructions. (*Id.* at p. 1057, citing *Barker*, *supra*, 20 Cal.3d at pp. 428-430.)

In the context of prescription drugs, *Brown* explained the relationship of "comment k" to section 402A. In the Court's words: "[t]he comment provides that the producer of a properly manufactured prescription drug may be held liable for injuries caused by the product *only if* it was not accompanied by a warning of dangers that the manufacturer knew or should have known about." (*Brown*, *supra*, 44 Cal.3d at p. 1058, italics added.) "[T]he comment was intended to and should apply to all prescription drugs." (*Id.* at fn. 11.)

Brown held that a drug manufacturer's liability for a defectively designed drug should not be measured by the standards of strict liability. (*Id.* at p. 1061.) Rather, due to the public interest in the development, availability, and affordability of drugs, comment k supplied the appropriate test for determining responsibility. (*Id.*)

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As technology advanced and product innovations became increasingly more complex, the line between strict liability and negligence became—in some cases—harder to draw. For example, the Court in *Carlin v. Superior Court* recognized that simply because a claim "sounds" in negligence does not mean that it is divorced from strict liability standards. ((1996) 13 Cal.4th 1103, 1112.) "The claim that a particular component 'rings of' or 'sounds in' negligence has not precluded its acceptance in the context of strict liability." (*Id.*) As the Court recognized, "the strict liability doctrine has incorporated some well-settled rules from the law of negligence and has survived judicial challenges asserting that such incorporation violates the fundamental principles of the doctrine." (*Id.*)

Thus, there are two tests for a plaintiff to prove a "design defect" under California law: (1) the consumer-expectation test (set forth in CACI 1203); and (2) the risk-benefit test (set forth in CACI 1204). Only the latter test applies to product-defect claims involving prescription drugs.

The consumer-expectation test is rooted in the Supreme Court's decision in *Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 560, in which the Court held that "[a] manufacturer, distributor, or retailer is liable in tort if a defect in the manufacture or design of its product causes injury while the product is being used in a reasonably foreseeable way." (*Id.*; see CACI 1203.) *Brown* and its progeny have clarified that the consumer-expectation test is "inappropriate to prescription drugs."

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(*Brown*, *supra*, 44 Cal. 3d at p. 1061; see also *Trejo v. Johnson & Johnson* (2017) 13 Cal.App.5th 110 [similar].)

That leaves the risk-benefit test, discussed in *Kim v. Toyota Motor Corp.* (2018) 6 Cal.5th 21, 30, which "requires the plaintiff to first 'demonstrate[] that the product's design proximately caused his injury.' If the plaintiff makes this initial showing, the defendant must then 'establish, in light of the relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design.'" (See CACI 1204.)

Here, Plaintiffs' negligence allegations borrow rhetoric from the risk-benefit test. Plaintiffs argue that Gilead's supposed failure to more rapidly market a feasible alternative medication (TAF) can exist as its own independent basis for negligence. (R. at 132.) In so doing, they attempt to divorce their claim from products liability law by stating that TDF was "not defective." (R. at 132 ["But Plaintiffs' claim is not that the TDF medications are 'negligently designed' or 'defective[] for purposes of establishing liability under a theory of negligence.'"].)

At its core, Plaintiffs' theory of liability is governed by products liability standards. If a feasible alternative drug was unreasonably delayed in favor of TDF, then the jury could consider that factor under the risk-benefit analysis. Indeed, "[w]here liability depends on the proof of a design defect, no practical difference exists between negligence and strict liability; the claims merge." (*Lambert v. Gen. Motors* (1998) 67 Cal.App.4th 1179, 1185.) But allowing a plaintiff to transform one factor into a self-executing claim for relief—as Plaintiffs attempt to do here—would

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undermine the risk-benefit test that governs products liability claims relating to prescription drugs.

In the end, there is no need for a newly-enunciated rule. "Manufacturers are not insurers of their products and are liable in tort only when defects *in their products* cause injury." (*Taylor v. Elliot Turbomachinery Co., Inc.* (2009) 171 Cal.App.4th 564, 576 [emphasis added].) For this reason, the availability of a "safer alternative design" is a *factor* in the risk-benefit test under products liability law, not an independent and discrete theory of negligence. No matter how ardently it is re-articulated or divorced from existing products liability standards, Plaintiffs' negligence claim is nonetheless governed by products liability jurisprudence.

A contrary conclusion would undermine clarity in the law. It would impose a novel, expansive, and amorphous duty on manufacturers to release a maximally safe product even if an *existing product is not defective*—a duty that courts in other jurisdictions have repeatedly rejected. (See *Romero v. International Harvester Co.* (10th Cir. 1992) 979 F.2d 1444, 1451 ["Ms. Romero cites no Colorado case, and our research reveals none, which holds that a manufacturer of a *non-defective* product, under then-current standards, must warn previous purchasers when a new safety device is developed"], citing *Sexton v. Bell Helmets, Inc.*, 926 F.2d 331, 337 (4th Cir. 1991) ["[A] product can only be defective if it is imperfect when measured against a standard existing at the time of sale or against reasonable consumer expectations held at the time of sale"]; *Wallace v. Dorsey Trailers Southeast, Inc.* (8th Cir. 1988) 849 F.2d 341, 344 [applying

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Missouri law, court concluded defendant "was not negligent, as a matter of law, in failing to retrofit the allegedly defective aerial bucket lift"]; *Gates v. Ford Motor Co.* (10th Cir. 1974) 494 F.2d 458, 460 [applying Oklahoma law, this court stated "the rule is well settled that a manufacturer does not have a legal duty to produce a product incorporating only features representing the ultimate in safety.... To recover, appellant necessarily must establish that the tractor was defective when manufactured"]; *Habecker v. Clark Equip. Co.* (M.D.Pa. 1992) 797 F.Supp. 381, 386 [following a Pennsylvania decision holding that "there is no cause of action for a continuing duty to warn purchasers of new developments which may make the product more safe"]; *Butler v. Navistar Int'l Transp. Co.*, No. 89-0064-H, 1991 WL 441735, at *6, 1991 U.S.Dist. LEXIS 16701, at *19-20 (W.D.Va. Oct. 18, 1991) [rejecting plaintiff's argument that defendant had a duty to retrofit, stating "[p]laintiff cites no authority for this position"]; *Moorehead v. Clark Equip. Co.*, No. 86 C 1442, 1987 WL 26158, at *2, 1987 U.S.Dist. LEXIS 11096, at *5 (N.D.Ill. Dec. 2, 1987) [rejecting under Illinois law "the continuing duty of a manufacturer to notify prior purchasers of new safety devices"]; *Caterpillar Tractor Co. v. Ford*, 406 So.2d 854, 857 (Ala. 1981) [holding that plaintiff seeking to impose liability for death resulting from lack of rollover protection structure on tractor must show that the tractor was defective when sold]; *Jackson v. New Jersey Mfrs. Ins. Co.* (1979) 166 N.J.Super. 448, 400 A.2d 81, 89, *cert. denied*, 81 N.J. 330, 407 A.2d 1204 ["There is no duty upon the seller of a machine faultlessly designed and manufactured ... to notify its customers after the time of sale

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of changes in the state of the art concerning the safe operation of such machine and advise them to install any new, updated or improved safeguards developed since the time of sale"]; *Lynch v. McStome and Lincoln Plaza Assocs.* (Pa.Super.Ct.1988) 378 Pa.Super. 430, 548 A.2d 1276, 1281 [rejecting, under Pennsylvania law, duty to retrofit or warn previous purchasers of new design]; *Dion v. Ford Motor Co.* (Tex.Ct.App. 1991) 804 S.W.2d 302, 310 ["Ford did not assume a duty to improve upon the safety of its tractor by replacing an existing rollover protection system with an improved rollover protection system"]; see generally, Victor Schwartz, *The Post-Sale Duty to Warn: Two Unfortunate Forks in the Road to a Reasonable Doctrine*, 58 N.Y.U.L.Rev. 892 (1983).)

The result is clear. Plaintiffs' claim of an unprecedented duty to innovate maximally safe products following a non-defective predecessor is meritless, and the writ petition should be granted.

B. Because products liability law protects consumers for the very acts or omissions alleged in this action, no additional rules or "duty" formulations under general negligence are required.

Because Plaintiffs cannot establish the existence of a duty, their claims against Gilead are foreclosed. But that does not mean that a *new duty* should be recognized. To the contrary, the existing policies that define products liability jurisprudence supply the roadmap. For example, the Court asks at Question 4 what Plaintiffs need to prove about Gilead's knowledge of TAF *relative to TDF* in order to establish that Gilead's duty of care "required it

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to continue development of TAF." (See Order, 9/7/23, at Question No. 4.) The Court then asks if the "expense and uncertainty associated with drug development and approval require clear legal rules establishing when such a duty arises," and if so, what those rules should be. (*Id.*)

Clear tort rules, duties, and liability standards are critical to manufacturers and commerce. (*See In re Petition of Germain* (2d Cir. 2016) 824 F.3d 258, 275 [observing that "courts should strive to adopt clear legal rules"]; *Caster v. Hennessey* (11th Cir. 1984) 727 F.2d 1075, 1077 ["A basic function of the law is to foster certainty in business relationships, not to create uncertainty by establishing ambivalent criteria for the construction of those relationships…"].) Such rules promote certainty and predictability in manufacturing operations, commercial transactions, and investment decisions.

A standard that predicates liability on hypothetical conduct, or on the subjective perception that a company is not innovating fast enough, is unworkable in every meaningful sense. If accepted, Plaintiffs' negligence theory would impede innovation, stifle progress, and undermine the ability of businesses to structure their affairs. Manufacturers must be able to know what the law requires of them, so they can conform their conduct to reasonable standards of compliance to help mitigate risk. If manufacturers are discouraged from innovating new products due to the unpredictable costs that may arise from negligence lawsuits, paralysis in the marketplace will ensue.

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This case highlights these concerns. Plaintiffs' negligence theory circumvents a settled framework that provides predictability to businesses operating in complex and highly regulated marketplaces. The risk of unbridled negligence liability would have deleterious effects. Foremost among them, manufacturers would *decrease investment* in the development of innovative products. This would impede the release of better products, instead penalizing companies for any perceived delay or business-related decisions that affect their marketing strategies. Manufacturers would have a sharply diminished financial incentive to develop—much less release—new products. Fewer products would be developed or improved, which in turn would decrease access to valuable drugs while depriving the public of viable alternatives.

Fortunately, clear legal rules already exist. California's products liability law protects consumers from defective products under a consumer-expectation or risk-benefit calculus. This existing framework strikes the appropriate balance between the efficacy of a current formulation against the feasibility of an alternative safer design. It is then left for the trier of fact to assess whether an original product was defective. Here, Gilead had no duty to develop or release TAF because TDF was not defective. To permit an independent negligence cause of action based on the premise that a company *could have* brought an alternative product to market sooner is to transform *an evaluative factor* in the existing risk-benefit calculus into a stand-alone theory of liability. Nothing in *Brown*, *Barker*, or *Soule* authorizes, let alone

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mandates, such a result. No liability exists when companies choose to innovate new, better, or safer alternatives to already *non-defective* products.

C. If this Court were to permit a negligence cause of action premised on a company's failure to bring an alternative product to market sooner, California's product-liability scheme would be undermined, and innovation would be stifled.

The California Supreme Court has often stated that "duty is not an immutable fact of nature, but only an expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection." (*Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456, 472, citing *Dillon v. Legg* (1968) 68 Cal.2d 728, 734; *Ballard v. Uribe* (1986) 41 Cal.3d 564, 572, fn. 6.)

"When addressing conduct on the part of a defendant that is "deliberative, and ... undertaken to promote a chosen goal, ... [c]hief among the factors which must be considered is the social value of the interest which the actor is seeking to advance." (Prosser & Keeton on Torts (5th ed.1984) § 31, p. 171, italics added, fn. omitted; *Schwartz v. Helms Bakery Limited* (1967) 67 Cal.2d 232, 237, fn. 3; see also *Wright v. Arcade School Dist.* (1964) 230 Cal.App.2d 272, 278; *Raymond v. Paradise Unified School Dist.* (1963) 218 Cal.App.2d 1, 8 [both listing, as the first policy consideration in duty analysis, "[t]he social utility of the activity out of which the injury arises"].)

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Here, even if this Court were to proceed to the *Rowland v. Christian* (1968) 69 Cal.2d 108 analysis for purposes of Question No. 5, public policy compels finding no duty. Nothing about existing products liability standards is ill-suited to address Plaintiffs' claims, especially within the context of adverse policy implications. California's products liability laws exist to *protect consumers* and provide clear rules and limitations on boundless assertions of liability like the one this Court faces here.

The U.S. biopharmaceutical innovation ecosystem benefits patients. By the numbers, the United States is the world's dominant source of innovative medicines, delivering life-saving treatments and even cures for a wide array of diseases and other previously unmet health needs. A December 2022 study by Brussels-based economic research firm Vital Transformation tells the tale: since 2011, U.S. annual investment in biopharmaceutical R&D increased from $80 billion to $201 billion; 223 of 363 FDA approved medicines originated in the United States; and partnerships underpinned by IP licensing nearly tripled from 1,172 to 3,069.[1]

Once a new medicine achieves regulatory approval, continued innovations, such as the development of new dosage forms, formulations, and routes of administration are critical to optimizing the benefit of that medicine to patients. Further

[1] Vital Transformation, "The US Ecosystem for Medicines. How New Drug Innovations Get To Patients," December 5, 2022. Available at https://vitaltransformation.com/2022/12/the-us-ecosystem-for-medicines-how-new-drug-innovations-get-to-patients/

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innovations to adapt the medicine to treat other diseases frequently bring medical benefits to entirely new patient populations. Innovative post-launch advances in manufacturing often increase quality, consistency, and efficiency, and enhance the ability to manufacture at scale. These post-launch innovations require costly additional research and development and sometimes further clinical trials to prove the safety and efficacy of these further inventions.

It is for these important reasons that Plaintiffs' negligence cause of action raises serious policy concerns. Promoting innovation and disclosing ground-breaking new products benefits the public at large. This is especially true with respect to new drugs and pharmaceuticals that are designed to benefit public health and safety—most of which evolve incrementally over time. (Joanna Shepherd, *Deterring Innovation: New York v. Actavis and the Duty to Subsidize Competitors' Market Entry*, 17 Minn. J.L. Sci. & Tech. 663, 703-04 (2016) [citing studies showing that most new drug approvals by the FDA are for "incremental innovations"].) While the threat of tort liability typically creates incentives for firms to improve existing products, in this case the threat of tort liability creates powerful *disincentives* against innovation. The paradigm is effectively inverted, as Plaintiffs' theory of negligence is dangerously predicated on subjective interpretations regarding how, in what form, and how fast, a company should invest in innovation. If Plaintiffs' theory were adopted, manufacturers would be confronted with the impossible task of weighing the risk of incalculable liability against the speed of its research,

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development, and marketing decisions. And numerous studies have found that "actions that reduce brand innovation will have long-term negative effects on consumer health and health care spending." (*Id.* at p. 706 [citing studies].)

If anything, both practice and reality suggest that more patents support innovation and economic growth, patient choice, and the public good. Innovation is not a one-off, siloed process. From delivery efficacy and patient compliance to dosages, mitigation of side effects, extended-release formulations, and entirely new treatments, so-called follow-on innovations deliver invaluable benefits to patients and consumers.[2]

To be sure, these concerns are not limited to pharmaceutical manufacturers. Numerous industries would be harmed by the imposition of tort liability on companies that fail to develop and successfully commercialize improved versions of their existing products. Consider the example of an automobile manufacturer who, year-after-year, challenges its own exemplary safety record by introducing new models of existing vehicles into the marketplace with innovative design features. It is under no legal or regulatory obligation to do so. And yet, despite the company's proven track record of introducing new and different products into the marketplace, a plaintiff could nonetheless sue the

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[2] Professor Kristen Osenga, *Are "Patent Thickets" To Blame For High Drug Prices*, Richmond-Times Dispatch, Nov. 20, 2022, note 3 ("It's no secret that drug manufacturers regularly continue to innovate drugs long after they're originally proven safe and effective. There are countless legitimate reasons to do so. Sometimes, post-market research suggests that a particular dosage or delivery method could be superior to the original.").

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manufacturer in negligence by claiming that the company "should have" released its new product "sooner"—even though the current model is safe for use, approved by all applicable regulatory authorities, and continues to be widely purchased by interested consumers.

There is no sound basis for the Court to approve an expansive negligence theory that permits plaintiffs to arbitrarily second-guess the judgment of corporate decision-makers. Among the numerous problems that it would pose, it would undermine the strong presumption in California that corporate board decisions are "based on sound business judgment." (*Berg & Berg Enters., LLC v. Boyle* (2009) 178 Cal.App.4th 1020, 1045; see *Hill v. State Farm Mut. Automobile Ins. Co.* (2008) 166 Cal.App.4th 1438, 1449 [holding that business decisions are not disturbed absent "fraud, oppression, illegality, or the like"].) Neither courts nor juries have suitable expertise in the area of pharmaceutical manufacturing, innovation, and commercialization to "scrutinize … decisions made by business persons who are likely more competent in the particular business matters at issue." (*Hill*, *supra*, 166 Cal.App.4th 1449; see *Lamden v. La Jolla Shores Clubdominium Homeowners Assn.* (1999) 21 Cal.4th 249, 259 ["the hindsight of the judicial process is an imperfect device for evaluating business decisions."].)

In the end, subjecting manufacturers to negligence liability in these circumstances would "chill innovation and give inventors pause in deciding whether to share their creations with the public." (*In re Cipro Cases I & II* (2015) 61 Cal.4th 116, 139.) No

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conceivable good is achieved by such an outcome. Indeed, as the California Supreme Court has recognized, "discourag[ing] the development and availability of life-sustaining and lifesaving drugs" has the effect of "defeating a strong public interest." (*Carlin*, *supra*, at pp. 1126-1127.) That is precisely the consequence that would arise here. As *Brown* highlighted, "[p]ublic policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction." (*Brown*, *supra*, 44 Cal.3d at pp. 1063-65.) In the end, innovation is stifled, not fostered, by "commandeering brand manufacturers' operations" via an overbroad application of negligence liability. (*Id.*; see also *Shepherd*, *supra*, at pp. 704-05 (2016).)

This Court should follow governing precedent, reject Plaintiffs' amorphous theory of negligence, grant the petition, and reverse the trial court's entry of summary judgment.

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CONCLUSION

For the foregoing reasons, this Court should grant the relief requested in Gilead's petition.

Respectfully submitted,

Dated: September 28, 2023 DLA PIPER LLP (US)

By: _____

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WORD COUNT DECLARATION

(Cal. Rules of Ct., rule 8.204(b), (c))

The attached Supplemental Amici Brief complies with the type limitations of the California Rules of Court, Rules 8.204(b), (c), and is mono-spaced as required. Furthermore, the brief complies with the imposed word count limitations imposed by this Court in its September 7, 2023 Order re: Supplemental Briefing.

This brief contains 13-point font, in Century Schoolbook typeface, and contains 4,041 words, not including the Table of Contents and Authorities, the caption page, signature blocks, and this Word Count Declaration.

Dated: September 28, 2023 DLA PIPER LLP (US)

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PROOF OF SERVICE

I am a citizen of the United States, over 18 years of age, and not a party to the within action. I am employed by the law firm of DLA Piper LLP (US). My business address is 2000 Avenue of the Stars, Suite 400, Los Angeles, CA 90067.

On September 28, 2023, I served the within **APPLICATION OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, CALIFORNIA CHAMBER OF COMMERCE, THE ALLIANCE FOR AUTOMOTIVE INNOVATION, AND WASHINGTON LEGAL FOUNDATION FOR LEAVE TO FILE AMICI CURIAE BRIEF IN RESPONSE TO THE COURT'S SEPTEMBER 7, 2023 ORDER RE: SUPPLEMENTAL BRIEFING AND IN SUPPORT OF PETITIONER GILEAD SCIENCES, INC.; PROPOSED SUPPLEMENTAL AMICI CURIAE BRIEF** on the parties interested in this proceeding, as addressed below, by causing true copies thereof to be distributed as follows:

All Counsel—As listed on TrueFiling Servicing Notifications List (Via TrueFile)

I am familiar with my firm's practice for collecting and processing correspondence for mailing and/or electronic service. Under that practice, any copies placed in the mail would be deposited with the service carrier that day in the ordinary course of business.

I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed September 28, 2023 at Los Angeles, California.

/s/ Alicia Prado

Alicia Prado

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