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July 7, 2022

Court of Appeal
First Appellate District, Division 4
350 McAllister Street
San Francisco, California 94102-7421

RE: *Gilead Sciences, Inc. v. Superior Court*
First App. Dist. Case No. – A165558
JCCP No. 5043
S.F. Superior Case No. CJC-19-005043
Hon. Andrew Y.S. Cheng, (415) 551-3830

Dear Honorable Justices of the First Appellate District, Division 4:

We write on behalf of amici curiae, the California Chamber of Commerce and the Chamber of Commerce of the United States of America, urging this Court to grant the petition for writ of mandate or other appropriate relief filed by Gilead Sciences, Inc. ("Gilead") on July 6, 2022. We respectfully ask for permission to file this letter on behalf of amici.

The writ petition of July 6, 2022, filed by Gilead asks this Court to correct the Superior Court's adoption of a novel theory of liability under California negligence law that a manufacturer of a *non-defective product* nonetheless has the legal duty to research and develop new products that may offer a better "safety profile," even at the expense of efficacy, cost, or other factors. The petition correctly argues that no such duty exists in California, and the trial court erred in denying summary judgment. Amici hereby submit the present letter, arguing that imposition of such a duty contravenes

negligence law in California and would upend mass tort litigation throughout the State.

Authority for permitting this amici letter

California Rules of Court, rule 8.487 expressly permits the filing of amicus briefs after an appellate court issues an alternative writ or order to show cause. (Cal. Rules of Court, rule 8.487(e)(1).) However, the Advisory Committee comment to California Rules of Court, rule 8.487 makes clear that amicus letters are also permissible before a court issues an alternative writ or order to show cause.

Specifically, the Advisory Committee comment states:

> Subdivisions (d) and (e). *These provisions do not alter the court's authority to request or permit the filing of amicus briefs or amicus letters in writ proceedings in circumstances not covered by these subdivisions, such as before the court has determined whether to issue an alternative writ or order to show cause* or when it notifies the parties that it is considering issuing a peremptory writ in the first instance. (Emphasis added.)

Accordingly, California Courts of Appeal have considered the filing of amicus letters in connection with a writ petition in deciding whether to issue an order to show cause. (*Regents of University of California v. Superior Court* (2013) 220 Cal.App.4th 549, 557-558 [indicating that amicus letters were filed in support of a writ petition and that "based on the amicus curiae submissions we have received," the matter "appears to be of widespread interest" such that writ review was appropriate]; *see Los Angeles County Board of Supervisors v. Superior Court of Los Angeles County* (2015) 235 Cal.App.4th 114 [to wit, "The Association of Southern California Defense Counsel, as amicus curiae, filed a[n] [amicus] letter in support of issuance of the writ"], rev'd. on other grounds in (2016) 2 Cal.5th 282.)

We ask the Court to respectfully consider this amici letter in support of granting Gilead's petition for writ of mandate.

Interest of amici curiae

The Chamber of Commerce of the United States of America ("US 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—including throughout the State of California. An important function of the US Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and federal and state courts. To that end, the US Chamber regularly files amicus curiae briefs in cases, like this one, that raise issues of concern to the business community. Many of the US Chamber's members are companies and professional organizations which seek to enforce their rights in the courts. Indeed, the US Chamber routinely files amicus curiae briefs in cases pending before California courts, including cases involving pharmaceutical and labor and employment matters.

The California Chamber of Commerce ("CalChamber") has more than 13,000 members, both individual and corporate, representing virtually every economic interest in the State. While CalChamber represents several of the largest corporations in California, seventy-five percent of its members have 100 or fewer employees. CalChamber acts on behalf of the business community to improve the State's economic and employment climate by representing business on a broad range of legislative, regulatory, and legal issues.

No party or counsel for a party in the pending case authored the proposed amici curiae letter in whole or in part or made a monetary contribution intended to fund the preparation or submission of this proposed letter. No person or entity other than the amici, its members, or its counsel made a monetary contribution intended to fund the preparation or submission of the proposed letter.

Argument

I. California negligence law requires a defect, not to maximize safety at all costs.

Plaintiffs' theory of negligence erroneously dispenses with the requirement that the product be *defective*, which is an essential element of California negligence law. (*See, e.g.*, *Brady v. Calsol, Inc.* (2015) 241 Cal.App.4th 1212, 1218 ["A products liability case may rest on either a theory of strict liability or negligence.... In asserting a claim for negligence, the **plaintiff must prove the defect in the product** was due to the defendant's negligence," emphasis added].) The trial court's ruling acknowledged that Plaintiffs did not allege that TDF drugs were defective, that Gilead should

have stopped selling TDF, that the risks of TDF outweighed the benefits, or, that the formulation of TDF should have been changed in any way. (See MSJ Ruling, 6/14/22, at p. 11:19-25.)

California law does not impose a free-floating requirement that safety be maximized notwithstanding the tradeoffs for other benefits and costs. That requirement is captured in the standard formulation of negligence law that a person bears only "a duty to use *ordinary* care and 'is liable for injuries caused by his failure to exercise *reasonable* care in the circumstances.'" (*Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456, 472; *see also Southern California Gas Leak Cases* (2019) 7 Cal.5th 391, 397-398, quoting *Centinela Freeman Emergency Medical Associates v. Health Net of California, Inc.* (2016) 1 Cal.5th 994, 1012; *Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370, 397.) The reasonable care standard requires balancing the "likelihood and severity of potential harm from the product against the burden of taking safety measures to reduce or avoid the harm." See Judicial Council of California Civil Jury Instructions, CACI No. 1221 (Negligence – Basic Standard of Care) (2022). California courts, therefore, "have consistently held that manufacturers are not insurers of their products; they are liable in tort only when "defects" in their products cause injury. (*Soule v. Gen. Motors Corp.* (1994) 8 Cal.4th 548, 568.)

Plaintiffs' formulation would singularly focus on safety to the exclusion of other considerations including costs, efficacy, and speed of development. These factors are rightfully crucial to considering whether there was a design defect in the development of not only pharmaceutical, but also other consumer products. The perverse incentives that would result are obvious and are the reason courts nationwide reject a safety-only standard for negligent product design. As the Comments to the Restatement of Torts (Third) suggests, "[s]ociety does not benefit from products that are excessively safe—for example, automobiles designed with maximum speeds of 20 miles per hour—any more than it benefits from products that are too risky." (Restatement (Third) of Torts: Prod. Liab. § 2 (1998).)

Rather, when it comes to product design, and particularly pharmaceuticals' design, manufacturers must frequently balance and trade-off safety with efficacy, costs, and feasibility. The flexibility to make these choices is essential to ensuring the availability and development of innovative and existing treatments. (*See Pannu v. Land Rover North America, Inc.* (2011) 191 Cal.App.4th 1298, 1311-1312 [observing in the strict-liability context "when the ultimate issue of design defect calls for a careful assessment of feasibility,

practicality, risk, and benefit, the case should not be resolved simply on the basis of ordinary consumer expectations [because] '... in many instances it is simply impossible to eliminate the balancing or weighing of competing considerations in determining whether a product is defectively designed or not"] (citation omitted); *see also Barker v. Lull Eng'g Co.,* 20 Cal.3d 413, 418 (1978) [recognizing the "relative complexity of design decisions and the trade-offs that are frequently required in the adoption of alternative design"].)

For these reasons, courts in other jurisdictions have recognized the threat of a safety-maximizing standard and have resoundingly rejected it. For example, in *Brown v. Sears, Roebuck Co.*, the Tenth Circuit affirmed dismissal of a product liability action because the Utah Supreme Court "refused to recognize a duty 'to refrain from marketing a non-defective product when a safer model is available.'" (*Brown v. Sears, Roebuck Co.* (10th Cir. 2003) 328 F.3d 1274, 1283, citing *Slisze v. Stanley-Bostitch* (Utah 1999) 979 P.2d 317, 320 ["We have never, *nor has any other jurisdiction*, recognized a duty on the part of a manufacturer to refrain from marketing a non-defective product when a safer model is available, or a duty to inform the consumer of the availability of the safer model"].)

Several other courts have reached the same conclusion. (See, e.g., *Batts v. Tow-Motor Forklift Co.* (5th Cir. 1992) 978 F.2d 1386, 1395 [noting Mississippi law does not impose a "duty to provide a perfectly safe product"]; *Veliz v. Rental Service Corp. USA, Inc.* (M.D. Fla. 2003) 313 F.Supp.2d 1317, 1330-31 ["The Defendant is, as a matter of law, under no duty to produce a fail-safe product" because "[t]o hold otherwise would require the Defendant to assume the role of an insurer; a manufacturer is not liable for all accidents involving its product"]; *Smith v. 2328 Univ. Ave. Corp.* (N.Y. App. Div. 2008) 52 A.D.3d 216, 217 [holding New York law "does not impose a duty upon a manufacturer to refrain from the lawful distribution of a non-defective product"].)

Thus, the theory of liability advanced by Plaintiffs would displace well-settled California negligence law that requires proof that the product is defective, not merely that the manufacturer failed to develop the "safest" alternative product. It would, moreover, stifle innovation, consumer and physician choices by failing to balance safety against a range of other reasonable design considerations.

II. Plaintiffs' negligence theory collides with Evidence Code section 1151's exclusion of evidence regarding subsequent remedial measures.

In this case, Plaintiffs argued Gilead is liable solely because it "should have more quickly developed and obtained [FDA] approval for TAF," which Plaintiffs contend would have had fewer side effects for certain individuals. (See MSJ Ruling, 6/14/22, at 6.) This theory—based on the delayed distribution of an allegedly safer alternative—conflicts with Evidence Code § 1151, which excludes evidence of subsequent remedial measures when that evidence is offered to prove *negligence*.[1] (*Ault v. International Harvester Co.* (1974) 13 Cal.3d 113, 118.)

The purpose of section 1151 is to encourage individuals, companies, and other entities to take remedial measures to prevent injuries. If the trial court's decision is left in place, product manufacturers may decline to pursue innovative improvements that may later be used against them. Here, Plaintiffs concede that TDF is not defective. Their only evidence of negligence is Gilead's subsequent development of another, "safer" product in TAF. As such, Plaintiffs' unprecedented negligence theory defeats both Section 1151 and the very policy that statute is intended to create.

* * *

The trial court's decision below misapplies California law by failing to require evidence of a product defect to establish a negligence claim. That rule exists for sound policy reasons: to promote innovation and diversity of reasonable products, to avoid casting manufacturers in the role of insurer, and to strike a reasonable balance between safety and other important product features. The petition for a writ of mandate should accordingly be granted and the decision below reversed.

[1] The Rule provides, in pertinent part: "When, after the occurrence of an event, remedial or precautionary measures are taken, which, if taken previously, would have tended to make the event less likely to occur, evidence of such subsequent measures is inadmissible to prove negligence or culpable conduct in connection with the event." (Evid. Code, § 1151.)

Respectfully submitted,

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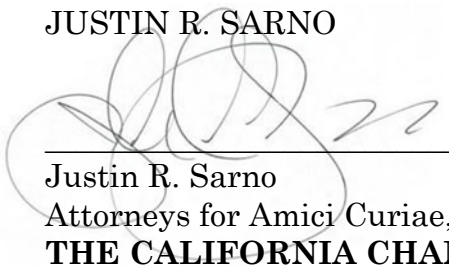

Justin R. Sarno
Attorneys for Amici Curiae,
THE CALIFORNIA CHAMBER OF COMMERCE, THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA

cc: See attached Proof of Service

PROOF OF SERVICE

***Gilead Sciences, Inc. v. Superior Court* | Case No. A165558**

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 550 South Hope Street, Suite 2400, Los Angeles, CA 90071.

On July 7, 2022, I served the within **AMICI CURIAE LETTER BY THE CALIFORNIA CHAMBER OF COMMERCE AND THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA IN SUPPORT OF PETITION FOR WRIT OF MANDATE** on the parties interested in this proceeding, as addressed below, by causing true copies thereof to be distributed as follows:

SEE ATTACHED SERVICE LIST

BY MAIL: I enclosed the document(s) in a sealed envelope or package addressed to the persons at the addresses listed in the Service List and placed the envelope for collection and mailing, following our ordinary business practices. I am readily familiar with DLA PIPER LLP's practice for collecting and processing correspondence for mailing. On the same day that correspondence is placed for collection and mailing, it is deposited in the ordinary course of business with the United States Postal Service, in a sealed envelope with postage fully prepaid.

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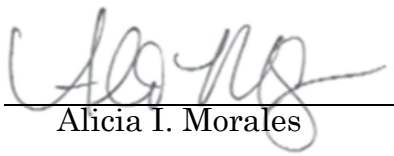
I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed July 7, 2022, at Los Angeles, California.



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