No. S233898

IN THE
SUPREME COURT OF CALIFORNIA

T.H., A MINOR, ET AL.,
Plaintiffs and Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant and Respondent.

Review of a Decision of the California Court of Appeal,
Fourth Appellate District, Division One, No. D067839
Reversing a Judgment of the Superior Court of San Diego County,
Super. Ct. No. 37-2013-00070440-CU-MM-CTL, Hon. Joan M. Lewis

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Application by the Chamber of Commerce of the United States of America For Leave to File A Brief As Amicus Curiae in Support of Respondent

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APPLICATION OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA FOR LEAVE TO FILE A BRIEF AS AMICUS CURIAE IN SUPPORT OF RESPONDENT

To the Honorable Tani Cantil-Sakauye, Chief Justice:

The Chamber of Commerce of the United States of America (Chamber) respectfully moves for leave to file a brief as amicus curiae in this matter in support of respondent.

THE AMICUS CURIAE

The Chamber of Commerce of the United States of America is the largest organization of businesses in the world. It represents 300,000 direct members and represents the interests of more than 3 million companies and professional organizations of all sizes, in every industry, and across all regions of the country.

One of the Chamber's most important responsibilities is representing its members before the courts, legislatures, and executive branches of the States and the federal government. The Chamber regularly files briefs as amicus curiae in litigation that touches on issues of vital concern to the Nation's business community. In fulfilling this role, the Chamber has appeared many times before this Court and the Courts of Appeal.

INTEREST OF AMICUS CURIAE

The Chamber seeks permission to file this brief to assist the Court in understanding the perspective of the business community on the proper standard for imposing tort liability for harm arising from a

product. This proceeding may have a widespread, serious impact on product developers in all fields that have until now relied on their understanding of long-settled principles of tort liability. As the Nation's leading business organization, the Chamber is uniquely positioned to explain the prevailing rule nationwide for imposing liability on a manufacturer only for harm traceable to the manufacturer's own product, and to address the significant policy consequences that might arise from expanding that rule by holding a manufacturer responsible for harms inflicted by its competitors' products.

CONCLUSION

The application for leave to file the attached brief as amicus curiae should be granted.

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DECEMBER 7, 2016

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Brief of the Chamber of Commerce of the United States of America As Amicus Curiae in Support of Respondent

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CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

Pursuant to California Rule of Court 8.208, the following brief is filed by the Chamber of Commerce of the United States of America, a non-profit organization and not a party to this action. The Chamber of Commerce of the United States of America and its counsel certify that it knows of no entity or person that must be listed under Rule 8.208.

CALIFORNIA RULE OF COURT 8.200(c)(3) STATEMENT

Counsel for the Chamber of Commerce of the United States of America certifies that this brief was not written in whole or part by counsel for any party, and no person or entity other than the Chamber of Commerce of the United States of America or its counsel has made a monetary contribution to the preparation or submission of this brief.

S/ Kannon K. Shanmugam
KANNON K. SHANMUGAM

DECEMBER 7, 2016

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INTRODUCTION

It is a fundamental and well-settled principle of tort law, both in California and across the Nation, that liability for harm caused by products is limited to the persons who actually made or sold the injurious products. That principle applies regardless of the theory of liability upon which a plaintiff proceeds. A manufacturer thus has no duty to warn about products made and sold by a competitor, and it cannot be held liable for injuries caused by its competitor's products when the manufacturer has made no representations about those products. Similarly, a former manufacturer—which at one time made a product but no longer does so—cannot be held liable for injuries caused by products made by another. In each instance, the manufacturer neither controls the manufacture of the product that caused the injury nor has a duty (or, in many instances, even the ability) to warn consumers about the product.

That longstanding principle of tort liability applies with equal force in the pharmaceutical industry, as courts around the country have confirmed. More than a hundred state and federal courts to have considered the questions presented here have concluded that pharmaceutical manufacturers, like all other manufacturers, may be held liable only for harm caused by their own products. There is no reason to carve out an exception for the pharmaceutical industry and send California

down the path toward eroding basic tort doctrines and disturbing settled expectations about the scope of tort liability.

Creating an exception to ordinarily applicable tort principles in the pharmaceutical context would lead to undesirable public-policy consequences. The cost of innovation would inevitably increase, and investment in developing and marketing innovative products would inevitably decrease—harming the economy and, uniquely in this field, public health. The Court should not tamper with prevailing tort principles and risk such profound problems for industrial and pharmaceutical innovation.

ARGUMENT

I. FUNDAMENTAL PRINCIPLES OF TORT LAW PRECLUDE THE IMPOSITION OF LIABILITY ON A FORMER MANUFACTURER FOR HARM CAUSED BY PRODUCTS MANUFACTURED BY ANOTHER

The American business community organizes its activities across the country in reliance on certain universally applicable rules of tort law. One of those principles is the venerable principle that a company can be held liable only for harms caused by products it actually made or sold. That principle, and others like it, provide a backstop on which manufacturers and other businesses depend. No matter the theory of liability, in any jurisdiction, under any set of facts, liability does not exist unless some instrumentality connects a product, act, omission, or

representation to a particular injury. No such link exists when a plaintiff is injured by a product the defendant manufacturer did not make and about which it has not made any representations. And that goes double when a manufacturer has left the field and has turned over responsibility for manufacturing and warning about the product to another entity.

As this Court has explained, "as a general rule, the imposition of liability depends upon a showing by the plaintiff that his or her injuries were caused by the act of the defendant or by an instrumentality under the defendant's control." *Sindell* v. *Abbott Laboratories*, 26 Cal. 3d 588, 597 (1980) (citations omitted). That rule, moreover, "applies whether the injury resulted from an accidental event or from the use of a defective product." *Id* at 597-598. "[G]eneral tort principles" do not "impose liability with respect to a defendant that did not sell, distribute, manufacture, or otherwise have contact with the allegedly harmful product." *Schrock* v. *Wyeth, Inc.*, 727 F.3d 1273, 1284 (10th Cir. 2013). Absent the link of a common "instrumentality" leading from the defendant to the plaintiff, defendants would pay for harms they did not cause, breaking the essential connection that justifies imposing liability in the first place.[1]

[1] This Court's recent decision in *Kesner* v. *Superior Court of Alameda County*, No. S219534, 2016 WL 7010174 (Cal. Dec. 1, 2016), follows the same rule. There, this Court held that employers have a duty

The foregoing rule holds no matter the theory of liability: whether a plaintiff frames the claim in terms of fraud, strict liability, or something in between, tort law always requires a link between the plaintiff's harm and the defendant's act or statement. As this Court noted only a few months ago, the Third Restatement of Torts puts the question of failure-to-warn liability in straightforward terms: "the overarching inquiry" for failure-to-warn liability, regardless of the "doctrinal categor[y]" the plaintiff pleads, is "whether 'foreseeable risks of harm posed by *the product* could have been reduced or avoided' by warnings and the absence of a warning renders *the product* unsafe." *Webb* v. *Special Electric Co.*, 63 Cal. 4th 167, 181 n.6 (2016) (emphasis added) (quoting Restatement (Third) of Torts: Products Liability § 2(b) (1998)).

This requirement of an instrumentality, accepted in case after case throughout the country, applies with full force in California. *See Sindell*, 26 Cal. 3d at 597-598. Contrary to plaintiffs' suggestion (Br. 23-26, 49-50), Section 311 of the Second Restatement of Torts does not

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to prevent harm when their employees "act as vectors carrying asbestos from the premises to household members." Slip op. 2; *see also id.* at 9 (observing that "it was foreseeable that people who work with or around asbestos may carry asbestos fibers home with them"). In other words, this Court imposed liability precisely because the plaintiffs' injuries were caused by "asbestos fibers that [the defendants] used on [their] property"—an instrumentality linking the defendants' alleged negligence with the plaintiffs' harm. *Id.* at 30.

do away with the fundamental requirement of an "instrumentality" linking the plaintiff and the defendant. To the contrary, this Court has applied Section 311 to hold parties liable precisely because their statements were *about* the instrument that caused the injury at issue—and reliance on those representations put the injured party in harm's way.

For example, in both *Garcia* v. *Superior Court*, 50 Cal. 3d 728, 736-737 (1990), and *Randi W.* v. *Muroc Joint Unified School District*, 14 Cal. 4th 1066, 1077-1078 (1997), the defendants had made representations about the future conduct of specific individuals, and those same individuals later injured others. Those individuals—the subject of the representations at issue in each case—provided the very "instrumentality" required under the general principles of tort law to link the alleged wrongdoers' misrepresentations to the plaintiffs' harm. *See Garcia*, 50 Cal. 3d at 736. And the alleged wrongdoers could fairly be held liable for the dangers posed by their statements, because they made representations *about* the individuals who caused the injuries. The reasonable reliance of others on those representations effectively aimed dangerous individuals at the ultimate victims and led directly to those victims' eventual harm. *See Randi W.*, 14 Cal. 4th at 1078.[2]

[2] Similarly, in *Hanberry* v. *Hearst Corp.*, 276 Cal. App. 2d 680 (1969), the plaintiff was injured by a product whose quality the defendant had certified. *See id.* at 685.

In this case, plaintiffs attempt to vault over that fundamental principle of tort law by layering two unsupportable propositions on top of each other: *first*, that a former manufacturer can be liable for injuries caused by products it no longer makes but has divested to another entity, and *second*, that the former manufacturer can be liable for injuries caused not even by its divested product but by a product made by another. Neither proposition finds any support in the law. A manufacturer should not face liability for harm caused by a product it did not make—whether that product is one it formerly made but no longer makes, or a version of its product that was actually made by a competitor.

To begin with, even when a manufacturer continues to make its own innovative product, it should only face liability when that product caused a plaintiff's harm. Where, as here, the plaintiff was injured by a product made by a competitor, no common instrumentality exists, and the resulting gap precludes liability. For the same reason, only the manufacturer of the product causing injury should face the possibility of failure-to-warn liability based on inadequate or misleading warnings about the product. The innovator manufacturer never made a statement *about* "the product" that injured the plaintiff. Only the actual manufacturer's knowledge of risk and actions to remediate it provide a basis for misrepresentation liability; the innovator manufacturer's statements, made about a product the plaintiff never used, cannot. *See*

Small v. *Fritz Companies*, 30 Cal. 4th 167, 173-174 (2003); Restatement (Second) of Torts § 311(1) (1965); *cf. Kesner* v. *Superior Court of Alameda County*, No. S219534, 2016 WL 7010174 (Cal. Dec. 1, 2016), slip op. 17 (noting that this Court's "duty analysis looks to the time when the duty was assertedly owed"); *Brown* v. *Superior Court*, 44 Cal. 3d 1049, 1060 n.8 (1988) (agreeing with the proposition that "a manufacturer's knowledge should be measured *at the time a drug is distributed*" (emphasis added)).

The gap between plaintiff and defendant in a case such as this one, brought against a manufacturer that had entirely left the market by the time the plaintiff was injured, is even larger. Here, the innovator manufacturer no longer even had control over the original product at the time of the injury. And, attenuating liability even further, the plaintiff was not injured by the original product, now made and sold by another, but instead was injured by an alternative version made and sold by a competitor. No even arguable instrumentality linked the innovator manufacturer's acts and statements with the plaintiff's injury. It would "stretch . . . foreseeability" far beyond that concept's capacity if a manufacturer faced liability for harm even after another company has acquired control over, and responsibility for, the original product whose competing alternative caused the plaintiff's injuries. *Foster* v. *American Home Products Corp.*, 29 F.3d 165, 171 (4th Cir. 1994).

The same reasoning applies when a plaintiff seeks to hold the original, divested manufacturer liable on a failure-to-warn theory of liability. The warnings issued by a previous manufacturer provide no basis for failure-to-warn liability after that manufacturer has sold the right to make, and profit from, that product. At the point of divestiture, the obligation to issue adequate warnings—and liability for inadequate ones—falls on the product's current manufacturer, "ensur[ing] that those 'best situated' to prevent such injuries are incentivized to do so." *Kesner*, slip op. 21 (quoting *Escola* v. *Coca Cola Bottling Co.*, 24 Cal. 2d 453, 462 (1944) (Traynor, J., concurring)). Nor could a plaintiff plausibly claim to have reasonably relied on any past statements of a previous manufacturer when the current manufacturer continued to produce the product and to make representations about its features and safety. *See Small*, 30 Cal. 4th at 173-174; *Brown*, 44 Cal. 3d at 1060 n.8; Restatement (Second) of Torts § 311(1). The original manufacturer's warnings were about its product, not about the product produced by the new manufacturer after divestiture—and certainly not about that product's competing alternatives.

Courts nationwide have agreed that a former, divested manufacturer—regardless of industry—should not be liable for injuries caused by its former product (or competing versions thereof), on the ground that the divested manufacturer lacked the power to make changes to the product or its warnings after divestiture. *See*, *e.g.*, *In re Darvocet,*

Darvon & Propoxyphene Products Liability Litigation, 756 F.3d 917, 940 (6th Cir. 2014); *Lyman* v. *Pfizer, Inc.*, Civ. No. 09-262, 2012 WL 2970627, at *16 (D. Vt. July 20, 2012); *Christian* v. *Minnesota Mining & Manufacturing Co.*, 126 F. Supp. 2d 951, 957-959 (D. Md. 2001); *McConkey* v. *McGhan Medical Corp.*, 144 F. Supp. 2d 958, 963-964 (E.D. Tenn. 2000).

In short, it is immaterial whether a plaintiff, injured by a product, asserts a claim arising in fraud, negligence, or strict liability. If the defendant manufacturer did not produce that product or make representations about it, then it cannot be liable. Nor does the outcome change if the plaintiff argues that he or she was harmed by the defendant's statements about its own product (a product the plaintiff never used), as opposed to statements about the product that actually inflicted the plaintiff's injury. Under fundamental rules that govern tort disputes everywhere—rules that California law incorporates and applies—only the producer or seller of a product, or the one who makes representations about it, should be held responsible for harm that product inflicts.

II. THERE IS NO VALID JUSTIFICATION TO CREATE AN EXCEPTION TO FUNDAMENTAL PRINCIPLES OF TORT LAW IN THE CONTEXT OF THE PHARMACEUTICAL INDUSTRY

The foregoing basic principles of tort law apply across all industries, and there is no reason to carve out an exception to those principles

solely for pharmaceutical manufacturers. Courts across the Nation have overwhelmingly held that pharmaceutical manufacturers are not liable for injuries caused by their competitors' products. In the absence of an instrumentality linking a defendant's product or statements to the plaintiff's injuries, those courts—including every federal court of appeals to consider the question and state courts in more than a dozen jurisdictions—have concluded that such a defendant cannot be considered to have caused the plaintiff's injuries or to have a duty to warn against them.

Contrary to plaintiffs' contention (Br. 36), there is no "unique twist" to this case or any of the other cases presenting the same question that have been decided over the last two decades. Instead, this case requires nothing more than a simple application of the well-established principles that govern every tort case. Under those principles, the answer is clear: a manufacturer may be called to account only for the harms its own products inflict, regardless of the theory of liability on which the plaintiff's claim is based.

A. By way of background, a pharmaceutical manufacturer seeking regulatory approval from the Food and Drug Administration (FDA) for a new drug must submit a new drug application (NDA), showing that the drug is safe for use, effective for its indications, and that the proposed label accurately and sufficiently describes the risks of its use. *See* 21 U.S.C. § 355(b)(1), (d). Once granted, an NDA brings

with it certain responsibilities, including the obligation to submit annual reports demonstrating the safety, effectiveness, and appropriate labeling of approved drugs. *See* 21 C.F.R. §§ 314.80, 314.81. Pharmaceutical manufacturers that hold NDAs may also submit supplemental applications to change the label and accompanying warnings of a drug; they are required to do so if they learn of a risk not already adequately identified. *See* 21 C.F.R. §§ 314.70, 314.71.

A pharmaceutical manufacturer may sell an NDA to another company, transferring ownership of the right to make the drug as well as the attendant regulatory obligations. *See* 21 C.F.R. § 314.72. Thereafter, the new NDA holder has exclusive authority to revise the label and submit supplemental applications regarding label changes, and it has the exclusive responsibility to monitor the market and submit annual reports and supplemental applications to FDA. *See* 21 C.F.R. §§ 314.70, 314.71.

Congress has also created a streamlined process for approval of generic versions of brand-name drugs once the patent exclusivity accorded to new pharmaceutical products expires. *See* Drug Price Competition and Patent Term Restoration (Hatch-Waxman) Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j)). A generic pharmaceutical manufacturer can submit an abbreviated new drug application (ANDA), which requires only that the manufacturer show its product is "bioequivalent" to the brand-name drug.

See 21 U.S.C. § 355(j)(2)(A)(iv). That allows the generic manufacturer to rely on the safety and efficacy studies conducted by the original brand-name manufacturer at its own expense. *See id.* After ANDA approval, a generic manufacturer is required to maintain a label and accompanying warnings for its product that are "the same" as those used for the brand-name drug with which the generic version competes. *PLIVA, Inc.* v. *Mensing* (2011), 564 U.S. 604, 613 (citing 21 U.S.C. § 355(j)(2)(A)(v), 355(j)(4)(G), and 21 C.F.R. §§ 314.94(a)(8), 314.127 (a)(7)).

While generic pharmaceutical manufacturers are not authorized independently to update the labels for their products, *Mensing*, 564 U.S. at 613, they otherwise have similar responsibilities to those of NDA holders: they are also required to monitor the market and to submit annual reports and supplemental applications (when appropriate) to FDA. *See* 21 C.F.R. §§ 314.70, 314.71, 314.80, 314.81, 314.97, 314.98; Abbreviated New Drug Application Regulations, 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992).

B. Since 1996, at least 134 state and federal decisions have concluded that pharmaceutical manufacturers cannot be held liable for products made and sold by others. Those decisions rely on three basic lines of reasoning. *First*, general principles of tort law impose liability on manufacturers only for injuries caused by their own products, and do not impose a duty on manufacturers to warn consumers about the

risks associated with other manufacturers' products. *Second*, the labels and warnings issued by innovator manufacturers are representations only about the safety of their own products, not about the safety of their competitors' products. *Third*, policy considerations, especially the need to promote innovation, strongly counsel against creating a special rule for pharmaceutical manufacturers for injuries resulting from their competitors' products.

The first federal court of appeals to confront this question was the Fourth Circuit, in a 1994 case on whether a plaintiff injured by taking the generic version of a drug could recover for his injuries from the manufacturer of the drug's brand-name analogue. *See Foster*, 29 F.3d at 168-169. The Fourth Circuit concluded that the brand-name manufacturer could not be held liable. *See id.* at 169. The court reasoned that each manufacturer was responsible for preventing the consumers of its own products from being injured, and correspondingly liable only for its own products' harms: it "stretch[ed] the concept of foreseeability too far" to require brand-name manufacturers to take responsibility for harm that befell those who never used their products. *See id.* at 169-171.

Since *Foster*, six other federal courts of appeals have likewise held that brand-name pharmaceutical manufacturers should not be held liable for injuries caused by their competitors' products. For example, the Eighth Circuit held, in an opinion reinstated after a reversal

on other grounds by the Supreme Court, that a plaintiff could not adequately show that the brand-name manufacturers "owed her a duty of care necessary to trigger liability" under Minnesota law, in part because their statements about their products were representations made to "*their* customers, not the customers of their competitors." *Mensing* v. *Wyeth, Inc.*, 588 F.3d 603, 613 n.9, 614 (2009) (emphasis added), *rev'd*, 564 U.S. 604 (2011), *opinion reinstated in relevant part*, 658 F.3d 867 (8th Cir. 2011).

The Sixth Circuit followed suit, applying Kentucky law to "reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company." *Smith* v. *Wyeth, Inc.*, 657 F.3d 420, 424 (2011). Several years later, the Sixth Circuit revisited the issue in a multidistrict litigation, examining the law of some 22 States and concluding in each case either that a manufacturer owed no duty to a plaintiff injured by a drug produced by its competitor, or that the plaintiff's suit was otherwise barred under state-specific product-liability statutes or rules. *See Darvocet*, 756 F.3d at 937-939, 941-954.

The Fifth, Ninth, Tenth, and Eleventh Circuits have also held that a plaintiff has a claim only against the manufacturer of the product that caused the injury, no matter the theory of liability. *See Lashley* v. *Pfizer, Inc.*, 750 F.3d 470, 476 (5th Cir. 2014) (per curiam) (concluding that, "because [a]ppellants did not ingest the brand manufacturers'

products, these defendants have no common-law duty to them"); *Moretti* v. *Wyeth, Inc.*, 579 Fed. Appx. 563, 565 (9th Cir. 2014) (holding that "Nevada law [does not] recognize[] a claim against the [b]rand [d]efendants for misrepresentation"), *cert. denied*, 135 S. Ct. 1398 (2015); *Guarino* v. *Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013) (concluding that "Florida law does not recognize a [misrepresentation] claim against the brand manufacturer of a prescription drug when the plaintiff is known to have consumed only the generic form"); *Schrock*, 727 F.3d at 1283-1286 (noting that "[n]o authority is cited to suggest that a manufacturer may be held liable under Oklahoma law for concealing a defect in a product that is never purchased or used by the plaintiff").

In all of these cases, the courts, while applying the law of different States, reached the same conclusion. While there are certain variations in tort law from State to State, the law of each State grows out of and incorporates certain common principles. One of those principles is that a defendant can be held liable only for harm fairly traceable to its own acts or omissions—and, in the product-liability context, an individual manufacturer can thus be called to account only for harms caused by its own products. Courts have consistently concluded that manufacturers cannot be held responsible for failing to warn against or

prevent harm caused by products they did not make, from which they did not profit, and about which they made no statements at all.[3]

C. For much the same reasons, courts have refused to disrupt settled principles of tort law in order to hold former, divested manufacturers liable for injuries caused by products they no longer make. Whether the claim sounds in fraud, negligence, or strict liability, there is no plausible basis to impose a duty on manufacturers to avoid harm from products made by another. *See*, *e.g.*, *Darvocet*, 756 F.3d at 940; *Lyman*, 2012 WL 2970627, at *16-17. Even the Court of Appeals' decision in *Conte* v. *Wyeth, Inc.*, 168 Cal. App. 4th 89 (2008)—the sole extant state-court case finding brand-name manufacturers liable for injuries

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[3] Only *Wyeth* v. *Weeks*, 159 So. 3d 649, 670, 672 (Ala. 2014), threatened to reshape the settled understanding on the question presented here. But *Weeks* was promptly repudiated by the Alabama legislature, which enacted a statutory prohibition on holding a defendant liable for harms caused by any product it had not "designed, manufactured, sold, or leased." Ala. Code § 6-5-530(a) (2016).

In any case, *Weeks* rested on a basic misunderstanding of the state of the law. The Alabama Supreme Court scarcely considered the vast body of law rejecting liability for brand-name manufacturers for injuries caused by generic products, instead considering only the Fourth Circuit's decades-old decision in *Foster*. *See Weeks*, 159 So. 3d at 666-670. The Alabama Supreme Court found *Foster* unpersuasive largely because the Fourth Circuit understood generic manufacturers to be responsible for the content of their own labels. *See id.* at 669-670. As discussed above, however, the Fourth Circuit was ultimately correct in this regard: although generic pharmaceutical manufacturers cannot unilaterally *revise* the labels or warnings accompanying the drugs they sell, they remain responsible under FDA regulations to inform FDA of all adverse drug reactions and, when appropriate, to propose new or different warnings to address the product's risks. *See* p. 11, *supra*.

caused by products other than their own—apparently assumed that such manufacturers would no longer face liability if they left the market and no longer sold the brand-name product at all. *See id.* at 107.

D. The United States Supreme Court's decision in *Mensing* supports the conclusion that a former brand-name pharmaceutical manufacturer—no longer legally authorized to make any changes to the label or warnings accompanying the brand-name drug—cannot face liability for harm caused by a generic version of that drug produced by another manufacturer. In *Mensing*, the Supreme Court, deferring to FDA's interpretation, held that the governing statutes and regulations forbade a generic manufacturer from independently altering the label or warnings accompanying its product without prior approval from FDA, thus preempting the state-law duty the *Mensing* plaintiffs argued the generic manufacturers had failed to honor. 564 U.S. at 614-615. The logic of that decision applies with equal force here. Under FDA's regulations, a manufacturer that transfers its NDA to a new owner simultaneously transfers all the rights and obligations attendant to that application, 21 C.F.R. § 314.72; no one other than a current NDA holder is permitted to revise the drug's label or warnings unilaterally, 21 C.F.R. § 314.71.[4]

[4] On the other hand, a current application holder—whether brand-name or generic—has an ongoing responsibility to advise FDA of adverse drug reactions and, when necessary, propose enhanced or altered labels and warnings for individual products. *See* p. 11, *supra*.

In other words, a manufacturer, having sold the right to make a given drug: (1) no longer makes that drug; (2) did not publish the warnings accompanying either the current brand-name or generic product; and (3) unlike current drug manufacturers, cannot change the drug's warnings in any way. Barred by law from taking any action that would protect it from liability when a consumer is injured by inadequate warnings on the generic version of the drug, the manufacturer should not face liability for failing to do what the law forbids. As the Court recognized in *Mensing*, "federal drug regulation has dealt" those injured by generic drugs an "unfortunate hand." 564 U.S. at 625 (majority opinion); *see also id.* at 644 (Sotomayor, J., dissenting) (noting that "[if] brand-name manufacturers . . . leave the market . . . there will be no manufacturer subject to failure-to-warn liability").

As in other similarly situated cases, plaintiffs here argue that, in the wake of *Mensing* and *Wyeth* v. *Levine*, 555 U.S. 555 (2009), the law anomalously treats brand-name and generic pharmaceutical manufacturers differently: under *Levine*, consumers injured by brand-name pharmaceuticals may sue brand-name manufacturers for their harms, while under *Mensing*, generic manufacturers are not liable for injuries their products inflict. But the mere fact of this inconsistency in *federal* preemption law does not justify reshaping the accepted principles of *state* tort liability and discarding principles that guide the decisionmaking of manufacturers in all industries. "As always, Congress and the

FDA retain the authority to change the law and regulations if they so desire," and resolving inconsistencies such as this one is the proper province of those federal actors. *Mensing*, 564 U.S. at 626. That is especially true given that the choice of liability rule implicates "health care policy for the [entire] country." Victor E. Schwartz et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 Fordham L. Rev. 1835, 1875 (2013) (Schwartz).

It would create more problems than it would solve if longstanding fundamental principles of tort law were modified to address potentially temporary anomalies in federal preemption law. That is especially true because the question of whether to expand tort liability to those that did not manufacture the injury-causing product "involves policy choices . . . more appropriately within the legislative domain." *Huck* v. *Wyeth, Inc.*, 850 N.W.2d 353, 376 (Iowa 2014) (internal quotation marks omitted), *cert. denied*, 135 S. Ct. 1699 (2015). And any exception this Court sought to carve into fundamental tort principles, even if intended to apply only to the pharmaceutical industry, would introduce uncertainty across all industries in the calculation of what tort liability an innovator should expect to face. The Court should not accept the invitation to create a far-reaching solution to a potentially temporary problem when that solution risks significant costs to the public and the economy by discouraging innovation.

III. CREATING AN EXCEPTION TO FUNDAMENTAL PRINCIPLES OF TORT LAW IN THE CONTEXT OF THE PHARMACEUTICAL INDUSTRY WOULD HAVE SERIOUS ADVERSE POLICY CONSEQUENCES

Courts across the Nation have recognized that public-policy considerations strongly support the conclusion that fundamental principles of tort law forbid imposing liability on a manufacturer for harm caused by its competitors' products, or on a former manufacturer after it left the business of making the product at all. Shifting liability onto innovative manufacturers in any industry comes at too high a cost and risks too much.

A. The original developer of a product incurs significant costs. And no matter how costly its development, a new product may never even be sold, much less prove successful, if regulatory or marketplace obstacles prove insuperable. Even if the developer manages to steer a product to the marketplace and market it successfully, it has no guarantee that its profits will ever cover its investment. And of course, the developer must also consider, and price in, the potential cost of liability to consumers for the product. The challenges a developer faces are all the more significant given the competition of alternatives, which can crowd the original developer out of the market entirely—especially when competitors can entirely forgo the cost of development, regulatory approval, and marketing.

As many courts have recognized, those challenges are especially acute for pharmaceutical manufacturers. *See Kelly* v. *Wyeth*, No. Civ.A.MICV200303314B, 2005 WL 4056740, at *4 (Mass. Super. Ct. May 6, 2005). Developing, and obtaining approval for, groundbreaking drugs can require enormous investment over decades. And federal law and regulations are especially solicitous towards competing generic versions. But similar problems "may arise with other types of consumer goods, ranging from nonprescription drugs and foods to household chemicals and appliances; in other words, crossover tort litigation could occur in any market served by brand-name companies that actively promote their wares but face competition from largely identical but lower-priced store brands" or other competing alternatives. Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 Tort Trial & Ins. Prac. L.J. 673, 694 (Spring-Summer 2010) (Noah).

Whatever the challenges of developing new products, developers have always been able to rely on the settled understanding that their exposure to risk is limited to the products they manufacture or sell themselves. That settled understanding allows manufacturers to anticipate their potential liability based on their sales; to set the price of their products at a level adequate to cover those projected costs; and to negotiate with insurers to cover that projected liability. Developers depend on that understanding when they make decisions about how to

develop new products. Relying on that understanding, American industry has achieved dazzling success in innovation in all fields, with appropriate opportunity for those injured by innovative products to recover from those that produced them. *See Huck*, 850 N.W.2d at 379-380. And at the same time, by placing liability solely on the actual manufacturer of a product, this rule sharpens manufacturers' incentives to ensure that their products are safe and bear adequate warnings, and underscores for consumers that a product's manufacturer is the authoritative source of warning information for that product.

Shifting the cost of harm to consumers onto manufacturers whose products the consumers did not even use risks permanently disrupting developers' ability to plan for the future and to project the size of their risk. Developers of new products would face liability arising from product sales made not by them but by their competitors, which took advantage of the innovators' initial investment in research, regulatory approval, and marketing. Such a shift would effectively force innovators in all industries to serve as insurers for the tort liability arising from all sales of their own and their competitors' products, increasing their cost but not the cost of competing alternatives—a particularly unjust result where the competitors were able to bring their products to market without paying for development, regulatory approval, or marketing. *See, e.g.*, Sarah C. Duncan, Note, *Allocating Liability for*

Deficient Warnings on Generic Drugs: A Prescription for Change, 13 Vand. J. Ent. & Tech. L. 185, 215 (2010); Schwartz 1861.

Nor is this merely a short-term issue that would dissipate once industries have navigated the transition to a new liability rule. The assignment of tort liability to manufacturers for products they do not make would expose product developers to risk based on sales activity and regulatory compliance they could neither control nor monitor, introducing lasting, unavoidable uncertainty into the calculus of product development. A manufacturer inevitably must consider tort liability to consumers of its products. But the new rule plaintiffs ask this Court to adopt here would not merely multiply the size of tort liability; it would also render it unpredictable. The loss of predictability in projecting risk is even costlier than the dollar value of tort judgments in favor of the class of consumers injured by competitors' products. *See* Schwartz 1870. And manufacturers would also face significant planning and compliance costs from the need to balance this new rule, applicable only in California, with the long-settled rule that would still apply throughout the rest of the Nation.

Unlike in this Court's recent decision in *Kesner*, there can be no doubt that the costs posed by the new liability rule plaintiffs urge here "would . . . impede[] [manufacturers'] ability to carry out an activity with significant social utility." *Kesner*, slip op. 20. To the contrary, such a change would have significant negative consequences. *First*, the cost

of innovative products would necessarily rise to fund the increased scope of liability that would follow once competing versions entered the market. That would have particularly grave consequences in the context of the pharmaceutical industry, where higher prices could have an effect on public health. *See, e.g.*, *Darvocet*, 756 F.3d at 944, 945, 947, 948-949; Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 Tenn. L. Rev. 1357, 1360 & nn.17-18 (1994) (T. Schwartz).

Second, confronted with ballooning and unpredictable liability costs, manufacturers would necessarily devote fewer resources to innovation and release fewer innovative new products. *See*, *e.g.*, *Darvocet*, 756 F.3d at 944, 945, 947, 948-949; T. Schwartz 1360 & nn.17-18. Manufacturers would have less incentive to launch new products because their profits from those products would be decreased (or wiped out altogether) by the murky and expanded scope of their tort exposure.

The results of a more expansive liability regime are highly unpredictable. Perhaps only blockbuster products, promising large and lasting profits, would prove worth the candle. Or perhaps manufacturers would eliminate development lines and product categories altogether, producing a smaller number of products in order to control their potential liability. No matter the specific strategy adopted by individual manufacturers, the aggregate consequence is clear and unavoidable: consumers would see fewer new products brought to market.

See Schwartz 1871. For most types of products, that decline might simply represent overall losses to the economy. For the pharmaceutical industry, however, the prospect is much more serious: public health as a whole would suffer, an "unfortunate consequence[]" of imposing excessive liability on pharmaceutical manufacturers that this Court has previously recognized. *Brown*, 44 Cal. 3d at 1064-1065; *see also* H. William Smith III, Note, *Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 Case W. Res. L. Rev. 207, 218 & n.80 (1992) (discussing this Court's efforts to shape the liability of pharmaceutical manufacturers to avoid the risk of "deter[ring] the marketing of new products for fear of 'large adverse monetary judgments'" (quoting *Brown*, 44 Cal. 3d at 1063)).

Those policy considerations have long informed the fundamental rule that tort liability can attach only where a common instrumentality links the injured person to the alleged wrongdoer. A more expansive liability regime would disturb the existing equilibrium between the undoubted need to redress injuries and the need to allocate liability in a way that maximizes innovation and overall well-being. This Court should not disregard those policy considerations by creating an exception to well-settled tort principles for pharmaceutical manufacturers.

Nor is there any valid reason to believe that such an exception could remain cabined to the pharmaceutical industry. As one state supreme court noted, creating such an exception would leave courts on a

"slippery slope." *Huck*, 850 N.W.2d at 380. "If a car seat manufacturer recognized as the industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor's seat that copied the design?" *Id.*; *see also* Schwartz 1869-1870 (noting that "there is no principle limiting competitor liability to prescription drugs"). At a minimum, a new rule of tort liability for the pharmaceutical industry would destabilize the assumptions made by manufacturers in other industries about how far tort liability can run, and prudent manufacturers in all industries would have to consider the possibility that such a rule would be applied to their products as well.

B. The negative implications for public policy would simply multiply if a manufacturer could face liability for harm caused by a competitor's product even after the manufacturer divested itself of the business of making its own product. Even if a manufacturer could ever be held liable for injury caused by a product it did not make or sell, that responsibility must end somewhere. Holding a former manufacturer liable in circumstances such as these reaches far beyond any sound limit.

In many industries, it is of course common for manufacturers to sell product lines, brands, and entire businesses to competitors. *Cf.* Noah 694. And in this regard, pharmaceutical manufacturers are "no differently situated." Schwartz 1879. A pharmaceutical manufacturer that divests an entire product line transfers the NDA associated with

that product and, under FDA regulations, also transfers all the rights and obligations associated with that application (including the sole authority to alter the drug's label or warnings). *See* 21 C.F.R. §§ 314.71, 314.72.

In any industry, including the pharmaceutical industry, a manufacturer that sells the right to make the original product can no longer take any action that would avoid tort liability for injuries caused by products it no longer makes, much less for injuries caused by competing versions thereof. Any recovery against that manufacturer for an injury caused by such a product would necessarily come from a defendant that did not cause the plaintiff's injury, because it did not create the product that injured the plaintiff. *See Lyman*, 2012 WL 2970627, at *17.[5] In the same way, imposing liability on a former manufacturer for the adequacy of warnings issued while that manufacturer still had control of a product it created would be senseless after that product was sold to another manufacturer. Transfer of the product carries with it the author-

[5] It is true, as plaintiffs point out, that juries have the option to apportion damage among multiple wrongdoers. Br. 69. But where, as here, the subsequent manufacturer proved unavailable or judgment-proof, only the original manufacturer would actually be available to pay any damages a jury awarded. Under the same circumstances, a manufacturer sued for damages caused by a product it had divested could not seek contribution or indemnification from the bankrupt or otherwise unavailable parties to whom it had sold the right to produce the innovative product in question.

ity to change the warnings and thus the sole responsibility for any liability from a failure to do so. In any case, any warnings the former manufacturer issued were only "about" the products it made itself, not about products later made by another manufacturer after divestiture.

The regime plaintiffs advocate would have profound consequences. Expanding tort liability to former manufacturers that have left the market entirely would open the door to perpetual liability for any manufacturer that develops a product. Once on the hook for damages caused by products it once made but no longer does, an innovator manufacturer would face tort liability it could never shut off. Its exposure to damages would multiply as long as competitors continued to sell their own products. And the situation would be even worse if innovators also faced failure-to-warn liability based on warnings they *once* issued regarding a product now made and sold by another. Meanwhile, the current manufacturer—the entity "best situated to prevent" injuries caused by its products, *Kesner*, slip op. 21—would face diminished incentives to maintain the accuracy and adequacy of its own product warnings, placing the public at risk.

What is more, expanding tort liability to former manufacturers that have left the market entirely would create even more uncertainty and further cripple manufacturers' ability to project future exposure to risk. Innovative developers would now have to guess not merely at the size of their own liability, but also at the cost of insuring the sales of the

product for an unknown period into the future. Any company contemplating investing in innovative research and development would have to weigh the benefits of new products against enormous risks it could neither calculate nor control. This unpredictability would also affect the ability of manufacturers to arrive at meaningful valuations of their product lines and businesses as a whole, hampering their access to credit and their ability to sell, and license, their own products and product lines. If the risk of liability is always a disincentive to investment, such a startling relaxation of the traditional limits on tort liability risks stopping innovation in its tracks.

The dramatic change to tort law that plaintiffs are seeking in this case threatens serious and unmistakable consequences. This Court should not adopt a rule that would disrupt the process of developing new products in any industry, much less the process of developing life-saving pharmaceuticals.

CONCLUSION

The judgment of the Court of Appeal should be reversed.

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CERTIFICATION OF WORD COUNT

Pursuant to California Rule of Court 8.204(c)(1), I certify that, according to the word-count feature of the computer program used to prepare this brief, this brief contains 6,818 words, including footnotes but excluding content identified in Rule 8.520(c)(3).

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DECEMBER 7, 2016

DECLARATION OF SERVICE BY MAIL

I, Kannon K. Shanmugam, counsel for amicus curiae, declare that I am over the age of eighteen years and not a party to or interested party in this action.

I further declare that, on December 7, 2016, I caused copies of the attached Brief of Amicus Curiae to be filed with the Clerk of the Court by placing true copies thereof in a sealed envelope with postage fully paid, for shipment via Federal Express.

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

Executed at Washington, DC, December 7, 2016.

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