No. S233898

IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

T. H., a Minor, etc., et al.,

Plaintiffs and Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant and Respondent.

Review of a Decision of the Court of Appeal
Fourth Appellate District, Division One, Case No. D067839

NOVARTIS'S CONSOLIDATED ANSWER TO AMICI CURIAE BRIEFS

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INTRODUCTION

Plaintiffs' amici, Public Citizen (PC), Consumer Attorneys of California and the American Association for Justice (collectively CAC) and the AARP and its Foundation unabashedly propose a rule grossly expanding traditional California tort law to impose novel duties of care on former manufacturers and innovator manufacturers for harms caused by another manufacturer's product. But Plaintiffs' amici conveniently ignore this Court's consistent bright line rule limiting the scope of a manufacturer's duty to injuries caused *by its own product*, and never identify any basis in law or policy suggesting that rule ought to be abandoned.

To the extent Plaintiffs' amici repeat the arguments presented in Plaintiffs' merits briefs, Novartis has already responded and will not repeat itself here. Instead, this brief addresses three legal errors in Plaintiffs' amici's briefs and responds to their misdirected tort policy arguments.

First, Plaintiffs' amici suggest Plaintiffs might develop case-specific facts justifying the imposition of a duty on Novartis for claimed injuries from other manufacturers' drugs. (AARP ACB:10-11, 16; CAC ACB:22; PC ACB:8.) That isn't how it works. As this Court recently explained, duty does not rest on "the facts of the particular case before us." (*Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1143-1144.) To the contrary, the "[a]nalysis of duty occurs at a higher level of generality" requiring courts to identify "clear, categorical, bright-line rules of law applicable to a general class of cases." (*Id.* at p. 1144.) The Court has identified such a clear, categorical, bright-line rule in repeatedly rejecting an "expansion of the duty of care as urged here [to] impose an obligation to compensate on those whose products caused the plaintiffs no harm." (*O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 365; *Sindell v. Abbott Laboratories* (1980)

26 Cal.3d 588, 615-616 (dis. opn. of Richardson, J.).) Case-specific exceptions to this rule would undermine it.

Second, Plaintiffs' amici suggest this Court's categorical rejection of the non-manufacturer duties of care should be restricted to causes of action sounding in strict liability and should not apply to negligence claims. (CAC ACB:20-22; PC ACB:8-9.) They are wrong. As this Court has explained, "there is little functional difference between these two theories in the failure to warn context." (*Webb v. Special Elec. Co., Inc.* (2016) 63 Cal.4th 167, 187.) Rather, the "same policy considerations that militate against imposing strict liability in this situation apply with equal force in the context of negligence." (*O'Neil, supra*, 53 Cal.4th at p. 366; *Sindell, supra,* 26 Cal.3d at pp. 595, 605.)

Third, Plaintiffs' amici observe that the Restatement Second of Torts, sections 310 and 311 imposes a duty of care for representations about third party conduct that causes injury (CAC ACB:17-19; PC ACB:7), ignoring the fact that Plaintiffs do not allege any such representations by Novartis. Indeed, Plaintiffs concede that Novartis did not make any representation about the generic drug companies that sold the alleged injury-causing drugs in 2007 or about the warning labels on those drugs. Rather, Plaintiffs' allegations against Novartis are limited to warnings Novartis provided six years earlier about its own branded drug product. This case thus stands in sharp contrast to the Restatement case law cited by Plaintiffs' amici, in which defendants made representations specific to the product or actor allegedly causing the plaintiffs' injuries. CAC's discussion of the doctrine of intervening cause fails for the same reason — Plaintiffs do not allege any negligence by Novartis that would give rise to a threshold duty. (CAC ACB:38-40.)

Plaintiffs' amici contend the novel duties they propose are necessary to advance the policy goal of current, updated warnings for mature drug products. But federal and state laws already impose significant duties on drug manufacturers to properly incentivize them to provide proper warnings for their products. In contrast, the former manufacturer duty Plaintiffs' amici champion would create perverse counter-incentives for successor brand manufacturers to delay updates to drug warning labels after purchasing the NDA from another manufacturer. And the proposed innovator duty would incentivize brand manufacturers to withdraw their NDAs upon entry of generics, leaving physicians and patients without a key player in ongoing safety monitoring and drug labeling.

Plaintiffs' amici's final policy salvo is that this Court must embrace at least the innovator duty because federal law partially preempts product liability claims against generic drug manufacturers. But the law is replete with protections and immunities for different categories of defendants without imposing new duties on other parties. Duties of care are based on a party's own conduct and relationship to an alleged injury.

Because Novartis was not involved in the manufacture, distribution or warnings for the drugs allegedly causing Plaintiffs' harm, Novartis owed no duty of care to Plaintiffs. The Court of Appeal's opinion should be reversed.

LEGAL ARGUMENT

"[S]ocial policy must at some point intervene to delimit liability even for foreseeable injury." (*O'Neil*, *supra*, 53 Cal.4th at pp. 365-366.) In California — as in every other state — that limit with regard to products liability has been drawn at those involved in the chain of distribution for the product allegedly causing injury. "Regardless of a defendant's position in

the chain of distribution, the basis for his liability remains that he has marketed or distributed a defective product and *that product* caused the plaintiff's injury." (*Id.* at p. 348, italics added.) This Court has "never held that a manufacturer's duty to warn extends to hazards arising exclusively from *other* manufacturers' products." (*Id.* at p. 351.)

I. THE IMPOSITION OF A DUTY OF CARE DOES NOT TURN ON THE FACTS OF A SPECIFIC CASE.

All of Plaintiffs' amici suggest a court's inquiries into whether a brand drug manufacturer owes a duty of care to consumers of successor or generic drugs turns on case-specific facts. AARP contends the existence of a duty is a "fact intensive question that cannot be resolved merely on a demurrer" and asks this Court to "permit a more flexible analysis" that "empowers a fact-finder to decide what, if any, harms were foreseeable for a name-brand manufacturer." (AARP ARB:16, 10-11; and see PC ACB:8; CAC ACB:22.)

These arguments fundamentally misconstrue the concept of duty and a court's role in determining whether a duty exists. As this Court recently explained, "duty differs from the other elements of tort. Breach, injury, and causation must be demonstrated on the basis of facts adduced at trial, and a jury's determination of each must take into account the particular context in which any act or injury occurred. Analysis of duty occurs at a higher level of generality." (*Kesner*, *supra*, 1 Cal.5th at p. 1144; see also *Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 774.) Thus, as to foreseeability, "the court's task in determining duty is not to decide whether a *particular* plaintiff's injury was reasonably foreseeable in light of a *particular* defendant's conduct, but rather to evaluate more generally whether the category of negligent conduct at issue is sufficiently likely to result in the kind of harm experienced that liability may appropriately be

imposed." (*Kesner*, *supra*, 1 Cal.5th at p. 1145.) Moreover, considerations of foreseeability and prevention of harm may be "outweighed, for *a category* of negligent conduct, by laws or mores indicating approval of the conduct or by the undesirable consequences of allowing potential liability." (*Id.* at p. 1150, italics omitted.) This broader societal balance cannot be achieved with a case-by-case analysis.

In *O'Neil*, this Court conducted the duty analysis at the requisite level of generality and held categorically that there is "No Duty of Care to Prevent Injuries from Another Manufacturer's Product." (*O'Neil*, *supra*, 53 Cal.4th at p. 363; see also *id.* at p. 342.) *O'Neil* did not turn on the specific facts in that case — which directly presented the question whether a manufacturer has a duty to warn with regard to products it formerly manufactured.[1] This Court similarly rejected plaintiffs' theories that would extend a duty to drug manufacturers to warn consumers of generic, chemically-identical drugs manufactured by another pharmaceutical

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[1] CAC's contention that *O'Neil* did not involve claims of former manufacturer liability based on a defendant's alleged failure to warn about the risks of its former product (CAC ACB:26-27) is plainly wrong. (*O'Neil*, *supra*, 53 Cal.4th at p. 352.) CAC's fallback argument — that this case falls within an exception to *O'Neil* for the combined use of products (CAC:28) misconstrues the *O'Neil* exception and was never raised by Plaintiffs. A "product manufacturer participates substantially in creating a harmful combined use *only* if it specifically designs its product for the combined use." (*Sanchez v. Hitachi Koki, Co., Ltd.* (2013) 217 Cal.App.4th 948, 957, italics added.)

company. (*Sindell*, *supra*, 26 Cal. 3d at pp. 595, 605; *Jolly v. Eli Lilly & Co.* (1988) 44 Cal.3d 1103, 1108, 1115.)

Amici's contention that the Court should abandon this approach to allow for case-specific inquiries would undermine the policy underlying duties of care. (*O'Neil*, *supra*, 53 Cal.4th at pp. 364-365.) Duties to warn provide bright line rules for (i) manufacturers as to the existence and scope of their warning responsibilities and (ii) consumers of a product about the identity of the entity to which they should look to for instruction on the safe use of products. (*Id.* at p. 365 [noting that "consumers could also suffer" because "the recognition of such a duty could lead to an overabundance of potentially conflicting product warnings"].) Case-by-case determinations of duty would undermine these broader objectives. The establishment of categorical duty rules allows tort law to "appropriately and equitably balance[] the practical realities of supplying products with the need for consumer safety," a balance that is lost if manufacturers do not have clarity as to the scope of their duty. (*Webb*, *supra*, 63 Cal.4th. at p. 187.)

Moreover, categorical duties of care are intended to strike "a workable balance between ensuring that reasonably foreseeable injuries are compensated and protecting courts and defendants from the costs associated with litigation of disproportionately meritless claims." (*Kesner*, *supra*, 1 Cal.5th at p. 1155.) This purpose cannot be achieved through fact-specific standards because "it frequently will be easy to raise factual questions" with regard to the foreseeability of harm as to any particular defendant, meaning that demurrer and summary judgment rarely would be available in these cases. (*Knight v. Jewett* (1992) 3 Cal.4th 296, 313.)

This case is a prime example. Here, even the Court of Appeal recognized that Plaintiffs had not alleged facts sufficient to satisfy their

appellate theory of foreseeability, but nevertheless held that Plaintiffs must be allowed to amend their complaint yet again to plead around that deficiency. The Court of Appeal holding thus leaves the legal question of duty at the mercy of the factual creativity of Plaintiffs' counsel.

II. NO PRACTICAL DISTINCTION BETWEEN STRICT LIABILITY AND NEGLIGENT FAILURE TO WARN JUSTIFIES A CHANGE IN THE SCOPE OF A DRUG MANUFACTURER'S DUTY.

Acknowledging that non-manufacturer Novartis does not have a duty to warn that could support a strict liability claim, Plaintiffs' amici contend this no-duty rule does not apply to negligent failure to warn claims because negligent misrepresentation and strict liability are distinct causes of action under California law. (CAC ACB:20-22; PC ACB:8-9.) Amici would thereby erase the large body of case law rejecting innovator duty because those cases supposedly were decided in states that do not differentiate between strict liability and negligent misrepresentation. (CAC ACB:20-22; PC ACB:8-9.)

In fact, as Novartis previously explained, the innovator duty rule has been widely rejected in other states without regard to whether those states construe misrepresentation claims as products liability claims. (RBM:27, fn. 11.) More generally, a manufacturer's duty of care in providing warnings does not depend on a plaintiff's ability to seek recovery under different legal theories. While the nature of the conduct necessary to establish *a breach* of a duty to warn may differ under a negligence or strict liability theory (that is, a failure to warn pursuant to applicable standard of care or failure to warn of known or knowable risks), this difference is irrelevant to the threshold question about whether a duty to warn exists.

CAC contends a manufacturer's duty to warn with regard to negligence claims should be broader than its duty to warn for strict liability claims because the negligence theory focuses on a defendant's conduct apart from any defect in the product itself. (CAC ACB:20.) Not so. This Court has held that strict liability failure to warn claims also "involve some consideration of the defendant's conduct and do not necessarily focus exclusively on the product's condition." (*Johnson v. American Standard, Inc.* (2008) 43 Cal.4th 56, 73.) This Court has explained that it "may also be true that the 'warning defect' theory is 'rooted in negligence' to a greater extent than are the manufacturing — or design-defect — theories. The 'warning defect' relates to a failure extraneous to the product itself." (*Ibid.*) Thus, in "failure to warn cases, whether asserted on negligence or strict liability grounds, there is but one *unitary* theory of liability which is negligence based — the duty to use reasonable care in promulgating a warning." (*Webb*, *supra*, 63 Cal.4th. at p. 187, italics added.)[2]

Indeed, this Court has held that a wide variety of duty-defining rules apply equally to strict liability and negligent failure to warn. (*Webb*, *supra*, 63 Cal.4th at pp. 183, 187 [rule that component seller owes no duty to warn either immediate buyer or ultimate consumer "applies to both strict liability and negligence claims," and "sophisticated intermediary defense applies to failure to warn claims sounding in either strict liability or negligence"]; *Johnson*, *supra*, 43 Cal.4th at p. 67 [under the "obvious danger" rule, no

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[2] CAC's heavy reliance on the subsequently-abrogated Alabama Supreme Court opinion in *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649, revd. by statute Ala. Code § 6-5-530, ignores California law as stated in *Johnson* and *Webb*. (CAC ACB:24-26.) In *Weeks*, the Alabama Supreme Court distinguished strict liability from negligence, holding that strict liability is tied exclusively to the product rather than the defendant's conduct. (*Weeks*, *supra*, 159 So.3d at p. 670.) California law is to the contrary.

need to warn under either a negligence or a strict liability theory]; *id.* at p. 72 ["there is no reason why the sophisticated user defense should not be as available against strict liability causes of action as it is for negligence causes of action"]; *O'Neil*, *supra*, 53 Cal.4th at p. 351, 363 [no strict liability or negligence duty to warn of defects in another manufacturer's product].)

Plaintiffs' amici provide no basis for a different approach here.

III. RESTATEMENT SECTIONS 310 AND 311 AND THE INTERVENING CAUSE DOCTRINE BASE THE FINDING OF DUTY ON A DEFENDANT'S REPRESENTATIONS ABOUT OR INVOLVEMENT WITH THE SPECIFIC INSTRUMENTALITY ALLEGEDLY CAUSING THE PLAINTIFF'S HARM.

Aside from the erroneous holding of *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89, all California case law applying section 310 and 311 of the Restatement Second of Torts, has limited a defendant's liability for a misrepresentation to a third party to circumstances in which the defendant made a misrepresentation specific to the product or actor alleged to have caused harm. (RBM:18-19; and see U.S. Chamber ACB:4-5.) Because Plaintiffs do not claim any such misrepresentation here, sections 310 and 311 are irrelevant.

CAC attempts to bolster the Court of Appeal's mistaken reliance on sections 310 and 311 by citing cases from other jurisdictions (CAC ACB:17-19), thereby underscoring the Court of Appeal's error. As is true in California, the section 310 and 311 case law from other states all

involves representations specific to the instrumentality allegedly causing the plaintiff's harm.[3]

The plaintiff in *Thomas v. Winchester* (1852) 6 N.Y. 397 sued the seller of a vegetable extract that allegedly caused the plaintiff's injury, alleging the container's label misrepresented the nature of the extract. The plaintiff in *Lawhon v. Ayres Corp.* (Ark. Ct. App. 1999) 992 S.W.2d 162 sued the company that regularly serviced the aircraft that crashed and caused the death of plaintiff's husband. The plaintiff in *Gerrity v. R.J. Reynolds Tobacco Co.* (Conn. 2003) 818 A.2d 769, a wrongful death action, alleged the decedent was forced to pay a higher price for the defendant's cigarettes due to the defendant's alleged misrepresentations about its product. The cross-plaintiff in *Thompson v. Hardy Chevrolet-Pontiac-Buick, Inc.* (Ga. Ct. App. 1992) 417 S.E.2d 358 alleged she had relied on the defendant car dealership's misrepresentations about the condition of the brakes of the car she purchased, brakes that subsequently failed and caused the accident that injured the plaintiff. The plaintiff in *Virginia Dare Stores, Inc. v. Schuman* (Md. 1938) 1 A.2d 897 was injured when the showcase on which he was standing collapsed; he sued the person who told him to stand on the showcase, representing that it would hold his weight.

None of these cases support the Court of Appeal's holding that a defendant can be held liable for a misrepresentation regarding a product that was not the cause of the plaintiff's injury.

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[3] Contrary to CAC's claim, Novartis does not contend that sections 310 and 311 do not apply to pharmaceutical companies. (CAC ACB:23.) The point is that a pharmaceutical company's duty arises from representations about the product alleged to have caused injury.

CAC's reliance on the superseding cause analysis in *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51 (CAC ACB:13, 38-40) is equally misplaced. *Stevens* considered whether a drug manufacturer's failure to provide an adequate warning of the risks of its drug was the *proximate cause* of the plaintiff's injury where the prescribing physician was aware of the risks when he prescribed the drug. There was no question in that case that the drug company owed a duty to warn — the plaintiff alleged her injury was caused by the defendant's drug, and this Court relied on this fact in its holding. (9 Cal.3d at p. 64 [one who supplies a product is subject to liability for physical harm caused by the use of the product if the supplier fails to exercise reasonable care to inform the user of its dangerous condition].) As with the Restatement case law, the Court's duty finding was based upon the drug manufacturer's representation concerning the specific drug allegedly causing the plaintiff's harm. The Court's subsequent discussion of the defendant's defense against liability based upon the doctor's alleged intervening negligence addresses the separate tort element of causation, not duty.[4]

IV. THE ADVERSE CONSEQUENCES TO PUBLIC HEALTH RESULTING FROM THE IMPOSITION OF A DUTY TO WARN OF THE DANGER OF INJURIES CAUSED BY ANOTHER MANUFACTURER'S PRODUCT FAR OUTWEIGH THE PURPORTED POLICY BENEFITS PROMISED BY PLAINTIFFS' AMICI.

All of Plaintiffs' amici contend that many drug risks emerge after a branded drug is off patent and generics have taken over the market. (AARP ACB:6-8; CAC ACB:35-36; PC ACB:3-4.) From this premise, amici jump

[4] As in *Stevens*, all of CAC's other cases discussing superseding cause involved a defendant with an acknowledged duty of care to a plaintiff relying on the superseding cause defense to defeat the plaintiff's showing of causation. (CAC ACB:40.)

to the assertion that the former manufacturer and innovator duties imposed by the Court of Appeal will advance public health by insuring ongoing monitoring and safety updates for mature drug products. This syllogism fails.

While asserting the proposed new duties to warn are needed to incentivize brand manufacturers to include proper warnings, Plaintiffs' amici acknowledge that brand manufacturers already are subject to extensive duties to warn under federal and state tort law with respect to injuries caused by their products. (AARP ACB:5-8; CAC ACB:14-15, 32-34, PC ACB:5-6.) Plaintiffs' amici offer no basis for their assertion that the imposition of additional duties about possible injuries from other manufacturer's products would cause brand manufacturers to more faithfully abide by their pre-existing duties.

To the contrary, amici's arguments demonstrate that the proposed new duties could *impede* the prompt updating of drug labels with newly identified risks based on the impact these duties would have on subsequent NDA holders and brand manufacturers when generics enter the market. AARP and CAC acknowledge, for example, that a former brand manufacturer would only remain on the hook for injuries caused by a subsequent manufacturer's drug — and thus lower the subsequent manufacturer's liability exposure — if the subsequent manufacturer freezes the existing warning label in place after purchasing the NDA. (AARP ACB:10; CAC ACB:22.) The proposed former manufacturer duty accordingly would prevent warning updates, not promote them. PC, in turn, acknowledges that brand manufacturers will withdraw their NDAs after the emergence of generics — and no longer serve in their important role in safety monitoring and updated warnings — if their continued participation in the market is no longer profitable. (PC ACB:10-11.) PC's

manufacturers may still be subject to liability in certain cases (indeed, Plaintiffs' claims against a generic drug manufacturer that supplied the drug allegedly causing their injuries are still pending in the trial court). In any event, there is no precedent for amici's suggestion that protections extended to certain defendants should create new duties for other parties. This Court rejected a similar argument in *Toland v. Sunland Housing Group, Inc.* (1998) 18 Cal.4th 253, 267 where it held the limitations of liability under the workers' compensation scheme did not justify the imposition of a new duty of care on individuals who hire independent contractors for whom the injured employee works. Such a result, this Court held, would impose an "unfair" liability on the third party which would exceed the liability for one "primarily responsible" for the worker's injuries. (*Ibid.*)

Similar arguments to those advanced by amici could be made to impose new duties on third parties in any number of transactions involving responsible parties who enjoy protections under the law, such as the government (protected by sovereign immunity), doctors (protected by statutory limitations on medical malpractice actions), architects and builders (protected by statutes of repose), or volunteers (protected by Good Samaritan statutes). The law does not establish protections for these parties for the purpose of imposing new duties of care on others.

CONCLUSION

For the reasons set forth above and in Novartis's merits briefs, the Court of Appeal's opinion should be reversed and the cause remanded to the trial court with directions to enter judgment for Novartis.

Dated: February 16, 2017 Respectfully submitted,

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CERTIFICATE OF WORD COUNT

Pursuant to rule 8.204(c)(1) of the California Rules of Court and in reliance on the word count of the computer program used to prepare this brief, counsel certifies that this brief was produced using 13-point type and contains 4230 words.

Dated: February 16, 2017

for

Eric G. Lasker

PROOF OF SERVICE

I declare that I am employed with the law firm of Morrison & Foerster LLP, whose address is 12351 High Bluff Drive, San Diego, California 92130. I am not a party to the within cause, and I am over the age of eighteen years.

I further declare that on February 16, 2017, I served a copy of:

NOVARTIS'S CONSOLIDATED ANSWER TO AMICI CURIAE BRIEFS

☒ **VIA U.S. MAIL** by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid, addressed as follows, for collection and mailing at Morrison & Foerster LLP, 12531 High Bluff Drive, San Diego, California 92130 in accordance with Morrison & Foerster LLP's ordinary business practices.

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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 on this 16th day of February, 2017, at San Diego, California.

Stacy Vinagre
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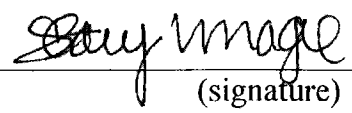
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