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 Court of Appeal,
Fourth Appellate District, Division One
Case No. D067839

Plaintiffs' Consolidated Answer to Amicus Curiae Briefs in Support of Respondent

Leslie A. Brueckner, Esq.
PUBLIC JUSTICE, P.C.
555 12TH Street, Suite 1230
Oakland, California 9460
Tel: (510) 520-6205
Fax: (510) 622-8155

Benjamin I. Siminou, Esq.
THORSNES BARTOLOTTA MCGUIRE LLP
2550 Fifth Avenue, 11th Floor
San Diego, California 92103
Tel: (619) 236-9363
Fax: (619) 236-9653

Attorneys for Plaintiffs and Appellants
T.H., a Minor, et al.

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Tel: (619) 236-9363
Fax: (619) 236-9653

Attorneys for Plaintiffs and Appellants
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ARGUMENT

Novartis's amici argue, predictably, that allowing brand-name manufacturers to be held liable for injuries caused by generic drugs would up-end California tort law and wreak havoc on the drug industry. None of amici's arguments withstands scrutiny.

I. Brand-Name Liability Is Entirely Consistent with California Tort Law.

A. Novartis Can Be Held Liable Even Though It Did Not Manufacture the Drug That Injured Plaintiffs.

Amici's principle legal argument is that Novartis can't be held liable because it didn't make the actual drug that injured Plaintiffs, a fact that would be fatal to Plaintiffs' claims under the law of strict products liability.

This argument fails on multiple levels.

1. Plaintiffs Seek Recovery for Negligent Misrepresentation Under Section 311 of the Restatement of Torts.

First, this is not a product-liability case, and the wrongdoing at issue does not concern the actual product that injured Plaintiffs. Rather, Plaintiffs seek recovery for Novartis's negligent misrepresentation of the risks of its *own* product, a

claim under Section 311 of the Restatement (Second) of Torts. And it has long been recognized that a negligent-misrepresentation claim involving physical injuries caused by a product is distinct from a products-liability claim. (See *Hanberry v. Hearst Corp.* (1969) 276 Cal.App.2d 680, 688–689 [recognizing negligent-misrepresentation claim based on reliance on "commercial endorsement" of product, but rejecting claim based strict liability in tort, because defendant had not manufactured product].)[1]

This distinction is underscored by the Restatement (Third) of Torts, which recognizes misrepresentation claims as entirely separate from product-liability claims. Section 9 of the Restatement provides that "separate causes of action set forth in the Restatement (Second) of Torts, governing liability for fraudulent and negligent misrepresentation, are contained in §§ 310 and 311. Case law has followed these Sections." (*Id.*) It goes on to state that "[a]lthough these Sections do not explicitly apply

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[1] (See also Brief of Consumer Attorneys of California and American Assn. for Justice, pp. 15–19 [explaining origins of tort of negligent misrepresentation claim].)

to commercial product sellers, *they admit of such application*." (*Ibid.*, emphasis added.)

Along similar lines, Section 2 of the Restatement (Third) of Torts, which defines the three categories of strict products liability, provides:

> Plaintiffs may ... join claims based on product defect ... and claims based on theories of recovery that do not rest on a premise of product defect at time of sale. *Claims based on misrepresentation*, express warranty, and implied warranty of fitness for particular purpose, in particular, *are not within the scope of this Chapter and thus are unaffected by it.*

(Rest.3d Torts, Product Liability, § 2, com. O, emphasis added.)

Thus, the "black letter of the Restatement [Third of Torts]" is *not* "incompatible with innovator liability." (Brief of Product Liability Advisory Council ("PLAC"), p. 16). In reality, the misrepresentation claims are "unaffected" by, and coextensive with, the chapter governing product liability. (*Id.*)

2. Negligent Misrepresentation Claims Are Not Subject to an Instrumentality Requirement.

Second, unlike product-liability claims, a claim for negligent misrepresentation under Section 311 has no "instrumentality" or "product-identification" requirement. Section 311 provides:

> One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results (a) to the other, or (b) to such third persons as the actor should expect to be put in peril by the action taken.

None of this Court's cases adopting Section 311 suggests that it should be limited to cases where the defendant manufactured or controlled the "instrumentality" that injured the plaintiff otherwise. (*See Randi W. v. Munroc Joint Unified School Dist.* (1997) 14 Cal.4th 1066, 1077 [holding that a school district's misrepresentations about a former employee in a letter of recommendation could render district liable under Section 311 for employee's molestation of student at his new school]; *Garcia v. Superior Court* (1990) 50 Cal.3d 728, 735–736 [holding that parole officer's misrepresentations to parolee's prior victim resulting in her death could be basis for liability under Section 311].)

The U.S. Chamber of Commerce (the "Chamber") attempts to distinguish *Garcia* and *Randi W.* on the ground that, in both cases, "the defendants had made representations about the future conduct of specific individuals, and those same individuals later injured others"—arguing that, unlike here, "[t]hose individuals ...

provided the very 'instrumentality' required under the general principles of tort law to link the alleged wrongdoers' misrepresentations to the plaintiffs' harm." (Chamber Br., p. 5.)

But unlike *Garcia* and *Randi W.*, where the "instrumentalities" that harmed the plaintiffs were individuals over whom the defendants had no formal relationships and exerted no control, Plaintiffs seek to hold Novartis liable for misrepresenting the risks of a drug that was pharmalogically identical to the "instrumentality" that ultimately injured them. (See 21 U.S.C. § 355(j)(2)(A)). And because federal law requires generic manufacturers to use the same warnings as the brand-name equivalent (see *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 613), Novartis could easily foresee that its inadequate labeling would be relied on by doctors when prescribing Brethine to patients whose prescriptions might ultimately be filled with generic Brethine. Thus the link between Novartis' misrepresentations and Plaintiffs' injuries was actually *more* direct and foreseeable than in either *Randi W.* or *Garcia*.[2]

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[2] (See Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers* (2011) 60 Duke L. J. 1123, 1174 ["If a brand-name drug manufacturer is negligent in designing its product or in

It would be no more justifiable to excuse Novartis for disseminating false information about Brethine simply because it didn't make the tablets that injured Plaintiffs, than it would be to conclude that Plaintiffs' mother's physician owed her no duty of care simply because he didn't make the tablets she ingested. In both cases, the defendant's duty toward the Plaintiffs arises independent of the manufacture or sale of the tablets, and the defendant's breach of the duty leads proximately to the Plaintiffs' injury, regardless of who manufactured the terbutaline she took.

3. Negligent-Misrepresentation Claims Are Not "Substantively Indistinguishable" from Product-Liability Claims.

Amici nonetheless insist that negligent-misrepresentation claims should be subject to an instrumentality requirement because they are "substantively indistinguishable" from product-liability claims. (See PLAC App., p. 3.) Not so.

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preparing labeling ..., it is highly foreseeable that the risk created will extend to those taking the generic substitutes .... And given that brand-name manufacturers effectively dictate crucial aspects of the generic products' designs and the contents of their labeling, the brand-name manufacturers' insistence that they have no control over generic drugs is like a person saying that he has no control over his own shadow."].)

This argument fails, first, because even if Plaintiffs' negligent-misrepresentation claim were "substantively indistinguishable" from a product-liability claim (and it is not—see below), allowing that fact to categorically preclude claims for product-caused injuries from being brought under Section 311 would turn the law of product liability against the very constituency it was designed to help.

The doctrine of strict product liability, first adopted in *Greenman v. Yuba Power Prods.* (1963) 59 Cal. 2d 57, 63, was intended to *assist* consumers and advance overall social goals by eliminating the need to prove fault in cases involving defective products. (*Ibid.*; see generally David G. Owen, *The Evolution of Products Liability* Law (2007) 21 Rev. Litig. 955, 966–974.) But Novartis and its amici seek to use the doctrine of strict liability as a *sword* against injury victims, arguing that product-liability claims were intended to displace all other available remedies, even where the plaintiffs can prove the defendant was negligent and would otherwise be left without any remedy. That cannot be how the law was intended to apply.

That aside, amici's argument that there is no real difference between negligent-misrepresentation claims and strict-

liability claims—and, as a result, that the former should be subject to the same "instrumentality" requirement as the latter—is wrong on its own terms, as the Alabama Supreme Court held in *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649.)

There, as here, the brand-name manufacturer argued that because the plaintiff's negligent-misrepresentation claim alleged physical injuries caused by a product, "the plaintiff must prove that the defendant manufactured the product the plaintiff claims injured him." (*Id.* at p. 656.) In rejecting this argument, *Weeks* explained that negligent misrepresentation "is *not* a claim that the drug ingested by [plaintiff] was defective; instead, it is a claim that Wyeth fraudulently misrepresented or suppressed information about the manner in which (i.e., the duration) the drug was to be taken." (*Id.* at p. 658.) And, because the plaintiff's claim was based "on what Wyeth said or did not say about Reglan and their assertion that those statements or omissions caused [plaintiff's] injuries ...," there was no basis for concluding that the misrepresentation claim "[was] in substance a products-liability claim." (*Id.* at p. 658.)[3]

[3] (See also *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 385-389 (Iowa 2014) (conc. & dis. opn. of Hecht, Wiggins, and Appel, JJ.)

The flawed attempt to equate negligent-misrepresentation claims with strict-liability claims was one of the central errors in *Foster v. American Home Products, Inc.*, 29 F.3d 165 (4th Cir. 1994), the ruling underlying the "mountain" of authority cited by amici. (See *Prescription for Fairness*, *supra*, 60 Duke L. J. at p. 1164.)

Weeks criticized *Foster* on this point, concluding that, "[b]ecause a warning label is not a part of the manufacturing process, we do not agree that the fact that a brand-name manufacturer did not produce the version of the drug ingested by the plaintiff bars the plaintiff's tort action [based on] failure to warn." (*Weeks*, 159 So.3d at p. 670.)

Foster and its progeny all make the same basic error: they fail to understand that where, as here, a brand-name manufacturer is being sued for negligently misrepresenting the defects of its own product, the fact that it did not make the product that injured the plaintiff is irrelevant to the underlying cause of action. The question, rather, is whether the

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[disagreeing with majority's imposition of instrumentality requirement and collecting cases rejecting same in product-liability context.])

manufacturer's wrongdoing with respect to its *own product* is the proximate cause of the plaintiff's injuries.

The policies underlying strict products liability make clear why the defendant's liability in such cases is tied to its status as the supplier or manufacturer of the injury-causing product. As reaffirmed in *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, the core rationale behind strict product liability "is to insure that the costs of injuries resulting from defective products *are borne by the manufacturers that put such products on the market* rather than by the injured persons who are powerless to protect themselves." (*Id.*, emphasis added.)

It thus makes sense that strict-liability claims can only be brought against the manufacturer of the product that caused the injury—that is the only way to achieve the cost-spreading goal behind strict liability. In contrast, in the context of a negligent-misrepresentation claim, the need to establish fault by the defendant obviates the need to strictly limit liability to those who made or sold the offending product. (See, e.g., *Hanberry, supra,* 276 Cal.App.2d at p. 686.)

Put another way, the reason for the instrumentality requirement in the strict-liability context—to ensure that the cost

of injuries are borne by the offending product's *manufacturer*—is simply not present in the negligence context, where the overriding consideration is not one of social cost spreading but rather determination of *fault*.

4. Amici's "Instrumentality" Case Law Does Not Help Its Cause.

Amici's main instrumentality case is *Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588, 597, which they cite for the proposition that, as a "general rule, the imposition of liability depends upon a showing that the plaintiff that his or her injuries were caused *by the act of the defendant* **or** *by an instrumentality under the defendant's control.*" (See U.S. Chamber of Commerce Br., p. 3, emphasis added.) As the bolded word in that sentence reveals, *Sindell* permits liability where the plaintiffs' injuries were caused by "[an] act of the defendant." (*Id.*) And in this case, Plaintiffs allege that their injuries *are* caused by "an act of the defendant"—specifically, Novartis's act of negligently misrepresenting the serious risks of its product to the developing fetal brain.

Where amici go wrong is by confusing negligent *design-defect* claims (which were alleged in *Sindell*) with negligent-

misrepresentation claims (which are alleged here). When it comes to the former, it makes sense to require that the defendant have made the injury-causing product, because the wrongdoing is *inseparable* from the "instrumentality." Again, the focus is on the *product*, not the defendant's conduct.

But in negligent-misrepresentation cases, the inquiry is whether the defendant misrepresented the facts and, if so, whether those *misrepresentations* presented a foreseeable risk of harm to a third party. The fact that, here, the "instrumentality" that injured Plaintiffs was another manufacturer's product does nothing to lessen the extent of Novartis's wrongdoing.

Amici's reliance on *Merrill v. Navegar* (2001) 26 Cal.4th 465, is equally misplaced. (See PLAC Br., p. 20.) *Merrill* held that a statute prohibiting "product-liability" claims against gun manufacturers barred the plaintiffs' negligence claim because the "allegations squarely fit within the risk/utility test for defective design that applies in a products liability action under both negligence and strict liability theories." (*Id.* at p. 481.) Properly understood, *Merrill* merely stands for the proposition that a statutory reference to "product liability" should be read broadly where doing so was necessary to effectuate the statute's manifest

purpose. (E.g., *id.* at p. 493 (conc. opn. of Kennard, J. ["The task of the judiciary is to interpret those statutes by ascertaining and effectuating the Legislature's intent. It is not for us to question the wisdom of the Legislature's considered judgments."].)

Kesner v. Superior Court (2016) 1 Cal. 5th 1132, does not further amici's cause either. Amici argue that *Kesner* supports their "instrumentality" theory because, there, the asbestos fibers that employees carried home from their workplace constituted "an instrumentality linking the defendant's alleged negligence with the plaintiffs' harm." (See Chamber Br., pp. 3–4, fn. 1.)

This argument improperly assumes that there must be some sort of physical "instrumentality" (such as asbestos fibers) linking a defendant's negligence and the plaintiffs' injuries. This Court has never held such a thing—neither *Garcia* nor *Randi W.* involved any kind of "physical instrumentality" linking the defendant and the plaintiff—and such a rule would make no sense in a negligent-misrepresentation case, where the very essence of the claim is informational in nature.

That aside, amici fail to recognize that, if anything, this is a far more persuasive case for recognition of a tort duty than *Kesner*. There, the predominant focus was the foreseeability of

the hazard (i.e., secondary exposure from asbestos fibers). (*Kesner*, *supra*, 1 Cal.5th at pp. 1145–1149.) But because, under the federal scheme, *all* warnings associated with a drug—brand-name or generic—are dictated by the brand-name manufacturer, the fact that consumers of generic drugs will rely on warnings issued by a brand-name manufacturer is at least as foreseeable as the secondary exposure this Court deemed foreseeable in *Kesner*.

And while the defendants' control over airborne asbestos fibers was a factor in *Kesner*, the control that brand-name manufacturers exert over *any* warnings associated with *any* form of their drug is *at least* as strong as the degree of control that landowners and employers have over stray asbestos fibers clinging to their employees' and visitors' clothing.

Stripped of these cases, all that amici are left with is *O'Neil v. Crane Co* (2012) 53 Cal.4th 553, which they argue established an instrumentality requirement for both strict-liability *and* negligence claims. Because *O'Neil* is addressed at length in Plaintiffs' Answer Brief (at pp. 28–36), Plaintiffs merely reemphasize one key point:

O'Neil helps *Plaintiffs*, not Novartis, because it reaffirmed the distinction between strict-liability and negligence claims. As to the former, *O'Neil* held that "a product manufacturer generally may not be held *strictly liable* for harm caused by another manufacturer's product." (*Id.* at p. 362, emphasis added.) But as to the latter, *O'Neil* applied the *Rowland* factors to determine whether to create an exception to the general duty of care under California law (*id.* at pp. 364–366), just as the Court of Appeal did in *Conte* and the decision below, and just as Plaintiffs ask the Court to do here.

If, as amici contend, *O'Neil* intended to categorically preclude negligence claims for product-caused injuries against defendants who did not make the injury-causing product, then why did *O'Neil* bother with a *Rowland*[4] analysis of the plaintiffs' negligence claim? Amici have no answer to that question, which is not surprising, for there is none.

5. Amici's Policy Arguments in Support of their "Instrumentality" Theory Lack Merit.

Amici insist that affirming the lower court's decision would result in an unprecedented "slippery slope" of tort liability by

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[4] (See *Rowland v. Christian* (1968) 69 Cal.2d 108, 112.)

allowing plaintiffs to sue companies for injuries caused by products they didn't make—including generically identical products (e.g., chlorine bleach), high-tech products, and counterfeit goods. (E.g., PLAC Br. at p. 24.)

This argument overlooks a crucial distinction between ordinary consumer goods and pharmaceutical drugs that undermines amici's "slippery slope" argument: Makers of ordinary consumer goods have *sole discretion* regarding the content of their own warning labels. In contrast, brand-name prescription drug manufacturers dictate the content of *all* warnings associated with that drug, whether brand-name or generic. (See *Mensing*, *supra*, 564 U.S. at p. 613.)

This matters because, in any case involving allegedly inadequate product warnings, the law presumes the plaintiff would have escaped injury if an adequate warning appeared on the product the plaintiff actually used. (See, e.g., *Johnson v. American Standard, Inc.* (2008) 43 Cal.4th 56, 65.)

And because, in the context of ordinary consumer goods, the absence of an adequate warning on the product the plaintiff actually used was solely the fault of the manufacturer of that product, the causal nexus between the plaintiff's injuries and

warnings issued by *another* company is inherently—if not fatally—attenuated.

But because the absence of adequate warnings on any generic drug label is the direct result of choices made by the *brand-name* manufacturer of that drug, the causal chain between the brand-name manufacturer's negligence in crafting those warnings and the plaintiff's resulting injury is inherently direct.

This distinction makes all the difference from a causal perspective. (E.g., *State Department of State Hospitals v. Superior Court* (2015) 61 Cal.4th 339, 356 [holding that causal chain between negligent omission and injury severed where occurrence of injuries depended on independent, discretionary acts of third parties].) Thus, existing tort rules would prevent amici's doomsday "slippery slope" of tort liability without the need to impose new and artificial limits on the tort of negligent misrepresentation.

* * *

In short, amici's attempt to derail this case by importing an "instrumentality" requirement from the law of products liability fails on all fronts. This case addresses whether brand-name manufacturers should be held liable for violation their *own* duty