

No. S233898

SUPREME COURT  
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IN THE SUPREME COURT  
OF THE STATE OF CALIFORNIA

Deputy

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

*Plaintiffs and Appellants,*

v.

NOVARTIS PHARMACEUTICALS  
CORPORATION,

*Defendant and Respondent.*

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

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REPLY BRIEF ON THE MERITS

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## INTRODUCTION

The Court of Appeal dismantled “the boundaries established over decades of product liability law,” *O’Neil v. Crane Co.* (2012) 53 Cal.4th 335, 365, which limit a manufacturer’s liability to injuries caused by its own products. Novartis Pharmaceuticals Corporation did not manufacture either of the generic drugs alleged to have caused Plaintiffs’ injuries. But the Court of Appeal held this dispositive fact irrelevant and imposed a negligence duty on Novartis because: (1) six years prior to Plaintiffs’ alleged injuries, Novartis had produced a branded version of the generic drugs at issue (the “former manufacturer duty”) and (2) the generic drug manufacturers provided the same label warnings as the manufacturer that had purchased the branded drug product line from Novartis (the “innovator duty”).

In asking this Court to uphold the Court of Appeal’s extraordinary ruling, Plaintiffs misstate *O’Neil* and *Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588, both of which categorically reject the imposition of a negligence duty on manufacturers for failure to warn about injuries caused by other manufacturers’ products. Plaintiffs also misconstrue the Restatement (Second) of Torts, which, as applied by this Court, requires a direct connection between a defendant and an alleged injury-producing product or actor for a duty to arise. Plaintiffs posture that the proposed rule is “longstanding” and “deeply rooted” in California’s tort law. (ABOM:23, 26.) The opposite is true. (*O’Neil, supra*, 53 Cal.4th 335; *Sindell, supra*, 26 Cal.3d 588; see *Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513.)

The Court of Appeal did not and Plaintiffs do not cite any case in the history of California jurisprudence (or anywhere else) in which a negligence duty has been imposed arising from a defendant’s status as a

former manufacturer. No such case exists. Plaintiffs' policy-based arguments in favor of a former manufacturer duty fare no better. Plaintiffs ignore the comprehensive federal regulatory regime for prescription drugs that imposes a duty to warn exclusively on current drug manufacturers and expressly prohibits former drug manufacturers from making any safety representations about their prior products. Plaintiffs likewise ignore routine due diligence practices and settled contract law that prevent their bogeyman scenario of a manufacturer earning a windfall profit by selling off a product line without disclosing product risks. The proposed duty would serve only to protect subsequent manufacturers who fail to update warning labels (so as to increase their own sales), by allowing them to point the finger back to a former manufacturer.

Plaintiffs likewise cannot dispute the overwhelming judicial rejection of the Court of Appeal's additional proposed duty on innovator manufacturers. (See generally *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.* (6th Cir. 2014) 756 F.3d 917, 938-939.) Imposition of an innovator duty would disrupt a carefully constructed two-tiered prescription drug market created under federal law to spur innovation while constraining drug costs. This regulatory scheme relies upon the continued presence of the innovator or brand manufacturer – *i.e.*, the holder of the New Drug Application (“NDA”) – after generic manufacturers enter the market, even as the brand manufacturer's market share rapidly diminishes. If the cost of this diminished market share is expansive liability for competitor generic drugs, brand manufacturers will sever their association with the drugs by withdrawing their NDAs, leaving the public without a key player in ongoing safety monitoring and labeling, and chilling research into new uses of existing drugs..

The Court of Appeal's flawed decision should be reversed.

## LEGAL ARGUMENT

The “scope of defendants’ duty, and the existence of duty is a pure question of law.” (*O’Neil, supra*, 53 Cal.4th at pp. 363-364.) The Court of Appeal imposed two duties to warn consumers of another manufacturer’s product, each of which is a necessary part of plaintiffs’ negligence claim against Novartis. First, the Court of Appeal imposed a duty on former drug manufacturers that extends indefinitely to consumers of the drug subsequently manufactured by others. Second, the Court of Appeal imposed a duty on innovator drug companies that extends over the entire market to consumers of competing drug companies’ copy-cat generic drugs. These rulings were in error.

This Court has stressed the vital importance of delineating duty so as to prevent unlimited escalations of tort liability. There “are clear judicial days on which a court can foresee forever and thus determine liability but none on which that foresight alone provides a socially and judicially acceptable limit on recovery of damages for [an] injury.” (*Erlich v. Menezes* (1999) 21 Cal.4th 543, 552.) This judicial limit serves as a necessary check on the creativity of plaintiffs’ counsel, who otherwise would be able to inundate the courts with all manner of cases alleging “foreseeable” consequences of corporate conduct.<sup>1</sup> The Court of Appeal’s

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<sup>1</sup> Plaintiffs’ allegations in this case amply demonstrate the lengths of plaintiffs’ counsel’s creativity. Plaintiffs offer no factual bases for their outlandish claims that Novartis concealed safety information to earn a windfall profit when it sold the Brethine NDA in 2001 or that Novartis had any reason to expect that the company that purchased the NDA (aaiPharma) would ignore subsequent scientific research allegedly demonstrating a safety risk. To the contrary, the same FDA Citizen’s Petition cited by Plaintiffs (ABOM:16, fn. 7) concluded in 2011 – *some 10 years after Novartis sold its NDA* – that “[a]t the present time, it is not possible to draw conclusions regarding an association between terbutaline exposure in utero and autism.” See FDA Response to Citizen’s Petition (Feb. 17, 2011), at p.

broad imposition of two separate duties on Novartis to warn about drugs it did not manufacture blew past this limit and is contrary to California law.

**I. CALIFORNIA LAW REJECTS THE IMPOSITION OF A NEGLIGENCE DUTY OWED TO CONSUMERS INJURED BY ANOTHER MANUFACTURER'S PRODUCT.**

Plaintiffs' argument that Novartis owes them a duty to warn consumers of two other manufacturers' drug products is directly contrary to *O'Neil* and *Sindell* and disregards well-established California law. (*Garcia v. Joseph Vince Co.* (1978) 84 Cal.App.3d 868, 874 ["Regardless of the theory which liability is predicated upon, whether negligence, breach of warranty, strict liability in tort, or other grounds, it is obvious that to hold a producer, manufacturer, or seller liable for injury caused by a particular product, there must first be proof that the defendant produced, manufactured, sold, or was in some way responsible for the product . . . ."].)<sup>2</sup>

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13, <<http://www.fda.gov/downloads/drugs/drugsafety/ucm243797.pdf>> [last accessed Nov. 4, 2016]. Plaintiffs' allegations regarding off-label promotion likewise ignore the undisputed fact that the Brethine label in 2001 included a warning against the use of the drug as a tocolytic. (ABOM:16 & fn. 7.)

<sup>2</sup> In *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063, this Court pointed to the unique and critical value of prescription drugs and warned against expansive theories of tort liability in prescription drug litigation. Relying on *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, Plaintiffs contend this concern should not immunize "Big Pharma" from tort liability, pointing to the fact that pharmaceutical companies are subject to the same type of strict liability failure to warn claims as other product manufacturers. But the question here is whether this Court should impose unique and more expansive duties on pharmaceutical manufacturers, duties *that do not exist for any other industry*. It should not.

**A. *O'Neil* holds that a product manufacturer may not be held liable in negligence for harm caused by another manufacturer's product.**

*O'Neil* is clear and unequivocal. Save for two exceptions (neither of which applies here), *O'Neil* “hold[s] that a product manufacturer may not be held liable *in strict liability or negligence* for harm caused by another manufacturer's product.” (*O'Neil*, 53 Cal.4th at p. 342 [emphasis added].)

Remarkably, Plaintiffs dismiss this holding as “a stray quote from the beginning of the decision.” (ABOM:30, fn. 10.) Plaintiffs argue instead that *O'Neil*'s holding “only applies to strict liability claims, not negligence claims,” pointing to a sentence buried some 20 pages into the opinion at the end of this Court's strict liability analysis. (*Id.* at pp. 29-30 [quoting *O'Neil, supra*, 53 Cal.4th at p. 362].) Plaintiffs simply ignore this Court's explanation in its subsequent negligence analysis that “[t]he same policy considerations that militate against imposing strict liability in this situation [of harm caused by another manufacturer's product] apply with equal force in the context of negligence.” (*O'Neil, supra*, 53 Cal.4th at p. 366.)

*O'Neil* repeatedly explains that its holding applies to both strict liability and negligence claims. *O'Neil* states that the fact that “the defendant manufactured, sold, or supplied the injury-causing product is a separate and threshold requirement that must be independently established. Moreover, in strict liability *as in negligence*, ‘foreseeability alone is not sufficient to create an independent tort duty.’” (*O'Neil, supra*, 53 Cal.4th at p. 362 [emphasis added].) *O'Neil* cites favorably to the Washington Supreme Court's holding that “the duty to warn, *in negligence* or strict liability, extends only to those entities in the chain of distribution of a hazardous product” and “[t]he general rule [is] that there is no duty under

common law products liability *or negligence* principles to warn of the dangers . . . in other manufacturers' products." (*Id.* at p. 356 [emphasis added] [citing *Simonetta v. Viad Corp.* (Wash. 2008) 197 P.3d 127, 133-134, 138; *Braaten v. Saberhagen Holdings* (Wash. 2008) 198 P.3d 493, 495].) The heading for *O'Neil's* analysis of plaintiff's negligent failure-to-warn claim likewise is unambiguous – there is “no duty of care to prevent injuries from another manufacturer's product.” (*O'Neil, supra*, 53 Cal.4th at p. 363.)

Plaintiffs' argument that strict liability and negligence are distinct causes of action misses the point. (ABOM:32.) *O'Neil* recognizes this distinction and properly analyzes each claim separately. But *O'Neil* holds that a plaintiff must – ***under both theories*** – satisfy the same threshold requirement that the defendant manufacturer manufactured the alleged injurious product. (*O'Neil, supra*, 53 Cal.4th at p. 362.)

*O'Neil's* rejection of a negligence duty under *Rowland v. Christian* (1968) 69 Cal.2d 108 is categorical and in no way limited to the facts before the Court.<sup>3</sup> For each of the *Rowland* factors, *O'Neil* explains that the balance weighs against imposing a negligence duty whenever a product manufacturer is sued for injury caused by another manufacturer's product.

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<sup>3</sup> The only case-specific fact cited by *O'Neil* in its *Rowland* analysis is the passage of time between the defendant's sale of its product and the plaintiff's alleged exposure, which the Court considered in analyzing the “closeness of the connection” factor. (*O'Neil, supra*, 53 Cal.4th at p. 364.) Even there, the fact provided only secondary support to the Court's primary finding that a defendant who does not manufacture, sell, or supply the alleged injury-causing product is extremely remote from the alleged injury. (*Ibid.*) In this case, of course, Plaintiffs want the Court to create a duty to warn consumers of other manufacturer's products that extends indefinitely, even decades after a defendant left the market entirely. (ABOM:69.)

(*O'Neil, supra*, 53 Cal.4th at p. 365; OBOM:19-20.) *O'Neil* concludes its negligence analysis with a broad repudiation of such a duty:

In short, expansion of the duty of care as urged here would impose an obligation to compensate on those whose products caused no harm. To do so would exceed the boundaries established over decades of product liability law. [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, internal citation omitted.)

Plaintiffs' attempt to distinguish *O'Neil* on its facts is misguided. Plaintiffs argue that "the key fact that makes [this case] different from *O'Neil*" is that "even though Plaintiffs were injured by another manufacturer's product, Novartis is being sued for breaching its own independent duty with regard to its own product." (ABOM:36.) Plaintiffs stress that they do not contend Novartis is liable for doing – or not doing – anything after it sold the Brethine NDA in December 2001. (ABOM:21.) But that is the same argument rejected in *O'Neil*. (See *O'Neil, supra*, 53 Cal.4th at p. 347 [reversing Court of Appeal's ruling that defendants could be liable because if they "had warned the hypothetical original user [of their own products], or protected that person by avoiding defective design, subsequent users, too, would have been protected"].) The *O'Neil* defendants likewise owed a duty to warn of risks posed by their own pre-replacement asbestos-containing products, and they have been held liable for negligent failure to warn in cases in which plaintiffs were exposed to their products. (*Paulus v. Crane Co.* (2014) 224 Cal.App.4th 1357, 1360 & fn. 2; *Faddish v. Warren Pumps, LLC* (E.D.Pa. Oct. 22, 2010, Civ. A. No. 09-70626) 2010 WL 4178337, \*1, \*2.) *O'Neil* holds, however, that this

negligence duty cannot be extended to injuries caused by another manufacturer's product.

**B. *Sindell* rejects the proposed negligence duty in pharmaceutical cases.**

The duty to warn about another manufacturer's product likewise was rejected specifically in the context of pharmaceutical products litigation in *Sindell v. Abbott Laboratories, supra*, 26 Cal.3d at p. 605. *Sindell* holds that a drug manufacturer may not be held liable "if it could be demonstrated that the product which caused the injury was not made by the defendant." (*Ibid.*) Plaintiffs dismiss this holding in a footnote, claiming that *Sindell* is inapposite because it "involve[d] strict-product liability claims, not negligent-misrepresentation claims." (ABOM:36, fn. 14.) Not so.

In *Sindell*, the plaintiff's first cause of action alleged "that defendants were jointly and individually *negligent* in that they manufactured, marketed and promoted [the drug at issue]... *without adequate testing or warning.*" (*Sindell, supra*, 26 Cal.3d at p. 595 [emphasis added]; see also *id.* at p. 601.) The *Sindell* plaintiff relied on *Summers v. Tice* (1948) 33 Cal.2d 80 and *Orser v. George* (1967) 252 Cal.App.2d 660, both of which addressed negligence (see *Sindell, supra*, 26 Cal.3d at pp. 598-599, 606), and on the Restatement Second of Torts, section 433B, which is part of the Restatement's Chapter 16 discussion of the "Causal Relationship Necessary to Responsibility for Negligence." (*Id.* at p. 599.) Aside from a passing reference to plaintiff's other causes of action (*id.* at p. 595), the doctrine of strict liability played no role in *Sindell*'s holding.

In *Jolly v. Eli Lilly & Co.* (1988) 44 Cal.3d 1103, 1108, 1115, the Court confirmed that its ruling in *Sindell* was based on negligent failure to

warn. And the Court again held that such a negligence claim cannot lie against a drug company for an injury caused by another manufacturer's drug. (*Id.* at p. 1115 & fn. 15.)

**C. The Restatement of Torts does not support the proposed negligence duty.**

Nor does Restatement Second of Torts, sections 310 and 311, support the negligence duties proposed by the Court of Appeal. Sections 310 and 311 provide that a party may be liable for a misrepresentation to a third party if it is foreseeable that such misrepresentation may cause an injury to the plaintiff. But sections 310 and 311 only apply if the misrepresentation is specific to the product or chattel that is alleged to have caused harm. (*Id.*, § 310, coms. b-c, pp. 103-105; § 311, coms. c-e, pp. 107-109.)

Comment b to section 310 explains that a party may be liable for a misrepresentation “concerning the physical condition of a thing” giving rise to injury such as “the ice on a certain pond” or a “bottle of whiskey.” Comment c to section 310 explains that a party may be liable when the party “actively conceal[s] a defect” in a particular chattel such as “a defective wheel or axle” of an automobile. Likewise, the illustrations to comments c, d, and e of section 311 discuss misrepresentations regarding the specific alleged injury-causing products, such as a “tombstone” and a “boiler.” None of the comments to these Restatement sections suggest liability based on representations regarding a different product.

Aside from *Conte* – which has been uniformly rejected – the California cases cited by Plaintiffs to support their construction of the Restatement involve defendants who made misrepresentations about the injury-causing product or individual. The defendant in *Hanberry v. Hearst*

*Corp.* (1969) 276 Cal.App.2d 680, 683, placed its Good Housekeeping seal of approval on the product alleged to have caused the plaintiff's injury. On those facts, the Court held that "[s]ince the very purpose of [the defendant's] seal and certification is to induce consumers to purchase products so endorsed, it is foreseeable certain consumers will do so, relying upon respondent's representations concerning them, in some instances, even more than upon statements made by the retailer, manufacturer or distributor." (*Id.* at p. 684.) The defendant in *Garcia v. Superior Court* (1990) 50 Cal.3d 728, 733, made assurances to the plaintiff-decedent that she was safe from the individual who subsequently killed her. The defendants in *Randi W. v. Muroc Joint Unified School Dist.* (1997) 14 Cal.4th 1066, 1081, provided letters of recommendation for a school administrator – who subsequently molested several students – without disclosing their knowledge of that administrator's history of sexual misconduct.

In sharp contrast, our Plaintiffs concede that Novartis made no representation whatsoever regarding the generic terbutaline drugs that allegedly caused their 2007 injuries. (ABOM:21.) Sections 310 and 311 do not apply.

## **II. NEITHER CALIFORNIA LAW NOR CALIFORNIA POLICY SUPPORTS THE COURT OF APPEAL'S BREAK FROM ESTABLISHED PRECEDENT TO ADOPT A NOVEL "FORMER MANUFACTURER" THEORY OF LIABILITY.**

### **A. The Court of Appeal imposed a duty on Novartis as a former manufacturer that is unprecedented in California and in the United States generally.**

The Court of Appeal's imposition on Novartis of a duty to warn about a product sold by other manufacturers six years after Novartis left the

market is unprecedented and contrary to a solid wall of legal authority. Plaintiffs do not – because they cannot – point this Court to any other case imposing the Court of Appeal’s proposed duty. Nor do they explain why the Court should depart from the holdings in *O’Neil, Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513, *Gansberger v. Rockwell Internat. Corp.* (9th Cir. Aug. 9, 1990, No. 89-15687) 911 F.2d 738 [1990 WL 115595], or any of the similar holdings across the country rejecting such a duty in both pharmaceutical and non-pharmaceutical cases. (OBOM:25, 29, fns. 8, 10.)

Plaintiffs offer three suggestions to counter or distinguish the collective wisdom of every court – including this Court – that has rejected their proposed former manufacturer duty.

***First***, Plaintiffs suggest (incorrectly) that *O’Neil* does not involve a former manufacturer. (ABOM:35, 70.) While *O’Neil* arose in a component parts setting, the plaintiff there also sought to hold defendants liable for their alleged failure to warn about their original asbestos-containing gaskets and packing, which warning plaintiff alleged would have protected him against injury from the subsequent manufacturer’s identical replacement parts. (*O’Neil*, 53 Cal.4th at p. 347.) If this “former manufacturer” duty had been accepted, the Court would not need to have considered the additional component parts argument.

***Second***, Plaintiffs suggest that prior (and uniformly adverse) case law all turned on a determination that the former manufacturer could not have foreseen that a subsequent manufacturer would continue to provide (or fail to provide) the same product warnings. (ABOM:56, fn. 19.) Plaintiffs are wrong. Plaintiffs cite only to *Cadlo, supra*, 125 Cal.App.4th at pp. 517-518, but foreseeability was a certainty there – plaintiff specifically alleged

that the former manufacturer had “approved [the subsequent manufacturer’s] failure to warn of the known hazards of [the product],” “agreed [with the subsequent manufacturer] to the fraudulent concealment of [the product’s] hazardous qualities and agreed not to warn purchasers during the course of their distribution agreement” extending 5 years after the sale of the product line. Nonetheless, *Cadlo* held that the foreseeable consequences of the former manufacturer’s pre-divestment warnings could not support a finding of liability based on post-divestment product injury. (*Id.* at p. 520 [noting that “[a]fter 1958, Owens-Illinois made no representations about Kaylo, false or otherwise”].)

Plaintiffs have it exactly backwards in their related argument that FDA regulations make it more foreseeable that a subsequent manufacturer would leave the former manufacturer’s label unchanged. A drug company that purchases an NDA is subject to independent legal obligations under federal statute to update product warnings immediately upon obtaining the NDA and on an ongoing basis thereafter as soon as reasonable evidence of a health hazard emerges. (21 C.F.R. §§ 314.72, 201.80(e).)<sup>4</sup> A new NDA holder that fails to meet those responsibilities is subject to a host of FDA enforcement actions. (21 C.F.R. §§ 331(a)(b)(ii), 332, 333(b), 334, 335a, 335b.) Thus, again, in every pharmaceutical case in which this former manufacturer duty has been alleged, it has been rejected. (E.g., *Lyman v.*

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<sup>4</sup> Plaintiffs inexplicably cite 21 U.S.C. § 355 and 21 C.F.R. § 314.105(b) as requiring a new NDA holder to use the same warning label used by the prior NDA holder. (ABOM:53.) They do not. 21 U.S.C. § 355 sets forth broad obligations for NDA holders generally and in fact requires new NDA holders to monitor safety information and to keep labeling up to date. (*Id.* at § 355(o).) 21 C.F.R. § 314.105(b) likewise addresses NDA holders generally and provides that the FDA will not approve drug labeling if it does not contain appropriate safety warnings.

*Pfizer, Inc.* (D.Vt. July 20, 2012, No. 2:09-cv-262) 2012 WL 2970627, \*16-17.)

***Third***, Plaintiffs suggest that none of the prior cases rejecting former manufacturer liability involved a negligent misrepresentation claim. (ABOM:71.) Plaintiffs again are incorrect. (See *Cadlo, supra*, 125 Cal.App.4th at pp. 519-521 [demurrer properly sustained on negligent misrepresentation claim]; *In re Darvocet, Darvon and Propoxyphene Products Liability Litigation* (E.D.Ky. Mar. 7, 2012, Master File No. 2:11-md-2226-DCR) 2012 WL 767595, \*6-8 [former manufacturer not liable under product liability or misrepresentation theories]; *Lyman, supra*, 2012 WL 2970627, \*16-18 [dismissing negligence and fraudulent misrepresentation claims]; *In re Minnesota Breast Implant Litig.* (D.Minn. 1998) 36 F.Supp.2d 863, 873 [same].)

**B. The Court of Appeal's proposed duty would create a disincentive for subsequent manufacturers to update warnings.**

The Court of Appeal's proposed former manufacturer duty rests on the proposition that a subsequent drug manufacturer maintains the warning language used by the former manufacturer. (ABOM:63-64.) As Plaintiffs admit, only an actual change in the warning by the subsequent manufacturer would break the proposed chain of causation back to the former manufacturer. (*Ibid.*)<sup>5</sup>

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<sup>5</sup> Plaintiffs' reliance on *Cline v. Watkins* (1977) 66 Cal.App.3d 174 is misplaced. (ABOM:5.) In *Cline*, the defendant attorney had a direct fiduciary relationship with the plaintiff, and the issue before the Court was whether his direct negligence in failing to identify community property in a divorce action was excused by a subsequent attorney's failure to correct the error. Here, Novartis had no direct relationship with Plaintiffs.