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

REPLY IN SUPPORT OF PETITION FOR REVIEW

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INTRODUCTION

Plaintiffs' Answer to Novartis's Petition for Review demonstrates the fundamental confusion arising from the Court of Appeal's erroneous opinion and the need for this Court's review to settle important questions of law on the scope of duty for harm caused by another manufacturer's product and to secure uniformity of decision in California courts. The issues before this Court do not turn on any questions of fact, which were undisputed for purposes of appeal. Rather, they turn on "the scope of defendant's duty, and the existence of a duty is a pure question of law." (*O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 363-364.)

Plaintiffs acknowledge that the Court of Appeal imposed two separate duties of care on Novartis for injuries allegedly caused by other manufacturers' products: (1) a duty by which a prior manufacturer must warn users of a subsequent manufacturer's products and (2) a duty by which a manufacturer of a brand product must warn users of a competitor's generic copy-cat products. (Ans. 10.) That admission reveals the need for this Court's review. *O'Neil*, *supra*, 43 Cal.4th 335 and *Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513 reject both of the duties imposed here as a matter of law. Plaintiffs' attempt to avoid the plain conflict created by the Court of Appeal's opinion results in mischaracterizations of those prior California decisions.

Plaintiffs dismiss as "overblown" and "abstract" the policy concerns set forth in Novartis's Petition for Review. However, this Court expressly flagged those very policy concerns in *O'Neil*, *supra*, 43 Cal.4th 335 and *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063-1064, in rejecting the imposition of the type of overly-broad tort law duties imposed by the Court of Appeal in this case.

The legal principles and policy concerns that informed the decisions in *O'Neil*, *supra*, 43 Cal.4th 335 and *Cadlo*, *supra*, 125 Cal.App.4th 513 to maintain "the boundaries established over decades of product liability law" (*O'Neil*, *supra*, 53 Cal.4th at p. 365) likewise have led other courts across the country to overwhelmingly reject the Court of Appeal's overbroad definition of duty, both as to prior manufacturers and as to brand manufacturers. Plaintiffs contend that this Court should embrace the Court of Appeal for not "playing it safe and sticking with the majority." (Ans. 33.) To the contrary, it is the dangerous and largely unprecedented nature of the Court of Appeal's opinion that compels this Court's review.

I. THIS COURT'S REVIEW IS NECESSARY TO SETTLE THE LEGAL QUESTION WHETHER CALIFORNIA LAW IMPOSES DUTIES OF CARE TO CONSUMERS ALLEGEDLY INJURED BY ANOTHER MANUFACTURER'S PRODUCT.

In their attempt to avoid the conflict between the Court of Appeal's opinion and existing California law, Plaintiffs mischaracterize *O'Neil*, *Cadlo*, and various provisions of the Restatement (Second) of Torts.

A. The Court of Appeal's Opinion Conflicts with *O'Neil*.

Plaintiffs contend this Court's rejection of the negligence claims in *O'Neil* "was *not* predicated on the bare fact that the plaintiff's injuries were caused by another company's product" but was predicated instead on "the highly specific context of that case." (Ans. 16-17.) But this Court's holding was categorical and specifically intended to set forth a bright line prohibition of such claims, absent two exceptions that Plaintiffs concede do not apply here (Ans. 16): "We hold that a product manufacturer *may not be held liable* in strict liability or negligence for harm caused by another manufacturer's product unless the defendant's own product contributed substantially to the harm, or the defendant participated substantially in

creating a harmful combined use of the products." (*O'Neil*, *supra*, 53 Cal.4th at p. 342, italics added.) This Court explained that its holding applied regardless whether an individual plaintiff could present facts whereby such a defendant might have foreseen the possibility of injury from its alleged conduct:

> In short, expansion of the duty of care as urged here would impose an obligation to compensate on those whose products caused the plaintiff 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 . . . . 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 pp. 365-366, citation and quotation marks omitted.)

In so holding, this Court rejected a foreseeability argument that is markedly similar to the argument adopted by the Court of Appeal here. (*O'Neil*, *supra*, 53 Cal.4th at p. 347 [reversing Court of Appeal's ruling for plaintiff, which was based on plaintiff's argument that "[i]f respondents had warned the hypothetical original user, or protected that person by avoiding defective design, subsequent users, too, would have been protected."].)

Plaintiffs' other attempts to distinguish *O'Neil* are likewise without merit. Plaintiffs misstate the factual setting of *O'Neil*, suggesting the defendants in that case had never manufactured the types of asbestos-containing insulation and gaskets alleged to have caused that plaintiff's injuries and that the alleged hazards accordingly were "wholly independent of traits or characteristics of the defendant's own product." (Ans. 17.) But this Court explained that the defendants had included asbestos-containing insulation and gaskets in their original valves and pumps. (*O'Neil*, *supra*, 53 Cal.4th at p. 344.) Thus, both defendants have been held liable in other

asbestos personal injury cases for alleged exposures to the insulation and gaskets in those valves and pumps. (*Paulus v. Crane Co.* (2014) 224 Cal.App.4th 1357, 1364-1365; *McIntyre v. Warren Pumps LLC* (N.D.Cal. Apr. 30, 2007, No. C 06-06301 WHA) 2007 WL 1279638, *5.) The issue in *O'Neil*, as here, was whether those manufacturers could be liable for their manufacture of — and alleged failure to warn about — the original asbestos-containing insulation and gaskets when the plaintiff's alleged injuries were caused by a subsequent manufacturer's identical replacement parts. (*O'Neil*, *supra*, 53 Cal.4th at p. 347.) *O'Neil* held they could not.

Plaintiffs misapprehend *O'Neil's* footnote treatment of *Powell v. Standard Brands Paint Co.* (1985) 166 Cal.App.3d 357. (Ans. 18-19.) This Court rejected Mr. O'Neil's reliance on *Powell* because that court's musings about "generically identical" products were mere dicta. Had this Court agreed with such musings, it would have reached a different result because it was undisputed that the replacement gaskets and insulating materials alleged to have caused Mr. O'Neil's injuries were generically identical to those contained in the defendants' original products. (*O'Neil*, *supra*, 53 Cal.4th at p. 347 [replacement insulation and gaskets "no different" than originals].)

Without addressing *O'Neil's* rejection of the specific legal predicates of *Conte* (PFR 27-29), Plaintiffs ask this Court to defer on this issue to a string of cases purportedly holding that *O'Neil* did not impliedly or expressly overrule *Conte*'s innovator liability ruling. (Ans. 18.) But the only one of those cases to actually confront issue was a federal district court in Kentucky.[1] And that court properly recognized that it was not its

[1] After discussing both sides of this issue in connection with a discovery dispute, the magistrate judge in *Wendell v. Johnson & Johnson* (N.D.Cal. Apr. 22, 2013, No. 09-4124 CW (JSC)) 2013 WL 1741704, *4, stated that

role to address such a fundamental, unanswered question of California law. (*In re Darvocet, Darvon & Propoxyphene Products Liability Litigation* (E.D.Ky. Sept. 5, 2012, Master File No. 2:11-md-2226) 2012 WL 3842271, *6 ["Because a California trial court would be required to apply the holding in *Conte,* this Court is similarly bound."].)

B. The Court of Appeal's Opinion Conflicts with *Cadlo.*

To avoid the conflict presented by the contrary holding in *Cadlo*, Plaintiffs contend the plaintiff's claim there failed because he had not established that he had relied on the prior manufacturer's (Owens-Illinois') representations about its own Kaylo before it had stopped selling the product. (Ans. 20.) That is incorrect. *Cadlo* held that the plaintiff's claim failed because "[t]he Cadlos pleaded no facts to show that Owens-Illinois made a misrepresentation about [the *subsequent* manufacturer's product]." (*Cadlo*, *supra*, 125 Cal.App.4th at p. 521.) Likewise, Plaintiffs do not allege that Novartis made any representation about the generic drugs sold by Lehigh Valley and Global nor that Novartis made any representation about Brethine after selling the Brethine NDA in 2001, six years prior to their mother's use of the other manufacturers' generic drugs. (AOB:30.)

Plaintiffs cannot avoid the fundamental disagreement between the Court of Appeal's endorsement of prior manufacturer liability and the rejection of that theory in *Cadlo.* *Cadlo's* holding refusing to extend a manufacturer's duty to individuals allegedly injured by a subsequent manufacturer's products is clear: "We conclude that Owens-Illinois's historic role in the design, manufacture and marketing of Kaylo will not

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the issue "is for the District Court to resolve once the parties submit the matter to it for decision." And the Ninth Circuit made no mention of *O'Neil* whatsoever in its brief *dicta* discussion of *Conte*. *Rosa v. Taser Intern., Inc.* (9th Cir. 2012) 684 F.3d 941, 949.

support plaintiffs' liability claims against Owens-Illinois in the absence of an allegation or evidence that Owens-Illinois had actual connection with the design, manufacture, and distribution of the asbestos to which Anthony Cadlo was exposed." (*Cadlo*, *supra*, 125 Cal.App.4th at p. 516; see also *Gansberger v. Rockwell Intern. Corp.* (9th Cir. 1990) 911 F.2d 738, 1990 WL 115595, *3 ["We conclude that Gansberger seeks a broad extension of tort law to reach a former manufacturer. In the absence of a clear direction from California courts, we decline to approve this extension."].)

Plaintiffs' claim that *Conte v. Wyeth* (2008) 168 Cal.App.4th 89 supports their prior manufacturer liability argument is incorrect because the defendant in *Conte* was a *current* manufacturer of the brand drug at the time of that plaintiff's alleged exposure. (*Id.* at pp. 97-98, 100, 107.) *Conte* did not impose a duty of care on a prior manufacturer, and Plaintiffs cite no court other than the Court of Appeal here that has ever recognized such a duty. And in any event, any claimed agreement between the Court of Appeal here and *Conte* cannot cure the conflict between the Court of Appeal's opinion and *Cadlo* and *O'Neil.*

C. The Court of Appeal's Opinion Conflicts with Restatement (Second) of Torts Sections 310, 311, and 552, as Adopted by California.

In an attempt to explain why this Court should disregard the uniform rejection by other courts of each of the broad duties imposed by the Court of Appeal on prior manufacturers and brand manufacturers, Plaintiffs contend that California is unique in its adoption of sections 310 and 311 of the Restatement Second of Torts and in its purported rejection of section 552. (Ans. 30-31.) But sections 310 and 311 do not support either of the duties imposed by the Court of Appeal in this case and section 552 — which Plaintiffs concede is contrary to these duties — *has* been adopted in

California. (*Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370, 376.) Plaintiffs' arguments thus again demonstrate how this Court's review is required to resolve the confusion created by the Court of Appeal opinion.

Sections 310 and 311 provide that a party can be liable for a misrepresentation to a third party when it is foreseeable that the third party to whom the misrepresentation was made might rely on the representation to the detriment of the plaintiff. The commentary to these sections makes clear, however, that the representation must be specific to the actual product or chattel that is alleged to have caused the harm. Thus, comment b to section 310 explains that a party may be liable for a misrepresentation "concerning the physical condition of a thing" such as "the ice on a certain pond" or a "bottle of whiskey," and 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. (Rest.2d Torts, § 310, coms. b, c.) Likewise, the illustrations to comments c, d, and e of section 311 discuss misrepresentations regarding the specific alleged injury-causing products, e.g., a "tombstone" and a "boiler." (*Id.*, § 311, coms. c-e.) Nothing in either of those sections or their commentary supports Plaintiffs' claim that California law imposes a duty based upon an alleged misrepresentation about a different product than the one alleged to have caused injury.

Aside from the uniformly rejected opinion in *Conte*, each of the California cases cited by Plaintiffs as applying sections 310 and 311 also involve a representation specific to the injury-causing product or individual. *Hanberry v. Hearst Corp.* (1969) 276 Cal.App.2d 680, 683 holds that a defendant can be held liable where it had endorsed the specific product purchased by the plaintiff, allowed the seller to affix the defendant's seal of approval on the product, and been paid for its endorsement of the product. In *Garcia v. Superior Court* (1990) 50 Cal.3d 728, 733, liability was

allowed as to a parole officer who made assurances to the plaintiff-decedent about her safety from the specific individual who subsequently killed her. And in *Randi W. v. Muroc Joint Unified School District* (1997) 14 Cal.4th 1066, 1081, this Court held that former employers who provided letters of recommendation that failed to note a school administrator's history of sexual misconduct could be liable when that same school administrator abused additional victims at a new school after being hired in reliance on those recommendations.[2]

Plaintiffs' argument that the Court of Appeal's opinion is based on California's rejection of section 552 raises an additional conflict between the Court of Appeal and other California cases. Plaintiffs acknowledge that section 552 precludes liability in this case. (Ans. 31.) But contrary to their assertion, this Court has expressly adopted section 552 (*Bily*, *supra*, 3 Cal.4th at p. 376), and at least one other Court of Appeal has followed section 552 in a personal injury action. (*Formet v. Lloyd Termite Control Co.* (2010) 185 Cal.App.4th 595, 599-600.)

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[2] Plaintiffs' suggestion that California's adoption of sections 310 and 311 uniquely supports the Court of Appeal's imposition of a duty on brand manufacturers also ignores the fact that numerous other states that have adopted these Restatement sections have rejected innovator liability, including Arkansas (*Mandel v. U.S.* (8th Cir. 1983) 719 F.2d 963, 968 [applying section 310]; *Fullington v. Pfizer, Inc.* (8th Cir. 2013) 720 F.3d 739, 744 [rejecting innovator liability under Arkansas law]), Indiana (*Passmore v. Multi-Management Services, Inc.* (Ind. 2004) 810 N.E.2d 1022 [applying section 310]; *In re Darvocet, Darvon & Propoxyphene Products Liability Litigation* (6th Cir. 2014) 756 F.3d 917, 945 [rejecting innovator liability under Indiana law]), and Louisiana (*Guidry v. U.S. Tobacco Co., Inc.* (5th Cir. 1999) 188 F.3d 619, 627 [applying sections 310 and 311]; *Johnson v. Teva Pharmaceuticals USA, Inc.* (5th Cir. 2014) 758 F.3d 605, 614-616 [rejecting innovator liability under Louisiana law].)

D. Plaintiffs' Answer Underscores the Extraordinarily Broad Scope of the Duties Imposed by the Court of Appeal.

The duties imposed by the Court of Appeal in this case are virtually unlimited in time and scope, and far broader even than *Conte*, which addressed only one of the two duties imposed in this case.

It takes Plaintiffs nine pages to provide the numerous purported links in the chain whereby they contend Novartis could have foreseen that its actions with regard to the Brethine® label prior to its sale of the NDA in 2001 would cause a physician six years later to prescribe two other companies' generic terbutaline drugs. (Ans. 3-11.) This discussion omits a number of key points, including that the company that purchased the NDA — far from having "no choice but to adopt Novartis's label" as Plaintiffs contend (Ans. 7) — was required under federal law to monitor adverse drug event reports and the new studies alleged in Plaintiffs' complaint (1AA:22-42) and update the drug labels with any necessary warnings. (21 C.F.R. §§ 201.57(c)(6), 314.80(b) [NDA holder responsible for safety monitoring and labeling].) But at the end of this long discussion, Plaintiffs arrive at the extraordinarily broad consequences of the legal duties imposed by the Court of Appeal:

> As a result, Novartis knew or should have known that by failing to update Brethine's label before it sold the brand rights, Novartis was setting into motion a chain of events that would inspire physicians to continue prescribing Brethine [or bioequivalent generic drugs] for management of preterm labor *indefinitely*, resulting in severe birth defects for *thousands* of children. (Ans. 11, italics added.)

Such an indefinite and unending duty of care on a former brand product manufacturer upends what was thought to be settled California law. While "there are clear judicial days on which a court can foresee forever and thus determine liability" this Court wisely has recognized that there are

"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, citation omitted.) In cases like *O'Neil* and *Cadlo*, California courts properly delimited liability even for conceptually foreseeable injury to maintain the traditional boundaries established over decades of product liability law. With its ruling below, the Court of Appeal has eviscerated those boundaries.

Rather than supporting their claim that the Court of Appeal opinion fits within well-established California law, all of Plaintiffs' arguments highlight the extent to which the Court of Appeal opinion has unsettled California law and made it impossible for other courts to know which rule to follow. This Court should grant review to restore California law to its proper setting.

II. REVIEW IS NECESSARY TO ADDRESS THE IMPORTANT POLICY CONCERNS PREVIOUSLY ANNOUNCED BY THIS COURT BUT IGNORED BY THE COURT OF APPEAL.

The Court of Appeal ignored this Court's detailed discussion in *O'Neil* of the important policy concerns that would arise if California law were to impose a duty on a manufacturer for injury caused by another manufacturer's product. Plaintiffs likewise give this Court's concerns short shrift, offering no response to the concerns that the type of duties imposed by the Court of Appeal (1) improperly target defendants for the conduct of other companies over which they have no control, (2) impose excessive and unrealistic burdens on manufacturers to become experts in other manufacturers' products, and (3) would undermine consumer safety by inundating users with excessive warnings from every company that had any historical or indirect contact with the product. (*O'Neil*, *supra*, 53 Cal.4th at p. 363.)

Plaintiffs barely address this Court's additional concern about imposing a duty on a party that "derived no economic benefit from the sale of products that injured the plaintiff" (*O'Neil*, *supra*, 53 Cal.4th at p. 363.), and their Answer simply illustrates the unlimited scope of the duty the Court of Appeal introduced into California law. Plaintiffs contend that Novartis derived an economic benefit when it sold the Brethine NDA to aaiPharma in 2001, and that this benefit imposes a duty on Novartis going forward to all future sales of Brethine (or biologically equivalent generic drugs) by subsequent manufacturers. (Ans. 24.) But this argument could be made in every case in which one company sells a product line or business to another company.

If this approach is accepted, every such business transaction in California would impose an added financial risk to the seller in the form of an unlimited and uncontrollable contingent liability for injuries arising from the buyer's subsequent business activities. As a result, California companies would face a unique disadvantage in selling off business operations. California-based buyers in turn would face a disadvantage in the marketplace to competing prospective buyers in every other state, where the Court of Appeal's prior manufacturer duty has been rejected, because sellers would seek a premium from those buyers to offset this added liability.

The Court of Appeal likewise did not consider the separate policy concerns that have led this Court and numerous Courts of Appeal to be wary of imposing overly broad tort law duties on pharmaceutical and medical device companies. (*Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063-1064; *In re Coordinated Latex Glove Litigation* (2002) 99 Cal.App.4th 594, 611; *Hufft v. Horowitz* (1992) 4 Cal.App.4th 8, 18-19.)

Without citation of California cases, Plaintiffs contend this Court should disregard those policy concerns because the federal government has

set up a regulatory regime protecting generic drug manufacturers from state tort law claims. (Ans. 21-23.) But this protection for generic manufacturers is an integrated part of a carefully crafted two-tiered prescription drug market that the federal government has established to support the development of beneficial new drugs while lowering the costs of mature drugs. (PFR 23-24.) The Court of Appeal's ruling directly threatens this two-tiered market. (*Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, 377 [rejecting innovator liability].) Moreover, innovator manufacturers will now have an incentive to formally withdraw the NDA at the end of the drug exclusivity period rather than selling the NDA, which will move the drug to the "Discontinued Drug Product List" section of the FDA's Orange Book and deprive consumers of any NDA holder with ongoing responsibility to monitor the drug safety and labeling. (75 Fed.Reg. 48351 (Aug. 10, 2010).)

There is no indication that the Court of Appeal considered any of these important policy considerations before issuing its extraordinarily broad opinion, the consequences of which will be felt throughout California. These unanticipated consequences compel this Court's review.

CONCLUSION

For the reasons set forth in Novartis's Petition for Review and in this Reply, this Court should grant review.

Dated: May 19, 2016

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 Petition, counsel certifies that this Petition was produced using 13-point type and contains 3,745 words.

Dated: May 19, 2016

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 May 19, 2016, I served a copy of:

REPLY IN SUPPORT OF PETITION FOR REVIEW

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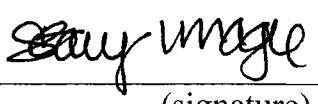
I declare under penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Executed at San Diego, California, May 19, 2016.

Stacy Vinagre
(typed)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