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No. S_____



# 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

# PETITION FOR REVIEW

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## TABLE OF CONTENTS

**Page**

**TABLE OF CONTENTS**
*(continued)*

**Page**

## TABLE OF AUTHORITIES

**Page(s)**

### CASES

## TABLE OF AUTHORITIES
*(continued)*

**Page(s)**

## TABLE OF AUTHORITIES
*(continued)*

**Page(s)**

## TABLE OF AUTHORITIES
*(continued)*

**Page(s)**

## TABLE OF AUTHORITIES
*(continued)*

**Page(s)**



**STATUTES AND RULES**



**OTHER AUTHORITIES**

## TABLE OF AUTHORITIES
*(continued)*

**Page(s)**

# INTRODUCTION

In *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 366, this Court held that imposing negligence liability on a product manufacturer for harm caused by another manufacturer's product "would exceed the boundaries established over decades of product liability law." In disregard of this holding, the Court of Appeal imposed two independent duties on such defendants in this case. First, creating a direct conflict between the First and Fourth Appellate Districts, the Court of Appeal held that a former product manufacturer could be held liable for harm caused by a subsequent manufacturer's product. (*Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513 [refusing to impose such liability].) Second, rejecting the reasoning in *O'Neil*, the Court of Appeal held that a manufacturer of a branded product could be held liable for harm caused by a generic manufacturer's copycat product.

# ISSUE PRESENTED

Does California impose liability on a former manufacturer of a branded product for injuries allegedly caused by a competitor's generic version of that product, although the former manufacturer divested all ownership interest in the branded product years before the generic product was sold and allegedly caused injuries?

# STATEMENT OF FACTS

Because this appeal arises from an order sustaining a demurrer, Plaintiffs' allegations are assumed as true. Minor plaintiffs Teagan and Cardwell Hamilton were diagnosed with autism in 2012. (1AA:43.) On October 8, 2013, Plaintiffs filed this lawsuit alleging that the minor plaintiffs' autism was caused by their mother's use during pregnancy of the generic drug terbutaline, manufactured by Lehigh Valley and Global

Pharmaceuticals. (1AA:1.) Terbutaline is an FDA-approved prescription bronchodilator drug indicated for treatment of asthma, but was prescribed to Mrs. Hamilton off-label as a tocolytic, *i.e.*, to prevent pre-term labor. (1AA:22, 42-43.) Plaintiffs claimed a failure-to-warn: At the time the drug was prescribed in 2007, Lehigh Valley and Global warned against tocolytic use, but the applicable product label did not mention potential harm to the fetus. (1AA:46-49.)

Plaintiffs sued the physician who prescribed the medication; the hospital; Lehigh Valley and Global as manufacturers of the drugs used by their mother; and a number of other pharmaceutical companies, including Novartis, which were alleged to have manufactured branded drugs containing terbutaline.[1] (1AA:3-5.) Plaintiffs alleged that the

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[1] Plaintiffs filed their first amended complaint on December 5, 2013, adding defendants NeoSan Pharmaceuticals, Inc. (the wholly-owned subsidiary through which aaiPharma had acquired Novartis's Brethine product line) and Sanofi-Aventis U.S., LLC. (1AA:16.) On April 25, 2014, plaintiffs amended their complaint to substitute Petitioner Novartis Pharmaceuticals Corporation for Novartis International AG. (1AA:55.) In 2014, plaintiffs voluntarily dismissed their claims against Lehigh Valley, which was insolvent, and against AstraZeneca, which had never marketed terbutaline in the United States. (AOB:11.) On September 22, 2014, the trial court sustained the demurrer of Sanofi-Aventis, the former brand manufacturer of Bricanyl, another terbutaline medication. (Slip Opn., 10.) The court rejected plaintiffs' reliance on *Conte*, holding that because there were no allegations that plaintiffs' mother took any Sanofi product, plaintiffs' harm was not foreseeable to Sanofi. (AOB:11 n.4.) On December 19, 2014, the trial court overruled the demurrer filed by Global, holding that Global could be liable as the generic manufacturer of the terbutaline used by the plaintiffs' mother. The trial court rejected Global's argument that plaintiffs' claims were preempted under *PLIVA, Inc. v. Mensing* (2011) 131 S.Ct. 2567, based on plaintiffs' allegations that Global's sales representatives had made oral representations as to terbutaline's safety that went beyond the FDA-approved product label. (AOB:12 n.4.)

pharmaceutical company defendants improperly promoted terbutaline for use as a tocolytic and that they knew or should have known of the alleged risk of terbutaline to cause autism in children exposed in utero. (1AA:40-42.) Plaintiffs alleged that this risk was identified in a series of studies conducted between the late 1970s and 2006. (1AA:22-42.)

Novartis filed a demurrer on June 11, 2014. (1AA:59.) Novartis argued that it owed Plaintiffs no duty because it had sold all rights and interests in its terbutaline product line, Brethine, to aaiPharma Inc. in 2001, and thereby left the market six years before Plaintiffs' mother's alleged 2007 terbutaline use.[2] (1AA:68-71.) Plaintiffs agreed via stipulation that Novartis had sold the Brethine NDA in 2001 but opposed the demurrer, arguing that Novartis owed Plaintiffs a duty because it was foreseeable that Novartis's alleged failure to include an adequate warning on the Brethine label in 2001 would cause Mrs. Hamilton's doctor to prescribe Lehigh Valley's and Global's generic terbutaline drugs six years later. (1AA:78-81, 98.)

The trial court sustained Novartis's demurrer on February 18, 2015. (1AA:101.) The trial court held that Plaintiffs could not succeed on their claims "because Novartis owed Plaintiffs no duty as a matter of law for claims that arise from the prescribing of terbutaline medication in 2007." (*Ibid.*)

The Court of Appeal reversed the trial court's holding that Novartis did not owe Plaintiffs a duty of care. (Slip Opn., 3.) In so ruling, the Court

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[2] Novartis also demurred to Plaintiffs' claims of concealment and intentional misrepresentation based on Plaintiffs' failure to plead those claims with specificity. The trial court sustained Novartis's demurrer to Plaintiffs' fraud-based claims "because of a lack of specificity" (1AA:101), and this ruling was upheld on appeal. (Slip Opn., 25.)

of Appeal created a clean split in California in light of *Cadlo* and ignored *O'Neil*, rejecting Novartis's argument that California law does not impose on former manufacturers a duty of care to customers of subsequent manufacturers. The Court of Appeal also embraced and adopted the otherwise outlier innovator duty ruling of *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89, though this Court has not before considered the issue and has instead signaled, including through *O'Neil,* that it would decline to create such a duty.

## WHY REVIEW SHOULD BE GRANTED

California has long been in the forefront nationwide on issues of product liability law. However, in its opinion below, the Court of Appeal imposed two new legal duties on product manufacturers that disregard this Court's most recent teaching on the proper limits to such liability and leave California sharply out of step with the rest of the country. *First*, the Court of Appeal held that a company that had manufactured a product solely in the past owes a duty of care to a subsequent manufacturer's customers and those who allege that they were injured by the subsequent manufacturer's product. *Second*, the Court of Appeal held that the innovator manufacturer of a branded product owes a duty of care to individuals who allege injury from a competitor's generic version of the product.

The Court of Appeal's extraordinarily broad ruling eviscerates what this Court just four years ago held to be a fundamental principle of California tort law: A defendant may not be held liable under strict liability or negligence doctrines for damage allegedly caused by another company's product. (See *O'Neil*, *supra*, 53 Cal.4th at p. 335.) The Court of Appeal's ruling also stands in sharp conflict with that of another California appellate court that squarely rejected the imposition of a duty of care on a former

product manufacturer. (*Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513.)

The material facts, all of which are undisputed, cleanly define the startling scope of these new duties. Plaintiffs allege that in 2007, their mother was prescribed terbutaline-containing medicines manufactured by Lehigh Valley and Global Pharmaceuticals. Plaintiffs allege that these medicines, beta agonist bronchodilators prescribed off-label for the prevention of premature labor, caused them to develop autism. Novartis Pharmaceuticals Corporation did not manufacture or market — and could not have manufactured or marketed — the medicines that allegedly caused Plaintiffs' injuries. It would have been unlawful for Novartis to do so: Although Novartis once was the New Drug Application (NDA)[3] holder for Brethine, a branded drug with the active ingredient terbutaline, Novartis had sold all of its rights and interests in Brethine to aaiPharma Inc. in 2001, six years before the alleged product use here. Plaintiffs correctly acknowledged below that this sale cut off not only Novartis's ability to manufacture or market the drug but also Novartis's responsibility under the Food, Drug, and Cosmetic Act (FDCA) to monitor for drug safety and to update the drug label. Manufacturer aaiPharma, which stood to profit from Brethine sales beginning in 2001 with its NDA purchase, assumed responsibility for the medicine's label at that time. (AOB:7, 32; Slip Opn., 8; 21 C.F.R., §§ 201.57(c)(6), 314.80(b) [NDA holder responsible for safety monitoring and labeling].) Generic manufacturers, such as defendants Lehigh Valley and Global Pharmaceuticals, in turn were obliged

[3] An NDA is the vehicle through which drug sponsors formally propose that the Food and Drug Administration (FDA) approve a new pharmaceutical for sale and marketing in the United States.

to market their products with the same label as that used by aaiPharma.[4] (AOB:29.)

The trial court sustained Novartis's demurrer, holding that Novartis — a company which had fully divested its rights in the product years before the alleged product use here — did not owe a duty of care to Plaintiffs, who in any event admittedly were not injured by a Novartis product. In a published opinion, the Court of Appeal reversed. The Court of Appeal held that because Novartis had a duty of care to consumers of its own product, Brethine, prior to its sale of the NDA, it therefore owed a duty of care to all future consumers of the drug manufactured and sold by subsequent manufacturers. The appellate court also held that Novartis — as the one-time manufacturer of the branded drug — owed a duty of care to users of copycat generic versions of the drug, citing to a 2008 California appellate court decision that the court acknowledged has been overwhelmingly rejected by other courts. (*Conte*, *supra*, 168 Cal.App.4th 89.) In tandem, the Court of Appeal's two holdings created a duty on an innovator company that runs, indefinitely and regardless of the innovator's divestiture of the product, to subsequent consumers of the product it previously manufactured and of the slew of copycat generic products manufactured by others, regardless of the identity of the actual product the consumer used.

Each of the new duties imposed by the Court of Appeal warrants review here. Review by this Court is necessary both to "settle an important

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[4] Once its drug receives FDA approval, the innovator company or a subsequent purchaser of the NDA can exclusively market and sell this "branded" product for as long as the company has patent protection. Once the patent life expires on a branded product, other manufacturers can file for FDA approval to market and sell copycat bioequivalent "generic" drugs carrying the same label as the branded product.

question of law" and "to secure uniformity of decision." (Cal. Rules of Court, rule 8.500(b)(1).)

The Court of Appeal's decision to impose a duty of care on a former manufacturer demonstrates significant uncertainties over a fundamental legal principle that this Court sought to clarify in *O'Neil*. *O'Neil* held that "expansion of the duty of care [to a non-manufacturer defendant] would impose an obligation to compensate on those whose products caused the plaintiffs no harm" and that "[t]o do so would exceed the boundaries established over decades of product liability law." (*O'Neil*, *supra*, 53 Cal.4th at p. 365.) Accordingly, *O'Neil* held that the original manufacturers of valves and pumps with asbestos-containing gaskets and packing materials owed no duty to a plaintiff exposed to a subsequent manufacturer's replacement gaskets and packing materials. (*Id.* at pp. 343-344.)

The Court of Appeal's imposition of a duty of care on a former manufacturer stands in sharp conflict with *Cadlo*, in which another Court of Appeal rejected an identical argument by a plaintiff injured by a product seven years after the defendant had sold the product line. (*Cadlo*, *supra*, 125 Cal.4th at p. 523.) Though creating perfect disharmony within California, the Court of Appeal below did not cite any legal authority in support of its finding of a duty running from a former manufacturer, and Novartis is unaware of any such authority anywhere in the United States.

The Court of Appeal's imposition of a duty of care on the innovator manufacturer of a branded drug for injuries allegedly caused by a generic drug likewise ignores this Court's guidance in *O'Neil* and the collective wisdom of virtually every other jurisdiction that has considered the issue. The Court of Appeal based its holding on the flawed legal reasoning in

*Conte*, *supra*, 168 Cal.App.4th 89, which had imposed a duty on innovator drug manufacturers based on the premise that the foreseeability of potential harm creates a legal duty. (*Id.* at pp. 104-105.) But this reasoning was squarely rejected in *O'Neil*, in which this Court explained that "foreseeability does not create a duty, but sets limits once a duty is established." (*O'Neil*, *supra*, 53 Cal.4th at p. 358 [quoting *Simonetta v. Viad Corp.* (2008) 165 Wash.2d 341, 197 P.3d 127, 131, fn. 4].) And *Conte* has been overwhelmingly rejected in other jurisdictions, where 28 other courts expressly have refused to follow its lead. In total, the *Conte* theory of innovator liability has been rejected in 35 states and 95 opinions nationwide, and the very small handful of cases that have accepted the theory have each been subsequently reversed or significantly limited.

This Court's review is vital also to settle conclusively the fundamental question whether a manufacturer owes a duty of care to consumers of other manufacturer's products in California. If allowed to stand, the Court of Appeal's ruling will leave companies that do business in California uniquely liable for damages caused by third-party products over which they did not and could not have any control. The Court of Appeal's flawed and dangerous opinion compels this Court's attention.

# LEGAL ARGUMENT

## I. THIS COURT'S REVIEW IS NECESSARY TO SECURE CONSISTENCY IN CALIFORNIA LAW ON WHETHER A NON-MANUFACTURER OWES A DUTY OF CARE TO CONSUMERS ALLEGEDLY INJURED BY ANOTHER MANUFACTURER'S PRODUCT.

### A. The Court of Appeal's opinion creates a district split on the issue of former manufacturer liability and is contrary to this Court's ruling in *O'Neil*.

The Court of Appeal's imposition of a former manufacturer duty of care directly conflicts with the First Appellate District's ruling in *Cadlo*, *supra*, 125 Cal.App.4th at p. 516. In *Cadlo*, plaintiffs alleged that Owens-Illinois — the original manufacturer of the asbestos-containing insulation product Kaylo — should be held liable for injuries allegedly caused by Kaylo that had been manufactured after OI had sold its Kaylo division to Owens-Corning Fiberglas. (*Ibid.*) Plaintiffs' allegations against OI were based upon a far more direct relationship with OCF than is alleged here between Novartis and aaiPharma (the company that purchased the NDA for Brethine) or with Lehigh Valley or Global (the manufacturers of the generic terbutaline used by Plaintiffs' mother). As another court noted in rejecting a similar claim, OI and OCF had co-marketed Kaylo for a number of years, OI maintained a partial ownership interest in OCF after it sold its Kaylo division, and the two companies historically had shared a number of common directors and executive officers. (See *Gillenwater v. Honeywell Intern., Inc.* (Ill.App.Ct. 2013) 996 N.E.2d 1179, 1194-1195; see also *Cadlo*, *supra*, 125 Cal.App.4th at p. 522 [discussing co-marketing agreement].)

Even with these corporate relations, *Cadlo* rejected the plaintiffs' claim that OI owed a duty of care to OCF's customers. The Court of Appeal explained:

> After [its sale of the product line in] 1958, Owens-Illinois made no representation about Kaylo, false or otherwise. Cadlo's first exposure to Kaylo was in 1965, and the Kaylo to which he was exposed was manufactured by OCF. Consequently, any misrepresentation about Kaylo's safety on which he might have relied would have been made by OCF.

(*Cadlo*, *supra*, 125 Cal.App.4th at p. 520.) The Court of Appeal dismissed plaintiffs' argument that OI could be liable for indirect communications about Kaylo, explaining that those communications still would need to have been made specifically about *OCF's* Kaylo. (*Id.* at p. 521.)

The Court of Appeal's imposition of a former manufacturer duty of care on Novartis likewise contravenes this Court's holding in *O'Neil.* In *O'Neil*, plaintiffs sought to hold the manufacturers of valves and pumps liable for injuries allegedly caused by exposures to asbestos from component gaskets and packing material. (See *O'Neil*, *supra*, 53 Cal.4th at p. 345.) Although the manufacturers had included asbestos-containing gaskets and packing materials in their original products, the gaskets and packing materials had been replaced over time during routine maintenance with gaskets and packing materials manufactured by other companies. (*Ibid.*) Plaintiff's injuries were allegedly caused by these replacement parts. (*Ibid.*)

As in this case, the Court of Appeal in *O'Neil* held that the original manufacturers owed a duty to the plaintiff. (See *O'Neil*, *supra*, 53 Cal.4th at pp. 346-347.) The Court of Appeal noted that the replacement gaskets

and packing material were "no different" from the gaskets and packing material that had been included in their pumps and valves by the original manufacturers. (*Id.* at p. 347.) The plaintiff presented evidence that the health risks were known when the original manufacturers had supplied the valves and pumps including the asbestos-containing parts. (*Id.* at pp. 345.). The Court of Appeal held that if the original manufacturers "had warned the hypothetical original user, or protected that person by avoiding defective design, subsequent users, too, would have been protected." (*Id.* at p. 347.)

This Court granted review and reversed. In its ruling, the Court emphasized that the imposition of a duty on a company that did not manufacture the alleged injury-causing product runs counter to both well-established California law and sound public policy. The Court explained that "manufacturers have a duty to warn consumers about the hazards inherent in their own products" but that "we have never held that a manufacturer's duty to warn extends to hazards arising exclusively from *other* manufacturer's products." (See *O'Neil*, *supra*, 53 Cal.4th at p. 351.)

The Court of Appeal below did not provide any public policy defense for its decision to impose a new duty of care on former product manufacturers, and its footnote attempt to distinguish *Cadlo* displays its fundamental misunderstanding of existing California law. The Court of Appeal argued that *Cadlo* is inapposite because Plaintiffs here allege that they relied on Novartis's representations about Brethine prior to its sale of the NDA in 2001. (Slip Opn., 20.) But as noted *supra*, *Cadlo* made clear that a former manufacturer could only be held liable if it had made misrepresentations specifically *about the subsequent manufacturer's product.* And *O'Neil* expressly rejected an identical Court of Appeal holding that imposed a duty of care on a former manufacturer based upon

the alleged impact that an original warning might have had on subsequent users of other manufacturers' products.

The Court of Appeal likewise did not cite to a single other case that had imposed a duty on a former manufacturer. Novartis is unaware of any such authority in California or anywhere in the country. To the contrary, in addition to *Cadlo* and *O'Neil*, former manufacturer liability was rejected under California law by the United States Court of Appeals for the Ninth Circuit in *Gansberger v. Rockwell International 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 clear direction from the California courts, we decline to approve this extension." And there is a solid wall of authority rejecting a former manufacturer duty of care in other jurisdictions, both in the pharmaceutical and non-pharmaceutical context. Thus, in pharmaceutical and medical device cases, courts have rejected arguments: (1) that Eli Lilly could be held liable for a plaintiff's use of the prescription drug propoxyphene manufactured after Lilly had sold its NDA to Neosan,[5] (2) that Wyeth could be held liable for a plaintiff's use of the prescription drug metoclopramide manufactured after Wyeth had sold its NDA to Schwarz Pharma,[6] and (3) that 3M could be held liable for plaintiffs' use of breast implants manufactured after it had sold its product line to McGhan Medical Corporation (notwithstanding evidence that the sale was motivated

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[5] *In re Darvocet, Darvon and Propoxyphene Products Liability Litigation* (E.D.Ky. Mar. 7, 2012, Master File No. 2:11-md-2226) 2012 WL 767595, *6-7, aff'd (6th Cir. 2014) 730 F.3d 917, 940.

[6] *Lyman v. Pfizer, Inc.* (D.Vt. July 20, 2012, No. 2:09-cv-262) 2012 WL 2970627, *16-17.

specifically by mounting legal claims against the product).[7] Courts likewise have rejected former manufacturer liability in cases involving such varied products as tire rims,[8] spray paint cans,[9] and vinegar.[10]

This Court's review is required to secure uniformity of California law on the issue of former manufacturer liability and to prevent the Court of Appeal's decision from imposing on manufacturers a duty of care to a subsequent manufacturer's customers in California that does not exist anywhere else in the country.

### B. The Court of Appeal's imposition of a duty on innovator manufacturers for injuries caused by a generic manufacturer's copycat drug product is contrary to California law and the overwhelming weight of national authority.

This Court's review is also necessary to reverse the Court of Appeal's erroneous holding that innovator manufacturers owe a duty of care to consumers of other companies' copycat generic drug products. It has been seven years since *Conte* proposed this new duty of care, and

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[7] *McConkey v. McGhan Medical Corp.* (E.D.Tenn. 2000) 144 F.Supp.2d 958; *In re Minnesota Breast Implant Litigation* (D.Minn. 1998) 36 F.Supp.2d 863; *Barbour v. Dow Corning Corp.* (Conn. Super. Ct. Apr. 19, 2002, No. X06CV930301054S) 2002 WL 983346, *3 (citing additional cases).

[8] *Emmons v. Bridgestone Americas Tire Operations, LLC* (E.D.Mo. Dec. 12, 2012, No. 1:10CV41 JAR) 2012 WL 6200411.

[9] *Jones v. Borden Inc.* (E.D.La. Aug. 28, 1995, No. Civ. A. No. 93-2620) 1995 WL 517298.

[10] *Fricke v. Owens-Corning Fiberglas Corp.* (La.Ct.App. 1993) 618 So.2d 473.