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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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

[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

[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

[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

[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.

neither *Conte*'s analysis nor its holding has stood the test of time. The Court should take review to make clear what its holding in *O'Neil* compels and to expressly reject the *Conte*-invented innovator manufacturer duty.

1. The development and availability of prescription drugs depends upon the separate markets for branded and generic drugs.

The cost to innovator pharmaceutical companies of developing a single new branded drug treatment has been estimated to exceed $2.5 billion. (See Tufts Center for the Study of Drug Development, *Cost of Developing a New Drug* (Nov. 18, 2014), available at http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014..pdf, last accessed on April 15, 2016.)

In order to provide the necessary incentive to support the development of such beneficial new drugs while at the same time securing lower cost alternatives for mature drug products, Congress has established a two-tier prescription drug market. Innovator companies that secure NDA approval for a new drug are granted a five-year period of market exclusivity for the drug, during which time competitor companies are excluded from the market. (See 21 U.S.C. §§ 355(c), 355(j)(5)(F).)[11] At the end of the exclusivity period, generic manufacturers are welcomed into the market to sell competitive generic drugs that are bioequivalent to the branded drug. These manufacturers are able to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent

[11] See also *Actavis Elizabeth LLC v. FDA* (D.C.Cir. 2010) 625 F.3d 760, 764 [explaining Congressional purpose to "provid[e] incentives for innovation by granting five-year exclusivity" to FDA-approved new drugs and barring sale of a competing drug].

branded drug, and their costs are also lowered because the FDCA mandates that they use the same labeling approved by FDA for the branded drug. (See *PLIVA, Inc. v. Mensing*, *supra*, 131 S.Ct. at p. 2574.) Upon entry of less expensive generic drugs, the innovator drug manufacturer rapidly loses market share and sales to the lower-cost generic manufacturers. (See H. Grabowski, G. Long & R. Mortimer, *Recent trends in brand-name and generic drug competition*, J. Med. Econ. 2013, 1-8, 6-7 [calculating that brand manufacturers retain only 11% of the drug market after the first year of generic entry], available at http://fds.duke.edu/db/attachment/2575, last accessed on April 15, 2016.)

This Court has long recognized that tort law has a significant impact on the development and availability of beneficial new drugs. In *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1064, the Court explained that "[p]ublic policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering." (*Id.* at p. 1063.) The Court warned that if drug manufacturers are subjected to expanded theories of liability "they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments." (*Ibid.*) And the Court cautioned that "the additional expense of insuring against such liability — assuming insurance would be available — and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most." (*Ibid.*)

Citing to "a host of examples of products which have greatly increased in price or have been withdrawn or withheld from the market

because of the fear that their producers would be held liable for large judgments," the Court cautioned that "[t]he possibility that the cost of insurance and of defending against lawsuits will diminish the availability and increase the price of pharmaceuticals is far from theoretical." (*Id.* at p. 1064.) The Court thus concluded that "the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use." (*Id.* at p. 1063; see also *Moore v. Regents of University of California* (1990) 51 Cal.3d 120, 146 [following *Brown* and rejecting liability theory that would "threaten[] to destroy the economic incentive to conduct important medical research."].)[12]

2. The Court of Appeal's imposition of a duty of care on innovator manufacturers relies on *Conte*'s flawed understanding of California law on negligence and foreseeability.

Notwithstanding the broader public interest, the First District Court of Appeal adopted an expanded duty of care for manufacturers of branded drugs in 2008, holding that such companies could be held liable for injuries

[12] Many California intermediate courts have taken these policy considerations to heart. (See, e.g., *In re Coordinated Latex Glove Litigation* (2002) 99 Cal.App.4th 594, 611 [noting that *Brown* instructs that in "cases involving products that create significant scientific concerns with respect to research and innovation, more protection for a manufacturer is justified than in cases of other important medical products (wheelchairs, for example), in which harm to some users can be more readily be avoided, due apparently to their more mechanical nature"]; *Hufft v. Horowitz* (1992) 4 Cal.App.4th 8, 18-19 [extending *Brown* to medical implants because imposing strict products liability rule would discourage manufacturers from researching and marketing new medical devices for fear of adverse judgments, the high cost of insurance, and the uncertainty of available insurance].)

caused by their competitor's generic drugs. (See *Conte, supra*, 168 Cal.App.4th 89.) The *Conte* court acknowledged that California law rejects the imposition of strict product liability against defendants that had not manufactured the product that was alleged to have caused harm (*id.* at pp. 100-102), and it also acknowledged that in imposing this new duty of care on innovator manufacturers it "depart[ed] from the majority of courts to have wrestled with this particular issue." (*Id.* at p. 110.)

The *Conte* court reasoned that "[n]egligence and strict product liability are separate and distinct bases for liability." (*Id.* at p. 101.) From this predicate, the court held that "the rule that a plaintiff in a products liability case must prove the defendant made or sold the allegedly defective product that causes injury *sheds no light* on" whether a manufacturer could be held liable in negligence for injury caused by another company's product. (*Id.* at p. 102, emphasis added.) The court "perceive[d] no logical or legal inconsistency between allowing the suit for negligence and disallowing the suit for strict products liability." (*Ibid*.)

The *Conte* court also concluded that the existence of a duty of care under California negligence law is defined by foreseeability. (*Id.* at pp. 103-105.) The court reasoned that "[t]he risk reasonably to be perceived defines the duty to be obeyed," and held that "in this case our duty analysis must look primarily to the foreseeability of physical harm." (*Id.* at pp. 103, 104.) The court then concluded that there was "no room for a reasonable difference of opinion" that an innovator manufacturer could foresee that a physician might rely on the branded drug label in prescribing a competitor's generic product. (*Id.* at pp. 104-105). With that, a new duty of care was born in the First Appellate District.

In its ruling below, the Court of Appeal hews closely to *Conte*, likewise relying on *Conte*'s distinction between negligence and strict product liability and *Conte*'s foreseeability analysis. (Slip Opn., 13-16, 18-20.) But time has shown that *Conte* was wrongly decided, and the Court of Appeal's adherence to *Conte* in the face of subsequent, conflicting California authority and the overwhelming rejection of *Conte* by other courts creates a deep fissure in California tort law that must be addressed.

3. The Court of Appeal's imposition of an innovator manufacturer duty of care upends the law on non-manufacturer liability by deviating from this Court's unanimous holding in *O'Neil*.

Conte and the Court of Appeal opinion below create a rule-swallowing exception to what should be settled California law that denies imposition of a duty of care on a company that did not manufacture the alleged injury-causing product.

O'Neil rejected the distinction that *Conte* and the Court of Appeal below drew between a defendant's duty of care for purposes of strict product liability and negligence. This Court made clear that the general principle limiting a manufacturer's duty to warn to the customers of its own products applies to both strict liability and negligence, citing with approval the rule stated by the Washington Supreme Court that "the duty to warn, *in negligence or strict liability*, extends only to those in the chain of distribution of a hazardous product." (*O'Neil*, *supra*, 53 Cal.4th at p. 356, emphasis added [citing *Simonetta v. Viad Corp.* (2008) 165 Wash.2d 341, 197 P.3d 127, 133-134.].) "[T]he general rule [is] that there is no duty under common law *products liability or negligence principles* to warn of

the dangers of exposures to asbestos in other manufacturers' products . . . ." (*Ibid.*, emphasis added [quoting *Braaten v. Saberhagen Holdings* (2008) 165 Wash.2d 373, 198 P.3d 493, 495-496].) This Court then explained that "in strict liability as in negligence, foreseeability alone is not sufficient to create an independent tort duty." (*Id.* at p. 362, internal quotation marks deleted.) And this Court held that the same policy considerations that preclude the imposition of strict liability on a non-manufacturer "apply with equal force in the context of negligence." (*Id.* at p. 366.)

This Court also took aim at the argument — essential to *Conte* and the Court of Appeal ruling below — that a negligence duty should be imposed on a non-manufacturer if it were foreseeable that its conduct might cause harm from the use of another company's product. This Court explained that "foreseeability alone is not sufficient to create an independent tort duty" and that "foreseeability is not synonymous with duty, nor is it a substitute." (*O'Neil*, *supra*, 53 Cal.4th at p. 364.) This Court cautioned, moreover, that "[i]n some cases, when the consequences of a negligent act must be limited to avoid an intolerable burden on society, policy considerations may dictate a cause of action should not be sanctioned no matter how foreseeable the risk." (*Ibid.*, internal quotation marks deleted.) This Court held that allowing a duty to be imposed upon a non-manufacturer was such a case, concluding that "[s]ocial policy must at some point intervene to delimit liability even for foreseeable injury." (*Id.* at pp. 365-366.)

O'Neil's ultimate holding is clear: "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.) Neither of those exceptions applies here. Although *O'Neil* arose in the context of an asbestos product liability action and, accordingly, did not have occasion to address *Conte* or pharmaceutical product liability directly, this Court's analysis was not limited to asbestos, and it leaves no room for the Court of Appeal's opinion below.

The Court of Appeal's putative *O'Neil* exception would hold a defendant liable for harm caused by another manufacturer's product so long as it "bears at least some direct responsibility for the alleged harm." (Slip Opn. 24.) But on a "clear judicial day[]" (*Erlich v. Menezes* (1999) 21 Cal.4th 543, 552), a court could find "at least some direct responsibility" for all manner of harm caused by non-manufacturer defendants (including a pump and valve manufacturer that failed to provide any warning of health risks from subsequently-replaced asbestos-containing gaskets and packing materials in its products). The Court of Appeal's exception would rob *O'Neil* of any practical force.

4. The Court of Appeal opinion contravenes a national consensus rejecting innovator liability.

The point that the Court of Appeal's devotion to *Conte* grossly disrupts traditional tort doctrine is readily proven up by the overwhelming rejection of an innovator manufacturer duty in other states. In a recent opinion, the United States Court of Appeals for the Sixth Circuit reviewed the legal landscape on the question of innovator liability and found that "an overwhelming majority of courts, in at least fifty-five decisions from twenty-two states, have rejected the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug." (*In re*

Darvocet & Propoxyphene Products Liability Litigation (6th Cir. 2014) 756 F.3d 917, 938-939.) Those fifty-five decisions included rulings of each of the six federal Courts of Appeals that had addressed the issue. (*Id.* at p. 939.)

In its survey of the national jurisprudence, the Sixth Circuit identified a number of policy considerations that weigh against the imposition of a duty on a brand manufacturer for injuries caused by a generic drug. First, in an analysis that echoes that of *O'Neil*, the Sixth Circuit stated that "[p]ermitting negligence claims against one manufacturer for injuries caused by a competitor's products would reflect an unprecedented departure from traditional . . . tort law." (*In re Darvocet*, *supra*, 756 F.3d at p. 943; see also *id.*, at pp. 944, 945, 947.) Second, the Sixth Circuit explained that it is improper for courts to punish brand manufacturers for any alleged foreseeability of harm that arose from Congress' policy decisions to lower the barriers of entry for generic drugs through mandates of parallel labeling. (*Id.* at p. 944; see also *id.* at pp. 945, 947.) Third, the Sixth Circuit warned that "there are grave health policy consequences associated with recognizing brand manufacturer liability in these situations, including higher priced brand name drugs and fewer innovator drugs," a concern that is even more pronounced under the Court of Appeal's ruling here extending the duty to reach even former brand manufacturers. (*Id.* at p. 944; see also *id.* at pp. 947, 948.)

The Sixth Circuit's ruling actually understates the breadth of the national consensus on this issue. Innovator liability now has been rejected in thirty-five states and at least ninety-five decisions. (Drug and Device Law, *Innovator Liability at 100* (July 18, 2014), http://druganddevicelaw.blogspot.com/2014/07/innovator-liability-at-100.html, last accessed on April 15, 2016.) Moreover, a full twenty-eight

of those ninety-five decisions expressly considered and rejected *Conte*'s analysis.[13] These courts have explained that "*Conte* is anomalous." (See *Burke v. Wyeth, Inc.* (S.D.Tex. Oct. 29, 2009, No. CIV. G-09-82) 2009 WL

[13] *In re Darvocet*, 756 F.3d at p. 941; *Johnson v. Teva Pharmaceuticals USA, Inc.* (5th Cir. 2014) 758 F.3d 605, 614-616 & fn.3; *Guarino v. Wyeth, LLC* (11th Cir. 2013) 719 F.3d 1245, 1251-1253; *Schrock v. Wyeth, Inc*. (10th Cir. 2013) 727 F.3d 1273, 1281-1286; *Strayhorn v. Wyeth Pharmaceuticals, Inc.* (6th Cir. 2013) 737 F.3d 378, 403-405; *Smith v. Wyeth, Inc*. (6th Cir. 2011) 657 F.3d. 420, 423-424; *Mensing v. Wyeth, Inc*. (8th Cir. 2009) 588 F.3d 603, 612-614, revd. in part on other grounds *PLIVA, Inc. v. Mensing* (2011) 131 S.Ct. 2567, reaffd. in pertinent part and vacated in part on other grounds, *Mensing v. Wyeth, Inc.* (8th Cir. 2011) 658 F.3d 867; *Moretti v. Wyeth, Inc*. (9th Cir. 2009) 579 F.Appx 563, 564; *Tsavaris v. Pfizer, Inc.* (S.D.Fla. Jan. 7, 2016, No. 1:15-cv-21826-KMM) 2016 WL 80221, *10, app. pending (11th Cir. Feb. 8, 2016, No. 16-10541); *Gardley-Starks v. Pfizer, Inc*. (N.D.Miss. 2013) 917 F.Supp.2d 597, 601-604 & fn. 4; *Washington v. Medicis Pharmaceuticals Corp*. (S.D.Miss. Feb. 7, 2013, No. 3:12cv126) 2013 WL 496063, *2-4; *Baymiller v. Ranbaxy Pharmaceuticals, Inc*. (D.Nev. 2012) 894 F.Supp.2d 1302, 1309-1311; *Phelps v. Wyeth, Inc*. (D.Or. 2012) 857 F.Supp.2d 1114, 1120-1121; *Metz v. Wyeth, LLC* (M.D. Fla. 2011) 830 F.Supp.2d 1291, 1293-1295, affd. (11th Cir. 2013) 525 F.Appx 893; *Levine v. Wyeth, Inc*. (M.D.Fla. 2010) 684 F.Supp.2d 1338, 1344-1346; *Howe v. Wyeth Inc*. (M.D.Fla. Apr. 26, 2010, No. 8:09-CV-610-T-17AEP) 2010 WL 1708857, *3-4; *Craig v. Pfizer, Inc*. (E.D.La. May 26, 2010, No. 3:10-00227) 2010 WL 2649545, *2-4, adopted (W.D.La. June 29, 2010) 2010 WL 2649544; *Fisher v. Pelstring* (D.S.C. July 28, 2010, No. 4:09-cv-00252) 2010 WL 2998474, *2-4; *Finnicum v. Wyeth, Inc*. (E.D.Tex. 2010) 708 F.Supp.2d 616, 620-622; *Hardy v. Wyeth, Inc*. (E.D.Tex. Mar. 8, 2010, No. 909CV152) 2010 WL 1049588, *2-5, adopted (E.D.Tex. Mar. 29, 2010) 2010 WL 1222183; *Burke v. Wyeth, Inc*. (S.D.Tex. Oct. 29, 2009, No. G-09-82) 2009 WL 3698480, *2-3; *Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, 369-381; *Gross v. Pfizer, Inc.* (D.Md. Nov. 9, 2010, No. 10-CV-00110-AW) 2010 WL 4485774, *2-3; *Meade v. Parsley* (S.D.W.Va. Nov. 13, 2009, No. 2:09-cv-00388) 2009 WL 3806716, *2-3; *Anselmo v. Sanofi-Aventis Inc. USA* (D.Kan. Oct. 13, 2014, No. 10-CV-77) 2014 WL 8849464, *2; *Franzman v. Wyeth, Inc*. (Mo.Ct.App. 2014) 451 S.W.3d 676, 689-692; *Short v. Eli Lilly & Co.* (Ind. Super. Ct. Mar. 25, 2009, Nos. 49D12-0601-CT-2187, 4:13-cv-00539-VEH) 2009 WL 9867531, *4-7.

3698480, *3; see also *Washington ex rel. Washington v. Medicis Pharmaceuticals Corp.* (S.D.Miss. Feb. 7, 2013, No. 3:12CV126-DPJ-FKB) 2013 WL 496063, *4 ["*Conte* broke from [the majority rule] . . . . And since that departure, *Conte* has gained little traction."]; *Phelps v. Wyeth, Inc.* (D.Or. May 28, 2010, No. 09-6168-TC) 2010 WL 2553619, *2 ["I cannot find that a decision to hold a manufacturer liable for injury caused by its competitor's product is rooted in common sense."]; *Moretti v. Wyeth, Inc.* (D.Nev. Mar. 20, 2009, No. 2:08-CV-00396-JCM (GWF)) 2009 WL 749532, *4 ["Simply put, *Conte* stands alone . . . ."].)

Plaintiffs' attempt in their briefing below to find any support for *Conte* only underscores the degree to which California now finds itself out of step with the rest of the country. Plaintiffs identified only four purportedly supportive opinions, one of which does not reach any finding on innovator liability, two of which are no longer good law, and a fourth which has been specifically limited so as would not apply in this case.[14]

This Court should grant review to prevent the Court of Appeal's aberrant ruling from disrupting California law on non-manufacturer

[14] *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649 (reversed by statute, Ala. Code § 6-5-530 (2015)); *Dolin v. SmithKline Beecham Corp.* (N.D.Ill. 2014) 62 F.Supp.3d 705 [prediction as to Illinois law rejected by *In re Darvocet, supra*, 756 F.3d at pp. 943-946]; *Bartlett v. Mutual Pharmaceutical Co.* (D.N.H. 2009) 659 F.Supp.2d 279 [no ruling on brand manufacturer liability; brand manufacturer liability rejected under New Hampshire law by *In re Darvocet & Propoxyphene Products Liab. Litig.* (E.D.Ky. Sept. 5, 2012, Master File No. 2:11-md-2226-DCR) 2012 WL 3842045, *7]; *Kellogg v. Wyeth, Inc.* (D.Vt. 2010) 762 F.Supp.2d 694 [held not to apply to a former brand manufacturer in *Lyman v. Pfizer, Inc.* (D.Vt. July 20, 2012, No. 2:09-cv-262) 2012 WL 2970627, *16-17].

liability, unsettling the national consensus against innovator liability, and isolating California from the rest of the national jurisprudence.

II. THIS COURT'S REVIEW IS NECESSARY TO SETTLE THE IMPORTANT QUESTION WHETHER PUBLIC POLICY LIMITS THE USE OF FORESEEABILITY TO IMPOSE A DUTY OF CARE ON FORMER MANUFACTURERS AND MANUFACTURERS OF BRANDED PRODUCTS NOT USED BY PLAINTIFFS.

This Court's review is necessary as well because the Court of Appeal's broad expansion of the duty of care to cover companies that did not manufacture the alleged injury-causing product will have damaging repercussions for all manner of companies doing business in California. As this Court explained in *O'Neil*, decades of product liability law have established clear boundaries that limit a manufacturer's duty of care solely to those who used the manufacturer's product. (*O'Neil*, *supra*, 53 Cal.4th at p. 365.) While the present case involves a pharmaceutical manufacturer, the Court of Appeal's expansion of the duty of care would extend to any former manufacturer or manufacturer of a branded product, whether the product at issue is a prescription drug, a consumer good, a computer, a piece of software, a chemical, a petroleum product, or any number of products upon which the California economy depends. Under the Court of Appeal's formulation, all that is required to impose a duty of care is some foreseeable scenario by which such product manufacturers "bear[] at least some direct responsibility for the alleged harm." (Slip Opn., 24.)

The Court of Appeal's formulation renders hopelessly unsettled what companies doing business in California have long thought was California law. This Court repeatedly has instructed that "'[d]uty' is not an immutable fact of nature 'but only an expression of the sum total of those

considerations of policy which lead the law to say that the particular plaintiff is entitled to protection.'" (*O'Neil*, *supra*, 53 Cal.4th at p. 364, citations omitted.) Courts accordingly "have invoked the concept of duty to limit generally the otherwise potentially infinite liability which would follow every negligent act." (*Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370, 397.) That is because "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*, *supra*, 21 Cal.4th at p. 552 [quoting *Thing v. La Chusa* (1989) 48 Cal.3d 644, 668; *Bily*, *supra*, 3 Cal.4th at p. 399 (same)].)

In *O'Neil*, this Court reiterated that "[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.) And this Court firmly grounded its limitation of liability to the manufacturer of the alleged injury-causing product in public policy considerations. This Court explained that "product manufacturers generally have no continuing business relationship with each other . . . [which] means that a manufacturer cannot be expected to exert pressure on other manufacturers to make their products safe and will not be able to share the costs of ensuring product safety with these other manufacturers." (*Id.* at p. 363, internal citations and quotation marks omitted.) As a policy matter, "[i]t is also unfair to require manufacturers of nondefective products to shoulder a burden of liability when they derived no economic benefit from the sale of products that injured the plaintiff." (*Ibid.*) Moreover, "[i]t does not comport with principles of strict liability to impose on manufacturers the responsibility and costs of becoming experts in other manufacturers' products [because] [s]uch a duty would impose an excessive and unrealistic burden on manufacturers." (*Ibid.*) And

"[p]erversely, such an expanded duty could undermine consumer safety by inundating users with excessive warnings" observing that "[t]o warn of all potential dangers would warn of nothing." (*Ibid.*)

The limits this Court confirmed in *O'Neil* on non-manufacturer liability were ignored below. Absent correction, this well-established boundary on product liability law will be no more.

CONCLUSION

The Court of Appeal's decision heralds an unprecedented expansion of product liability law that extends a defendant's duty of care to consumers who used a product long after the defendant had left the market and to consumers who used a competitor's generic version of the defendant's branded product. The decision ignores governing and conflicting California authorities and leaves California sharply out of step with the informed judgment of other courts throughout the country. For these reasons, this Court should grant review and settle the important questions of law and public policy raised by the decision below.

Dated: April 18, 2016 Respectfully submitted,

MORRISON & FOERSTER LLP

By: _____ for
Erin M. Bosman

Attorneys for Defendant
NOVARTIS PHARMACEUTICALS CORPORATION

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 7,409 words.

Dated: April 18, 2016

for

Erin M. Bosman

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 April 18, 2016, I served a copy of:

PETITION FOR REVIEW

☒ **BY U.S. MAIL [Code Civ. Proc sec. 1013(a)]** by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid, addressed as follows, for collection and mailing at Morrison & Foerster LLP, 12531 High Bluff Drive, San Diego, California 92130 in accordance with Morrison & Foerster LLP's ordinary business practices.

I am readily familiar with Morrison & Foerster LLP's practice for collection and processing of correspondence for mailing with the United States Postal Service, and know that in the ordinary course of Morrison & Foerster LLP's business practice the document described above will be deposited with the United States Postal Service on the same date that it is placed at Morrison & Foerster LLP with postage thereon fully prepaid for collection and mailing.

Benjamin I. Siminou Kevin F. Quinn Thorsnes, Bartolotta, McGuire LLP 2550 Fifth Avenue, 11th Floor San Diego, California 92103 T: (619) 236-9363 F: (619) 236-9653	Plaintiffs and Appellants Via U.S. Mail first-class
Clerk of the Court COURT OF APPEAL, Fourth District, - Division 1 750 B Street, Suite 300 San Diego, California 92101	Via U.S. Mail first-class
Clerk of the Court San Diego County Superior Court 220 West Broadway San Diego, California 92101 ATTN: Hon. Joan M. Lewis	Via U.S. Mail first-class

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, April 18, 2016.

Stacy Vinagre
(typed)

Stacy Vinagre
(signature)

EXHIBIT A

Filed 3/9/16

NOT TO BE PUBLISHED IN OFFICIAL REPORTS

COURT OF APPEAL, FOURTH APPELLATE DISTRICT

DIVISION ONE

STATE OF CALIFORNIA

T. H., a Minor, etc., et al., Plaintiffs and Appellants, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant and Respondent.	D067839 (Super. Ct. No. 37-2013-00070440-CU-MM-CTL)

APPEAL from a judgment of the Superior Court of San Diego County, Joan M. Lewis, Judge. Reversed.

Thorsnes Bartolotta McGuire, Benjamin I. Siminou and Kevin F. Quinn, for Plaintiffs and Appellants.

Hollingsworth, Eric G. Lasker; Morrison & Foerster, Erin M. Bosman and Julie Y. Park, for Defendant and Respondent.

INTRODUCTION

May Novartis Pharmaceuticals Corporation (Novartis), a former manufacturer of a brand-name asthma medication, be liable in negligence for neurological injuries allegedly sustained by twin minors in utero after their mother was prescribed and consumed a generic form of the medication nearly six years after Novartis sold its interests in the medication?

The minors allege Novartis knew or should have known physicians prescribed its asthma medication to pregnant women for the off-label purpose of preventing or inhibiting preterm labor. They allege studies available to Novartis before it sold the rights to its brand-name product in 2001 showed the drug was not effective for tocolysis (inhibiting preterm labor), it could cross the placenta, and it could interfere with fetal development. The minors more clearly contend on appeal Novartis had a duty to revise the label warnings while it still owned the drug to indicate a risk to fetal development and its failure to do so contributed to their injuries years later.

We conclude the minors have demonstrated they can amend their complaint to state a claim under California law for negligent failure to warn and negligent misrepresentation based on acts or omissions by Novartis prior to 2001, which allegedly caused or contributed to the minors' injuries in 2007. In reaching our conclusion, we follow the rationale of *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89 (*Conte*), which applied common law principles of duty and foreseeability to conclude a brand-name pharmaceutical manufacturer should "shoulder its share of responsibility for injuries caused, at least in part by its negligent … dissemination of inaccurate information" even

though the patient consumed a generic version of the medication manufactured by another company. (*Id.* at pp. 103, 109-110.)

We reject Novartis's invitation to follow other state authorities, which have held a brand-name manufacturer cannot be held liable under any theory for an injury caused by a product other than its own. We also reject Novartis's contention *Conte* is no longer viable after the Supreme Court decision in *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 342 (*O'Neil*), which held a pipe and valve manufacturer may not be held liable in strict liability or negligence for harm caused by separate products manufactured by other companies, even if those products were used in conjunction with the pipes and valves. The *O'Neil* court did not mention, let alone overrule *Conte*, *supra*, 168 Cal.App.4th 89, and, even if a product liability analysis could apply, the facts alleged in this case fall within an exception recognized by the Supreme Court for harm to which the defendant's product substantially contributed. We reverse and remand with directions for the trial court to enter a new order sustaining the demurrer with leave to amend the negligence and negligent misrepresentation causes of action.

FACTUAL AND PROCEDURAL BACKGROUND[1]

A

Terbutaline sulfate (terbutaline) was originally developed and released for use as a bronchodilator in the 1970s. It is a beta-agonist or beta-mimetic drug designed to act

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1 Because we review a demurrer ruling, we derive the facts from the first amended complaint, which we must accept as true. (*Shirk v. Vista Unified School Dist.* (2007) 42 Cal.4th 201, 205.)

upon the beta-2 receptors located in smooth muscle tissue to cause muscles to relax. The United States Food and Drug Administration (FDA) approved the use of terbutaline for the treatment of asthma in 1974. Novartis subsequently obtained a license to manufacture and market the oral form of terbutaline under the trade name Brethine and it owned the new drug application (NDA) for this brand-name drug until 2001.

Drug manufacturers allegedly perceived an opportunity to market terbutaline as a tocolytic to relax uterine smooth muscle tissue to prevent or inhibit preterm labor. A 1976 study by a Swedish physician, allegedly with ties to the original drug manufacturer, published results of a study of 30 women indicating terbutaline was safe and effective for acute (24-48 hours) and maintenance (after 48 hours) tocolysis. The original manufacturer allegedly promoted terbutaline as a tocolytic and its use for this purpose gained wide acceptance. However, neither the original manufacturer nor any of its successors or licensees sought FDA approval for the use of terbutaline as a tocolytic.

B

Studies began to question the safety and efficacy of using terbutaline as a tocolytic. In 1978, a study published in the British Journal of Obstetrics and Gynecology by researchers from Johns Hopkins School of Public Health questioned the validity of the Swedish report stating "relevant information about the effect of drugs on the mother and infant was too scanty to make conclusions about side effects possible." It noted "[d]ata from other sources show that labor inhibitors are potentially dangerous" and "may unfavorably alter the fetal, placental, or maternal circulation." The study indicated, "the role of drugs aimed at preventing or delaying premature birth is not yet established, and

further good clinical trials are urgently needed." The following year, the FDA ordered discontinuation of protocols for intravenous terbutaline use. A study in the Journal of Obstetrics and Gynecology reported pregnant patients who received acute tocolysis experienced pulmonary edema and congestive heart failure and several neonatal complications were reported including "hypoglycemia, hypotension, hypocalcemia, and death."

In 1982, military clinical investigators found the Swedish study could not be replicated. When they compared patients who had been given terbutaline for tocolytic therapy with patients given a placebo they found "[n]o significant difference in prolongation of pregnancy, birth weight, development of [respiratory distress syndrome], or infant survival." A 1984 study from the University of Southern California found similar results.

The Swedish physicians who conducted the original study acknowledged their data demonstrated "a rapid transfer of [t]erbutaline across the human placenta" and that concentrations of the drug in the fetus reached "levels similar to its mother," which they concluded "may help to explain fetal metabolic side effects." Another study in 1985 published in the Journal of Pharmacology and Experimental Therapy found a single dose of terbutaline given to pregnant rats produced stimulation of the beta receptors in the fetal brain, which interfered with an enzyme required for neuronal development.

Reports published in the mid-to-late 1980's regarding other beta-agonist drugs found: (1) six-year-old children born to mothers who received the drugs for tocolysis had statistically poorer academic achievement than children born to mothers with no such

treatment, (2) children born to mothers who received tocolytic treatment were found more often to be neurotic and more likely to have impairments with vision and language development than children whose mothers did not receive tocolytic treatment, and (3) biochemical evidence that terbutaline may interfere with fetal development. Ritodrine, a similar beta-agonist drug approved by the FDA for tocolysis, was withdrawn from the market by its manufacturer in the 1990's after the FDA advised against using it for maintenance tocolytic therapy due to concerns about its toxicity and questionable efficacy. Multiple other studies and trials conducted throughout the 1990's concluded maintenance tocolysis with beta-agonist drugs such as terbutaline provided no benefit and there were well-documented potential dangers to the mother and fetus.

The FDA invited terbutaline manufacturers in 1993 to submit applications for approval of tocolytic use and to review their labeling to clarify the uses and risks of the drug. The manufacturers allegedly decided not to voluntarily seek FDA review for tocolytic use. The manufacturers revised their labels distributed in the United States to warn against tocolytic use. Although not pleaded in the operative complaint, the opening brief asserts the drug label revisions in the early 1990's warned against tocolytic use, but only discussed minor risks to the mother and did not mention potential harm to the fetus.

The American College of Obstetricians and Gynecologists (ACOG) issued a technical bulletin to its members in 1995 stating "[t]o date, no studies have convincingly demonstrated an improvement in survival or any index of long-term neonatal outcome with the use of tocolytic therapy. On the other hand, the potential damages of tocolytic therapy to the mother and the neonate are well documented." Despite this information,

researchers from the University of Iowa reported in 1997 physicians were reluctant to discharge patients who received acute tocolytic treatment without medication and usually prescribed oral maintenance tocolysis because "the concerned patient often pressures her doctor to prescribe medication" and because these prescriptions "reduce … patient phone calls and complaints."

The FDA Associate Commissioner for Health Affairs issued a "Dear Colleague" letter in 1997 expressing the FDA's concerns about the use of terbutaline as a tocolytic agent. It noted adequate data establishing the safety and effectiveness of terbutaline for this purpose had not been submitted to the FDA and the information available indicated there was no documented benefit from prolonged treatment. It referred to and adopted ACOG's 1995 warning. The FDA later rejected a protest to the "Dear Colleague" letter noting, "[t]here is no approved application for the use of [t]erbutaline—by any route for administration—as a tocolytic agent, despite active promotion of subcutaneously administered [t]erbutaline for such use by some commercial parties." The FDA noted its review of articles and materials suggested oral terbutaline is "ineffective as a pregnancy maintenance treatment" and was toxic to mother and fetus.

An evaluation of various treatments for preterm labor released by the Agency for Healthcare Research and Quality of the United States Department of Health and Human Services in 2000 concluded there was no benefit to using tocolytic for maintenance therapy. A study published in 2001 reported children exposed to tocolytic treatment had impairment in motor, socio-emotional and cognitive development as well as higher rates of psychiatric disorders and reading disorders. Another study released the same year

identified the biological mechanism by which terbutaline can injure the developing brain. A physician from Duke Medical Center determined receptors in fetal brains do not desensitize, as mature brains would, when subjected to continuous doses of terbutaline. Instead, the sensitivity to terbutaline intensified and increased the response to the drug, which warped cell development. The study noted "there are long-term liabilities of tocolysis with [beta-adrenergic receptor] agonists, including abnormalities of cardiovascular and metabolic function, impaired school performance, and subsequent cognitive impairment and psychiatric disorders."

C

Novartis divested its interest in the NDA for Brethine in December 2001. Another pharmaceutical company became the NDA holder for Brethine thereafter.

D

Over the next several years, other studies were published implicating the use of terbutaline as a tocolytic in adverse neurological effects experienced by children and explaining the mechanisms of injury. By November 2005 researchers published a study finding a significant association between continuous terbutaline exposure and autism disorders in fraternal twins. The report indicated male twins whose mothers received terbutaline therapy and were born with a sibling outside the twin set who did not have autism had more than four times the risk of developing autism than male twins born to a similar family where the mother did not receive terbutaline.

E

In early September 2007 the twins' mother was hospitalized due to concerns she may go into premature labor. Her physician prescribed oral terbutaline to be given every six hours. She was given a generic version of terbutaline. When she was discharged from the hospital at the end of September 2007 another physician instructed her to continue taking oral terbutaline every six hours until the 32nd week of her pregnancy. She filled her prescription with another generic version of terbutaline and continued taking the medication until the twins were born in early October 2007. When the twins were approximately three years old, their pediatrician indicated they had developmental delay. They were diagnosed with autism in 2012.

F

The minors, appearing by and through their father and guardian ad litem, sued Novartis, other manufacturers of terbutaline, the physicians who prescribed the medication, and the hospital. The operative complaint asserts causes of action against Novartis for negligence, intentional misrepresentation, concealment, and negligent misrepresentation.

Novartis filed a demurrer arguing it had no duty to the minors because it did not manufacture the medication consumed by their mother and had no responsibility for the label or prescribing information in 2007 since it sold the rights to terbutaline six years earlier. It also argued the minors failed to plead with sufficient specificity any statement or misrepresentation by Novartis to support its fraud causes of action and they further failed to allege reliance on any statement by Novartis.

The minors opposed the demurrer arguing Novartis owed a duty of care to potential patients while it did own and manufacturer the product to adequately warn physicians and their pregnant patients the use of its product was not effective for tocolysis or safe for unborn children. The minors further argued their mother's physicians likely would not have prescribed her or other women terbutaline in 2007 if Novartis had either (1) not encouraged the off-label use as a tocolytic or (2) adequately warned of the potential risks known in 2001. They argued the gap between when Novartis owned the rights to the drug and when their mother consumed the drug did not go to the issues of duty or breach, but to causation. They argued they sufficiently pleaded the fraud causes of action.

The trial court sustained the demurrer without leave to amend concluding Novartis owed the twins "no duty as a matter of law for claims that arise from the [prescribing] of terbutaline medication in 2007." The court also sustained the demurrer to the causes of action for intentional misrepresentation, concealment and negligent misrepresentation because they failed to plead these fraud-based claims with sufficient specificity.

DISCUSSION

I

Standard of Review

"A demurrer is properly sustained when the complaint 'does not state facts sufficient to constitute a cause of action,' or where the court 'has no jurisdiction of the subject of the cause of action alleged in the pleading.' (Code Civ. Proc., § 430.10, subds. (e), (a).) 'On appeal from a dismissal following the sustaining of a demurrer, this court

reviews the complaint de novo to determine whether it alleges facts stating a cause of action under any legal theory. … [¶] Because the function of a demurrer is not to test the truth or accuracy of the facts alleged in the complaint, we assume the truth of all properly pleaded factual allegations. [Citation.] Whether the plaintiff will be able to prove these allegations is not relevant; our focus is on the legal sufficiency of the complaint.' " (*Debrunner v. Deutsche Bank National Trust Co.* (2012) 204 Cal.App.4th 433, 438.)

"If the court sustained the demurrer without leave to amend, as here, we must decide whether there is a reasonable possibility the plaintiff could cure the defect with an amendment. [Citation.] If we find that an amendment could cure the defect, we conclude that the trial court abused its discretion and we reverse; if not, no abuse of discretion has occurred. [Citation.] The plaintiff has the burden of proving that an amendment would cure the defect." (*Schifando v. City of Los Angeles* (2003) 31 Cal.4th 1074, 1081.)

II

Negligent Failure to Warn

A

"Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." (*Anderson v. Owens-Corning Fiberglas Corp.* (1991) 53 Cal.3d 987, 1002.) "In the case of prescription drugs … the physician stands in the shoes of the 'ordinary user' because it is through the physician that a patient learns of the properties and proper use of the drug …. Thus, the duty to warn in these cases runs to the

physician, not the patient." (*Valentine v. Baxter Healthcare Corp.* (1999) 68 Cal.App.4th 1467, 1483.) This is known as the learned intermediary doctrine. As such, a "pharmaceutical manufacturer may not be required to provide warning of a risk known to the medical community." (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1116.)

A manufacturer is not required to warn about speculative harm. "Knowledge of a potential side effect which is based on a single isolated report of a possible link between a prescription drug and an injury may not require a warning. 'If we overuse warnings, we invite mass consumer disregard and ultimate contempt for the warning process.' [Citation.] Moreover, both common sense and experience suggest that if every report of a possible risk, no matter how speculative, conjectural, or tentative, imposed an affirmative duty to give some warning, a manufacturer would be required to inundate physicians indiscriminately with notice of any and every hint of danger, thereby inevitably diluting the force of any specific warning given. [Citations.] The strength of the causal link thus is relevant both to the issue of whether a warning should be given at all, and, if one is required, what form it should take." (*Finn v. G. D. Searle & Co.* (1984) 35 Cal.3d 691, 701.)

However, "[t]he application of the failure-to-warn theory to pharmaceuticals requires determinations whether available evidence established a causal link between an alleged side effect and a prescription drug, whether any warning should have been given, and, if so, whether the warning was adequate. These are issues of fact involving, inter alia, questions concerning the state of the art, i.e., what was known or reasonably knowable by the application of scientific and medical knowledge available at the time of

manufacture and distribution of the prescription drug. They also necessarily involve questions concerning whether the risk, in light of accepted scientific norms, was more than merely speculative or conjectural, or so remote and insignificant as to be negligible." (*Carlin v. Superior Court, supra,* 13 Cal.4th at p. 1116.)

B

The issue here is whether Novartis can be held liable under a negligent failure to warn theory to minors allegedly injured as a result of their mother's ingestion of generic terbutaline for tocolysis years after Novartis divested itself of the NDA for Brethine. The minors do not claim Novartis had a duty to warn in the years after it divested the NDA. As they have clarified on appeal, they contend Novartis had sufficient information before it divested the NDA in 2001 to revise the drug label, package insert and corresponding entry in the *Physician's Desk* Reference to include warnings of potential fetal harm when terbutaline was used as a maintenance tocolytic. The minors assert they can amend their complaint to contend if Novartis had provided such warnings when it owned the NDA it is probable warnings would have remained in effect, or at least as strong, until 2007. They further assert they can amend their complaint to contend it is more likely than not their mother's physicians would not have prescribed terbutaline during her pregnancy if these warnings were in place in 2001. If the minors can in good faith amend their complaint to plead these facts, we conclude their claims for negligence and negligent misrepresentation can survive demurrer based on California law.

In *Conte, supra,* 168 Cal.App.4th 89, a California appellate court held "the common law duty to use due care owed by a [brand-name] prescription drug

manufacturer when providing product warnings extends not only to consumers of its own product, but also to those whose doctors foreseeably rely on the [brand-name] manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug." (*Id*. at pp. 94-95.) In reaching this conclusion, the court rejected the argument that Wyeth could not be liable because it did not manufacture or sell the product that caused the alleged injury. The court observed the argument would be sound if the plaintiff were pursuing a cause of action for strict product liability, but she was not. "Negligence and strict products liability are separate and distinct bases for liability that do not automatically collapse into each other because the plaintiff might allege both when a product warning contributes to her injury." (*Id*. at p. 101.) Rooting its decision in common sense and the common law of California, the court stated, "[w]e are not marking out new territory by recognizing that a defendant that authors and disseminates information about a product manufactured and sold by another may be liable for negligent misrepresentation where the defendant should reasonably expect others to rely on that information and the product causes injury, even though the defendant would not be liable in strict products liability because it did not manufacture or sell the product. (See *Hanberry v. Hearst Corp.* (1969) 276 Cal.App.2d 680 [misrepresentation claim permitted against magazine publisher that endorsed manufacturer's product])." (*Id*. at p. 102.)

The *Conte* court relied upon common law and civil law principles regarding foreseeability and duty noting, "[i]n California, the general rule is that 'all persons have a duty to use ordinary care to prevent others from being injured as the result of their

conduct.' " (*Conte, supra,* 168 Cal.App.4th at p. 103 & fn. 10, citing Civ. Code, § 1714.) It also looked to the rules set forth in the Restatement Second of Torts sections 310 and 311 regarding intentional and negligent misrepresentations involving risk of physical harm to others. (*Conte,* at pp. 103-104.) For conscious or intentional misrepresentation, section 311 provides for liability if an actor makes a misrepresentation and "should realize that it is likely to induce action by the other, or a third person, which involves an unreasonable risk of physical harm to the other." For negligent misrepresentations, section 311 states " '[o]ne 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.' " (*Conte,* at p. 104, italics omitted.) The court noted the close connection between duty and reasonable reliance. " 'The likelihood that one's statements about personal safety will be taken seriously is a primary factor in determining whether one has a duty to exercise care in making such statements. As the Restatement puts it, such a duty "extends to any person who, in the course of an activity which is in furtherance of his own interests, undertakes to give information to another, and knows or should realize that the safety of the person or others may depend on the accuracy of the information." ' " (*Ibid*.)

The *Conte* court concluded it was foreseeable a patient could be injured by relying on product information provided by a brand-name drug manufacturer even though the patient took a generic form of the drug. "In California, as in most states, pharmacists have long been authorized by statute to fill prescriptions for [brand-name] drugs with

their generic equivalents unless the prescribing physician expressly forbids such a substitution. [Citations.] It is therefore highly likely that a prescription for [a brand-name drug] written in reliance on [the manufacturer's] product information will be filled with [a generic drug]. And, because by law the generic and [brand-name] versions of drugs are biologically equivalent [citations], it is also eminently foreseeable that a physician might prescribe generic [medication] in reliance on [the manufacturer's] representations about [its brand-name drug]." (*Conte, supra,* 168 Cal.App.4th at p. 105.)[2]

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2 The United States Supreme Court has since confirmed generic drug manufacturers have an ongoing duty to keep their drug labels the same as those for the brand-name drug and generic manufacturers may only change their labels "to match an updated brand-name label or to follow the FDA's instructions." (*PLIVA, Inc. v. Mensing* (2011) ___ U.S. ___ [131 S.Ct. 2567, 2575, 180 L.Ed.2d 580, 589-590] (*PLIVA*).) As a result, the Supreme Court concluded federal law preempts failure-to-warn claims against generic drug manufacturers based on state law, even though such claims are not preempted against brand-name manufacturers. (*Id*. at ___ [131 S.Ct. at pp. 2580-2581, 180 L.Ed.2d at p. 595].)

In *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649, the Alabama Supreme Court noted the holding in *PLIVA* undermines the rationale of *Foster v. American Home Products Corp.* (4th Cir. 1994) 29 F.3d 165, 168-170 (*Foster*), which is the leading case holding a brand-name manufacturer cannot be held liable under any theory for harm resulting from consumption of a generic product. "[T]he *Foster* court relied on the finding that a generic manufacturer of a prescription drug is responsible for the accuracy of labels placed on its product. *Foster* was issued before the Supreme Court decided *PLIVA*, in which it held that a generic manufacturer's label must be identical to the brand-name label and that a generic manufacturer cannot unilaterally change its label to update a warning. The *Foster* court's finding that manufacturers of generic drugs are responsible for the representations they make in their labeling regarding their products is flawed based on the 'sameness' requirement subsequently discussed in *PLIVA*." (*Wyeth, Inc. v. Weeks, supra,* at pp. 669-670.) The Alabama Supreme Court further concluded the analysis in *Foster* confused strict liability and tort law. (*Id*. at p. 670.)

In addition to foreseeability, the court considered other policy factors such as "the degree of certainty that the plaintiff suffered injury; the closeness of the connection between the defendant's conduct and the plaintiff's injury; the moral blame attached to the defendant's conduct; the policy goal of preventing future harm; the burden to the defendant and consequences to the community of imposing a duty of care; and broader consequences including the availability, cost, and prevalence of insurance for the risk involved." (*Conte*, *supra*, 168 Cal.App.4th at pp. 105-106, citing the factors identified in *Rowland v. Christian* (1968) 69 Cal.2d 108, 113 (*Rowland*).) The court concluded the application of these factors did not support a departure from the general rule "that all persons have a duty to use ordinary care to prevent harming others." (*Conte*, at p. 106.)

The *Conte* court considered and rejected the analysis in *Foster*, *supra*, 29 F.3d 165. It recognized its holding was a departure from a majority of state and federal courts, but concluded "California law is well established that concurrent tortfeasors whose separate acts contribute to an injury are each liable." (*Conte*, *supra*, 168 Cal.App.4th at pp. 109-110.) The court found nothing novel or unjust in applying this principle to require a brand-name manufacturer "to shoulder its share of responsibility for injuries caused, at least in part, by its negligent … dissemination of inaccurate information." (*Ibid.*)

The Sixth Circuit in *Germain v. Teva Pharms., USA, Inc*. (*In re Darvocet, Darvon, & Propoxyphene Prods. Liab. Litig*) (6th Cir. 2014) 756 F.3d 917, 937-938 conducted a state-by-state analysis to determine if misrepresentation claims consolidated in a multidistrict litigation (MDL) would stand under the laws of each implicated state. In

doing so, the court observed the majority of state courts reject " 'the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug.' " (*Id.* at pp. 937-938, citing *Foster, supra,* 29 F.3d 165.) However, it recognized California and other states hold a contrary view finding "generic consumers' injurious reliance foreseeable" and "brand manufacturers know or should know that a significant number of patients whose doctors rely on their product information for brand name drugs are likely to have generic drugs dispensed to them." (*Id*. at pp. 938-939, citing *Conte, supra,* 168 Cal.App.4th 89.)

The federal district court overseeing the MDL action concluded plaintiffs asserting tortious misrepresentation claims under California law could state a claim based upon *Conte, supra,* 168 Cal.App.4th 89. (*In re: Darvocet* (E.D.Ky. Sept. 5, 2012, No. 2:11-md-2226-DCR) 2012 U.S. Dist. LEXIS 125816, at *17-21.) The court rejected the argument *O'Neil, supra*, 53 Cal.4th 335 overruled *Conte, supra*, 168 Cal.App.4th 89 and noted "[t]he reason for the … complete lack of citation to *Conte* is, therefore, most likely that the court believed the case to be irrelevant to determination of the issue at hand." (*In re: Darvocet, supra,* 2012 U.S. Dist. LEXIS 125816, at *18, fn. 6.) It also distinguished the *O'Neil* case noting the plaintiffs were not basing their claims on a combination of the use of a manufacturer's product with the product of another company, but, instead, upon representations made about a pharmaceutical drug "that caused them to 'ingest and suffer harm from a generic version of [the] drug.' " (*Id*. at *18-19.)

We conclude the *Conte* court's analysis applies with equal force to the facts presented in this case. We are not persuaded by Novartis's argument *Conte* applies only

to brand-name manufacturers who own the NDA at the time a generic medication causes injury. Although Novartis did not own the NDA for Brethine in 2007, it did own it until 2001 and was responsible for the label information prior to that time. (21 C.F.R. § 314.80(b).) The minors allege there was sufficient information prior to 2001 regarding the risk of fetal harm in using terbutaline as a maintenance tocolytic to require Novartis to revise the drug label.[3] The minors allege they were injured as a result of their mother's ingestion of the generic version of Brethine, which allegedly bore the same label information in 2007 as it did in 2001. They allege it was foreseeable physicians and their patients would continue to rely on Novartis's product label for adequate warnings. They also allege it was foreseeable a subsequent manufacturer would not change the label information, at least not to weaken any warnings about fetal harm Novartis should have included.[4] Whether or not these facts can be proven remains to be seen, but is not the

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[3] In the FAC, the minors allege the manufacturers revised their labels in the early 1990s. On appeal, the minors' opening brief admits Novartis revised its label to warn against tocolytic use. However, they claim the warning only disclosed minor maternal risks and was silent about fetal risks. Although not clearly alleged in the FAC, the minors contend on appeal their mother's physicians would not have prescribed, and their mother would not have agreed to take, terbutaline if there were adequate warnings of fetal risks. This contention has some resonance. A mother might disregard minor risks to her own health to take a medication not recommended for tocolysis if it meant prolonging a pregnancy to give her child the best chance to fully develop in utero. However, if a mother were informed there was no benefit to taking the medication and there was actually a risk to the fetus, she might make a different choice.

[4] The minors describe federal law regarding drug labels as a "one-way ratchet" whereby manufacturers may add or strengthen existing warnings, but may not remove or weaken warnings without FDA approval. (See *Wyeth v. Levine* (2009) 555 U.S. 555, 568 ["Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application. There is, however, an FDA regulation that permits

issue before us. Accepting these facts as true, we conclude they are sufficient to establish foreseeability and a connection between the alleged injuries and the harm.[5]

As to moral culpability, the *Conte* court noted "if [a brand-name manufacturer] misrepresented the risks of taking its medication, any moral culpability it might bear for that misrepresentation is not lessened if the person who is harmed by his or her reliance on it happened to ingest a generic version as a result, rather than [the brand-name]." (*Conte, supra,* 168 Cal.App.4th at p. 106.) A similar analysis applies to the facts here. If Novartis knew or should have known about fetal risk associated with tocolytic use and failed to disclose the risk while it owned the NDA, Novartis's moral culpability is not lessened simply because it no longer owned the NDA when the minors were allegedly harmed by their mother's ingestion of the generic form of the medication, particularly since the label allegedly was the same as that prepared by Novartis. On the other hand, the chance to prevent future harm is increased by imposing a duty on pharmaceutical

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a manufacturer to make certain changes to its label before receiving the agency's approval. Among other things, this 'changes being effected' (CBE) regulation [21 CFR § 314.70(c)(6)(iii)(A), (C)] provides that if a manufacturer is changing a label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction' or to 'add or strengthen an instruction about dosage and administration that is intended to increase the safe use of the drug product,' it may make the labeling change upon filing its supplemental application with the FDA; it need not wait for FDA approval"].)

[5] These factual allegations distinguish this case from *Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513. In that case, the court determined, for pleading purposes, a prior manufacturer of an asbestos-containing product knowingly misrepresented its product was safe and concealed its hazardous nature. However, the plaintiff in that case could not allege he ever saw the advertisements or representations made by the prior manufacturer and, therefore, could not establish reliance. (*Id*. at pp. 519-520.) In contrast, the minors state they may amend their complaint to allege actual reliance on Novartis's representations.

manufacturers to warn based on medical and scientific evidence available to them as long as they own a product line and are responsible for labeling under the FDA requirements.

Based on the limited record before us, we are unable to fully assess the remaining policy considerations regarding the burden to the defendant and consequences to the community of imposing a duty of care or broader consequences such as cost or insurance. (*Conte*, *supra*, 168 Cal.App.4th at p. 107.) At this juncture, however, we conclude there is no compelling reason in this case to depart from California's general rule of requiring a manufacturer to exercise ordinary care to prevent harm to others. (*Randi W. v. Muroc Joint Unified School Dist.* (1997) 14 Cal.4th 1066, 1077.)

C

We are also not persuaded by Novartis's argument *Conte* is no longer good law based on the Supreme Court's decision in *O'Neil*, *supra*, 53 Cal.4th 335 , which held "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." (*Id.* at p. 342.) In *O'Neil*, a manufacturer of valves and pumps used in Navy warships was sued for wrongful death allegedly caused by asbestos released from external insulation and internal gaskets and packing used with the pumps and valves, all of which were products made by third-party manufacturers. The plaintiffs alleged the manufacturer of the pumps and valves should be held strictly liable and negligent because it was foreseeable asbestos products would be used in conjunction with their products and workers would be harmed by the exposure. (*Id.* at p. 342.)

The Supreme Court declined to expand strict products liability to prevent injuries "caused by *other* products that might foreseeably be used in conjunction with a defendant's product" or to require manufacturers "to warn about the dangerous propensities of products they do not design, make, or sell." (*O'Neil, supra,* 53 Cal.4th at pp. 342-343.) The court recognized "exceptions to this rule arise when the defendant bears some direct responsibility for the harm, either because the defendant's own product contributed substantially to the harm [citation], or because the defendant participated substantially in creating a harmful combined use of the products." (*Id*. at p. 362.) After analyzing the *Rowland* factors[6] for the negligence claims, the court determined, under the specific facts of the case before it, an "expansion of the duty of care as urged here would impose an obligation to compensate on those whose products caused the plaintiffs no harm." (*Id*. at p. 365.)

O'Neil, supra, 53 Cal.4th 335 did not overrule or even mention *Conte, supra,* 168 Cal.App.4th 89 and its facts are distinguishable from those present in *Conte*. In *Conte*, the court determined the brand-name manufacturer bore direct responsibility for alleged harm arising from misrepresentations in the brand-name label even though the prescription was filled by a generic version of the same drug. (*Conte*, at p. 111.) As observed in *Wyeth, Inc. v. Weeks*, "[i]n the context of inadequate warnings by the brand-name manufacturer placed on a prescription drug manufactured by a generic manufacturer, it is not fundamentally unfair to hold the brand-name manufacturer liable

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6 (*Rowland, supra,* 69 Cal.2d at p. 113.)

for warnings on a product it did not produce … based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer and merely repeated, as allowed by the FDA, by the generic manufacturer. [¶] … Nothing in this opinion suggests that a plaintiff can sue Black & Decker for injuries caused by a power tool manufactured by Skil based on labeling or otherwise. The unique relationship between brand-name and generic drugs as a result of federal law and FDA regulations, combined with the learned-intermediary doctrine and the fact that representations regarding prescription drugs are made not to the plaintiff but to a third party, create the sui generis context in which we find prescription medication." (*Wyeth, Inc. v. Weeks*, *supra*, 159 So.3d at p. 677.)

Similarly here, Novartis manufactured the brand-name drug terbutaline and was responsible for the label warnings through 2001. Its formulation of the product was biologically identical to the product that allegedly caused the minors harm in 2007. Additionally, the label was allegedly the same in 2007 as it was in 2001. If the minors can prove Novartis failed to adequately warn about fetal risks it knew or should have known were associated with tocolytic use before it divested the product in 2001, they may be able to establish Novartis's conduct bore some direct relationship to the alleged harm in this case. Thus, even if the *O'Neil* rule precluding liability of a product manufacturer for injuries arising from another manufacturer's product could be viewed as applying to negligent failure to warn claims regarding pharmaceutical drugs, the facts

alleged in this case would fall within the recognized exception of liability for a defendant who bears at least some direct responsibility for the alleged harm.

III

Fraud Causes of Action

"The elements of fraud are (1) the defendant made a false representation as to a past or existing material fact; (2) the defendant knew the representation was false at the time it was made; (3) in making the representation, the defendant intended to deceive the plaintiff; (4) the plaintiff justifiably relied on the representation; and (5) the plaintiff suffered resulting damages. [Citation.] The elements of negligent misrepresentation are the same except for the second element, which for negligent misrepresentation is the defendant made the representation without reasonable ground for believing it to be true." (*West v. JPMorgan Chase Bank, N.A.* (2013) 214 Cal.App.4th 780, 792.) "The elements of an action for fraud based on concealment are: (1) the defendant concealed or suppressed a material fact; (2) the defendant had a duty to disclose the fact to the plaintiff; (3) the defendant intentionally concealed the fact with the intent to defraud the plaintiff; (4) the plaintiff was unaware of the fact and would not have acted as he did if he had known of the concealed fact; and (5) as a result of the concealment of the fact, the plaintiff sustained damage." (*Knox v. Dean* (2012) 205 Cal.App.4th 417, 433.)

Fraud must be pleaded with specificity rather than with " 'general and conclusory allegations.' " (*Small v. Fritz Companies, Inc.* (2003) 30 Cal.4th 167, 184.) The specificity requirement is necessary to (1) give the defendant sufficient notice of the

charges and (2) permit a court to weed out meritless fraud claims. (*West v. JPMorgan Chase Bank, N.A., supra*, 214 Cal.App.4th at p. 793.)

In this case, we conclude the minors have provided sufficient additional information on appeal to demonstrate they may amend their complaint to adequately allege a cause of action for negligent misrepresentation as recognized by *Conte*, *supra*, 168 Cal.App.4th at page 102. However, the minors have not met their burden of demonstrating they can amend their complaint to allege causes of action for intentional misrepresentation or concealment with sufficient specificity. As a result there is no basis upon which to grant leave to amend as to these causes of action. (*Schifando v. City of Los Angeles*, *supra*, 31 Cal.4th at p. 1081.)

DISPOSITION

The judgment is reversed and the matter is remanded with directions for the trial court to enter a new order sustaining Novartis's demurrer, but granting the minors leave to amend only the causes of action for negligence and negligent misrepresentation. Appellants are awarded their costs on appeal.

McCONNELL, P. J.

WE CONCUR:

NARES, J.

IRION, J.

I, KEVIN J. LANE, Clerk of the Court of Appeal, Fourth Appellate District, State of California, do hereby certify that this preceding and annexed is a true and correct copy of the original on file in my office.

WITNESS, my hand and the Seal of the Court this March 9, 2016

KEVIN J. LANE, CLERK

By A. Galvez
Deputy Clerk

EXHIBIT B

Filed 3/9/16

CERTIFIED FOR PUBLICATION

COURT OF APPEAL, FOURTH APPELLATE DISTRICT

DIVISION ONE

STATE OF CALIFORNIA

T. H., a Minor, etc., et al., Plaintiffs and Appellants, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant and Respondent.	D067839 (Super. Ct. No. 37-2013-00070440-CU-MM-CTL) ORDER CERTIFYING OPINION FOR PUBLICATION

THE COURT:

The opinion in this case filed March 9, 2016, was not certified for publication.

IT IS HEREBY CERTIFIED that the opinion meets the standards for publication specified in California Rules of Court, rule 8.1105(c); and

ORDERED that the words "Not to Be Published in the Official Reports" appearing on page 1 of said opinion be deleted and the opinion herein be published in the Official Reports.

McCONNELL, P. J.

Copies to: All parties

I, KEVIN J. LANE, Clerk of the Court of Appeal, Fourth Appellate District, State of California, do hereby certify that this preceding and annexed is a true and correct copy of the original on file in my office.

WITNESS, my hand and the Seal of the Court this March 9, 2016

KEVIN J. LANE, CLERK

By A. Galvez
Deputy Clerk