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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.

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