S233898

IN THE

SUPREME COURT OF CALIFORNIA

T.H., A MINOR, 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

Answer to Petition for Review

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INTRODUCTION

This case arose when Plaintiffs' mother, while pregnant with Plaintiffs, was prescribed Brethine, an FDA-approved asthma drug, for the "off-label" purpose of preventing her from going into preterm labor.

Unknown to both Plaintiffs' mother and her physician was that numerous studies had shown that Brethine was likely to cause fetal brain damage when administered to pregnant women.

That conclusion did not gain widespread adherence until 2011 when the FDA demanded that Brethine manufacturers issue warnings to obstetricians noting that it posed risks to fetal health.

But that now well-established conclusion did not come as a surprise to Novartis Pharmaceutical Corporation ("Novartis"), which held the brand rights to Brethine from the mid-1990s through December 2001. During that time, Novartis watched as Brethine's popularity as an asthma drug declined, but it's popularity as a "tocolytic"—i.e., a drug for managing preterm labor—soared. In that capacity, Novartis monitored scientific data and, by the fall of 2001, realized that the drug was dangerous when used as a tocolytic.

With that realization, Novartis made a business decision: Cognizant that continuing to market Brethine without a warning regarding the hazard it posed to fetal health would expose it to ongoing tort liability, but also aware that adding such a warning would cause Brethine's popularity as a tocolytic—and, thus, value—to plummet, Novartis chose instead to sell the brand

rights to aaiPharma in December 2001 for $26.6 million without first adding a necessary warning to Brethine's label regarding hazards to fetal health.

Of course, Novartis did so knowing that, because Brethine's market value was tied to its popularity as a tocolytic, no such warning was likely to ever appear on Brethine's label. As such, Novartis also knew that doctors would continue prescribing Brethine as a tocolytic indefinitely, with the predictable result that thousands of children would suffer severe birth defects.

Plaintiffs, fraternal twins, are two such children who, in view of the above, brought misrepresentation claims against Novartis. The Court of Appeal, applying fundamental principles of California tort law, wisely concluded that their claims may proceed.

Novartis now seeks review from this Court based on exaggerated claims that the Court of Appeal's opinion creates a split of published authority and will have bad policy implications for the State of California.

But as discussed below, the Court of Appeal's decision was grounded in long-standing and fundamental principles of California tort law, namely the rule that those who cause misinformation to be disseminated to the public are liable for the consequences of foreseeable reliance on that information. Moreover, numerous policy interests militate heavily in favor of assigning liability to drug companies who, like Novartis, shirk their duties to ensure accurate drug labels in the pursuit of profit.

POINTS & AUTHORITIES

I. Plaintiffs' injuries were a foreseeable consequence of Novartis's failure to fulfill a duty of care.

Novartis's petition focuses exclusively on law and policy, to the total exclusion of any fact-based analysis of the Court of Appeal's opinion. But the facts are essential to putting the Court of Appeal's decision in proper context, without which the sound logic behind it may be lost under hyperbolic sound bites calculated to deceive this Court into believing that an opinion reflecting the unremarkable application of long-settled tort principles is a direct threat to the orderly administration of tort law in California, the state's economy, and even public safety.

But as a dispassionate reading of the Court of Appeal's opinion reveals, rather than reflect some aberrant result, the Court of Appeal's opinion was grounded in the essential facts that have formed the core of tort liability—both here and elsewhere—for decades: Novartis breached a duty of care imposed by law, and Plaintiffs' injuries were a direct and foreseeable consequence of that breach.

A. Novartis had a duty to update Brethine's label to warn of potential hazards that were not adequately addressed by the existing label.

There is no dispute that, until December 2001, Novartis had a duty under federal law to "ensur[e] that its warnings remain adequate as long as the drug is on the market." (*Wyeth v. Levine* (2009) 555 U.S. 555, 568.) In particular, Novartis had a duty to update Brethine's warning label "as soon as there is reasonable evidence of an association of a serious hazard with a

drug; a causal relationship need not have been proved." (21 C.F.R. § 201.80(e); see also *id.* § 201.57(c)(6) [same].)

Thus, up until Novartis sold the Brethine brand rights to aaiPharma in December 2001, Novartis had a duty to update Brethine's warning label regarding potential hazards that were not adequately addressed in the existing label.

B. Prior to 2001, there were at least a dozen studies showing that Brethine posed risks to fetal health.

As Plaintiffs alleged, beginning in 1979 and running through the fall of 2001, at least a *dozen* studies from respected institutions raised legitimate evidence-backed concerns that Brethine was dangerous to the fetal brain when administered to pregnant women. (See AA 023—AA035.)

This evidence included a 2001 study in which German researchers determined that drugs like Brethine "are known to produce specific maternal and fetal side effects" with a particular disruptive effect on "a very sensitive period of brain development." (AA 033–034, ¶¶ 52–53.) It also included an October 2001 study from Duke University which confirmed that Brethine's active ingredient is dangerous to the fetal brain, concluding that "prenatal Terbutaline exposure elicits changes in regulators of [central nervous system] cell differentiation, leading to subsequent postnatal abnormalities in the development of neuronal projections, neurotransmitter utilization, and the expression of neural receptors." (AA 035, ¶ 54.)

In short, by the fall of 2001, there was certainly "reasonable evidence" that Brethine posed a "serious hazard" to fetal health when administered to pregnant women.

C. Novartis was aware of data that Brethine posed risks to fetal health.

Having established that, (1) up until December 2001, Novartis had a legal duty to update Brethine's label when there was "reasonable evidence" of a potential hazard, and (2) that there was "reasonable evidence" by December 2001 that Brethine posed a hazard to fetal health when administered to pregnant women, the next question is whether Novartis was aware of that data. There is ample reason to believe Novartis did.

First, federal law required Novartis to "promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." (21 C.F.R. § 314.80(b) (emphasis added).) To that end, federal law required Novartis to "develop written procedures for the surveillance, receipt, [and] evaluation … of postmarketing adverse drug experiences." (*Ibid.*; see also AA 041, ¶ 73.) This is sufficient to charge Novartis with constructive notice of the evidence that Brethine posed a risk to fetal health. (See, e.g., *Nelson v. Superior Court* (2001) 89 Cal.App.4th 565, 574.)

Plaintiffs also alleged a basis to infer that Novartis had actual knowledge of that data when they noted that, in October 1999, the Director of the FDA Center for Drug Evaluation and Research, issued a letter to Novartis in which she cited the aforementioned studies and noted that "numerous articles from the medical literature" had discussed the "side effects and toxocities" associated with tocolytic use of Brethine, findings which she characterized as "highly consistent." (AA 031–032, ¶ 48.)

D. Novartis failed to update the label to warn that Brethine may pose risks to fetal health.

At all times relevant to the complaint, the label that Novartis left on file with the FDA only mentioned possible side effects to the *mother* when Brethine was used for management of preterm labor. (AA 46–49.) There was absolutely no indication that the drug posed a risk to fetal health. (*Ibid.*)

Thus, in light of the data showing a link between prenatal exposure to Brethine's active ingredient, terbutaline sulfate, and serious birth defects, Novartis had a duty under federal law to update Brethine's label with such a warning.

But Novartis never did. Instead, Novartis responded to the rising tide of scientific data showing a link between its drug and birth defects by selling Brethine's brand rights to aaiPharma for $26.6 million in December 2001. This seemingly allowed Novartis to capitalize on Brethine's market value as a drug for managing preterm labor without incurring ongoing tort exposure for marketing a mislabeled drug. While doing so might have made

financial sense, it constituted a breach of Novartis's duties under federal law.

E. Novartis's failure to update the label before it sold the Brethine brand rights was a substantial factor in Plaintiffs' eventual exposure to Brethine.

An omission is the legal cause of injuries if the injuries would not have occurred had the omission been replaced by conduct in conformity with the alleged tortfeasor's duty of care. (See, e.g., *Saelzler v. Advanced Group 400* (2001) 25 Cal.4th 763, 778–779.) This thus begs the question: Would Plaintiffs avoided exposure to Brethine had Novartis fulfilled its obligation to update Brethine's label?

That question is the product of two underlying questions: First, had Novartis fulfilled its obligation to update Brethine's label prior to divesting the drug in December 2001, would that warning have remained in effect in 2007 when Plaintiffs were exposed to Brethine? And if so, would that warning have prevented Plaintiffs' exposure?

The answer to the first question is an unequivocal "yes."

As a threshold matter, federal law requires a purchaser of a drug's brand rights to use the label that the prior manufacturer left on file with the FDA. (See 21 U.S.C. § 355; 21 C.F.R. § 314.105(b).) When aaiPharma purchased the Brethine brand rights from Novartis, it therefore had no choice but to adopt Novartis's label.

Moreover, federal drug law creates a one-way ratchet in which a manufacturer can unilaterally *add* warnings to an existing label, but cannot remove or water-down existing

warnings without first obtaining the express consent of the FDA. (See *Wyeth v. Levine* (2009) 555 U.S. 555, 568 [holding "that if a manufacturer is changing a label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction ... that is intended to increase the safe use of the drug product,' ... it need not wait for FDA approval"]; 21 C.F.R. § 314.70(c)(6)(iii)(A)–(C) [giving manufacturers the unilateral ability "to add or strengthen a contraindication, warning, [or] precaution ... that is intended to increase the safe use of the product"].) Thus, had Novartis added a warning to the Brethine label regarding risks to fetal health, aaiPharma (and anyone to whom aaiPharma sold the Brethine brand rights) would have been stuck with that warning on their labels, too.

Relatedly, federal regulations require manufacturers of *generic* drugs to adopt, verbatim, the operative warning label used by the brand-name manufacturer. (*See* 21 U.S.C. § 355(j)(2)(A)(v) ["[T]he labeling proposed for the [generic] drug [must be] the same as the labeling approved for the [approved brand-name] drug."]; *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 613 (*Mensing*) ["[T]he warning labels of a brand-name drug and its generic copy must always be the same—thus, generic drug manufacturers have an ongoing federal duty of 'sameness.'"].)

Taking all of the above together, it becomes clear that, had Novartis added a warning regarding hazards to fetal health to the Brethine label before it sold the Brethine brand rights to aaiPharma, all subsequent Brethine manufacturers of Brethine—

brand-name or generic—would have had to use the same label with the same warning indefinitely.

That brings leads to the second of the two causation-related questions: Would a warning on the Brethine label regarding risks to fetal health have prevented Plaintiffs' exposure to Brethine?

Again, the answer is "yes." Plaintiffs alleged that, had a warning regarding risks to fetal health been present on the Brethine label, their mother's physician would not have prescribed (and Plaintiffs' mother would not have agreed to take) Brethine for management of preterm labor, whether brand-name or generic. (AA 049.)[1]

F. Plaintiffs' eventual exposure to Brethine was a foreseeable consequence of Novartis's failure to update Brethine's label.

Having established that (1) up until December 2001, Novartis had a legal duty to update Brethine's label when there was "reasonable evidence" of a potential hazard; (2) that there was "reasonable evidence" by December 2001 that Brethine posed a hazard to fetal health; (3) that Novartis knew or should have known about that data; (4) that Novartis breached its legal duty

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[1] It is worth noting here that under federal law, a "label" includes not only the fine print on a bottle or box containing the medication, but also includes the material inside the container ("package insert"), any marketing materials, and the *Physician's Desk Reference*, which is an exhaustive compendium of labels from drugs on the market which physicians consult in order to educate themselves regarding pertinent drug information. (See, e.g., 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(*l*)(2); *Mensing*, *supra*, 564 U.S. at 614–615.) Federal law requires that all such materials mirror content of the approved "label" on file with the FDA. (E.g., 21 C.F.R. § 201.100(d).)

by failing to update Brethine's label; and (5) that there was a causal nexus between Novartis's failure to update Brethine's label and Plaintiffs' exposure to Brethine, the final question is whether it was foreseeable to Novartis that its failure to update the label would cause doctors to continue prescribing Brethine for management of preterm labor years after it sold the brand rights to the drug.

At bottom, this question really boils down to another: Did Novartis have reason to anticipate that subsequent manufacturers might similarly fail to add a warning to the Brethine label regarding potential hazards to fetal health?

Again, the answer is an unequivocal "yes."

As a threshold matter, Novartis knew or should have known that no manufacturer of *generic* Brethine would issue such a warning, because, again, federal regulations required generic manufacturers to adopt, verbatim, the warning label used by the brand-name manufacturer. (*See* 21 U.S.C. § 355(j)(2)(A)(v); *Mensing*, *supra*, 504 U.S. at p. 613.)

Novartis also knew or should have known that any subsequent purchaser of the Brethine brand rights was unlikely to add such a warning for the very same reasons that Novartis itself declined to do so.

To be clear, Novartis's failure to update the label before selling the Brethine brand rights was no oversight. By 2001, the vast majority of Brethine's annual sales figures were attributable to its off-label use for management of preterm labor, *not* for its FDA-approved use as an asthma drug. (AA 040–042, ¶¶ 70–76.)

Thus, by 2001, Brethine's value—both to the consuming public and to any company's looking to buy its brand rights—was tied to its popularity as a tocolytic agent. Obviously, nothing would have presented a bigger threat to that market than a warning that Brethine may cause fetal brain damage. Accordingly, rather than neuter Brethine's market value by updating its label, Novartis chose to sell the Brethine "hot potato" to aaiPharma without first making the requisite changes to the drug's label. And because Brethine's value depended on its popularity as a tocolytic, it should come as little surprise that aaiPharma did not make the requisite changes to Brethine's label either. Indeed, it was not until 2011, when the FDA—citing many of the same studies available to Novartis before December 2001—stepped in and ordered manufacturers to begin warning that Brethine posed risks to fetal health.

Asa result, Novartis knew or should have known that by failing to update Brethine's label before it sold the brand rights, Novartis was setting into motion a chain of events that would inspire physicians to continue prescribing Brethine for management of preterm labor indefinitely, resulting in severe birth defects for thousands of children.

II. Holding Novartis liable under these facts is consistent with fundamental principles of California tort law.

A. Under California law, those who disseminate misinformation to the public are liable for the consequences of foreseeable reliance on those misrepresentations.

Rather than represent a drastic departure from California tort law, holding Novartis liable under those facts was consistent with the long-standing rule in California that those who misrepresent facts are liable for the foreseeable consequences of those misrepresentations.

That intuitive principle was first articulated in the Restatement (Second) of Torts, specifically sections 310 and 311.

Section 310 of that Restatement provides, "An actor who makes a representation is subject to liability to another for physical harm which results from an act done by the other or a third person in reliance upon the truth of the representation, if the actor . . . should realize that it is likely to induce action by the other, or a third person."

Similarly, section 311 provides, "One 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 . . . to such third persons as the actor should expect to be put in peril by the action taken."

The principles reflected in sections 310 and 311 of the Restatement surfaced in *Hanberry v. Hearst Corp.* (1969) 276

Cal.App.3d 680, in which a consumer sued the publishers of *Good Housekeeping Magazine* for giving a certain brand of shoes its "seal of approval" when, in fact, the shoes were defective and caused the consumer to slip and fall. Even though the magazine did not make the shoes, the consumer alleged the magazine was nonetheless liable for her injuries for negligently misrepresenting the quality of the shoes to its readership. Citing the section 311 of the Restatement, the court agreed, holding that the magazine had "the duty to use ordinary care in the issuance of its seal and certification of quality so that members of the consuming public who rely on its endorsement [were] not unreasonably exposed to the risk of harm." (*Id.* at p. 684.)

In *Garcia v. Superior Court* (1990) 50 Cal.3d 728 (*Garcia*), this Court formally adopted section 311 of the Restatement into the canon of California tort law. In that case, a parole officer dissuaded a parolee's prior victim from taking precautions by reassuring her that the parolee would "not come looking for her" after he was released from prison. The assurance turned out to be inaccurate; shortly after his release, the parolee kidnapped and shot his prior victim. (*Id.* at pp. 731–733.) Because it was foreseeable that a member of the public might rely on the reassurances of a parole officer in refraining from taking preventative measures upon the release of a parolee, this Court—citing *Hanberry* and section 311 of the Restatement—held that, once the parole officer elected to speak, he bore a duty to provide accurate information and could be held accountable for harm

caused by the inaccuracy of that information. (*Garcia*, *supra*, 50 Cal.3d at pp.735–736.)

And in *Randi W. v. Munroc Joint Unified School Dist.* (1997) 4 Cal.4th 1066, this Court formally adopted section 310 of the Restatement. In *Randi W.*, a student molested by a teacher sued the teacher's former school district for issuing a letter of recommendation which neglected to disclose the fact that the teacher had been terminated by that district for molesting students. Because it was foreseeable to the former school district that the new school might hire the teacher in the absence of that information, this Court—citing Restatement sections 310 and 311—held that the former school district owed the child victim a duty of due care. (*Randi W.*, *supra*, 14 Cal.4th at pp. 1070, 1077, 1081.)

And finally, in *Conte v. Wyeth* (2008) 168 Cal.App.4th 89, the Court of Appeal relied on the foregoing authorities to hold that a plaintiff injured by a generic drug could sue a brand-name drug manufacturer of that same drug for tortious misrepresentation. Central to *Conte*'s holding was the fact that federal drug law, by requiring generic drug manufacturers to copy the label used by brand-name manufacturers, made it imminently foreseeable to a brand-name manufacturer that the content of its warning label would be relied upon by a physician in choosing whether or not to prescribe even a generic form of that drug.

These authorities all stand for the sensible proposition that when a tortfeasor disseminates misinformation to the public, he

or she is liable for the foreseeable consequences of those misrepresentations.

B. The Court of Appeal's opinion in this case does not contradict this Court's opinion in *O'Neil*, nor does it create a split of lower-court authority.

Of the many assertions in Novartis's petition, none is more pointed than Novartis's claim that the Court of Appeal's opinion contradicts settled California law. In particular, Novartis argues that the Court of Appeal's decision contradicts this Court's recent decision in *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335 (*O'Neil*), and is at odds with *Cadlo v. Owens–Illinois, Inc.* (2004) 125 Cal.App.4th 513 (*Cadlo*). But as discussed below, there is no disharmony between the Court of Appeal's opinion in this case and the decisions in *O'Neil* and *Cadlo*.

1. *O'Neil* does *not* hold that a company can never be liable for injuries caused by another company's product.

Novartis argues that, by assigning liability to one company for injuries caused by another company's product, the Court of Appeal's decision in this case directly conflicts with this Court's decision in *O'Neil*.

In *O'Neil*, a former Navy officer acquired mesothelioma from asbestos exposure while working aboard a ship. Among other defendants, the plaintiff sued Crane Co., the manufacturer of the steam valves used in the ship on which he served. The plaintiff contended that his injuries were caused by asbestos-laden insulation and gaskets that were paired with Crane Co.'s steam valves when the ship was constructed.

In rejecting the plaintiffs' claims against Crane Co., this Court held "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 those products." (*O'Neil*, *supra*, 53 Cal.4th at p. 342.)

Because the Court of Appeal's opinion in this case holds Novartis liable for injuries caused by Brethine tablets manufactured by another company—and because neither of the two exceptions identified in that passage from *O'Neil* seem to apply—Novartis contends that the Court of Appeal's opinion runs afoul of *O'Neil*.

But that is an overly simplistic reading of *O'Neil* that divorces the decision from the highly specific context of that case.

As a threshold matter, the *O'Neil* court's general statements that the manufacturer of one product cannot be held liable for failing to warn about hazards in another company's product was in reference to *strict products liability*, *not* tort law in general. (*E.g.*, *O'Neil*, *supra*, 53 Cal.4th at p. 348, 361 ["From the outset, strict products liability in California has always been premised on harm caused by deficiencies in the defendant's own product."].)

And while Novartis will surely remind this Court that *O'Neil* dealt with negligence claims *in addition to* strict-liability claims, the *O'Neil* Court's conclusion that Crane Co. was not negligent was *not* predicated on the bare fact that the plaintiff's

injuries were caused by another company's product. Rather, it was because, quite literally, the *only* thing that could be said about Crane Co. was that it knew its otherwise safe steam valves would be paired with asbestos gaskets and insulation when the ship was assembled.

O'Neil thus stands for the proposition that, where another company's product poses hazards for reasons that are wholly independent of traits or characteristics of the defendant's own product, the defendant does not have an affirmative duty to warn of the hazards associated with the other company's product simply because it is foreseeable the two products will be used in concert. In other words, the maker of a spatula is not liable for failing to warn that a stove can cause burns simply because it is foreseeable that the spatula will be used around stoves.

But this case is far different. Plaintiffs do not rely solely on the fact that Novartis could foresee that its failure to update Brethine's label with a much-needed warning regarding the risks that Brethine posed to fetal health would set into motion a chain of events that would induce physicians to continue prescribing Brethine (brand name or generic) to pregnant women indefinitely.

Rather, Novartis's liability is predicated in the first instance on the fact that Novartis breached a federally mandated duty to update Brethine's label in light of ample scientific evidence showing that Brethine posed risks to fetal health.

In short, the different outcomes in *O'Neil* and the Court of Appeal's opinion here—and, for that matter, the decision *Conte*—

are due to the different circumstances of those cases, not because of a divergence in their respective views of California tort law.

Indeed, it is notable that every court to consider the issue has held that *O'Neil* did not impliedly or expressly overrule *Conte*, the virtually identical case on which the Court of Appeal relied in reaching its decision here. (*See In re Darvocet, Darvon & Propoxyphene Products Liability Litigation* (E.D. Ky. 2012) 2012 WL 3842271, at *5–6 ["The Court does not view *O'Neil* as limiting the holding in *Conte*, as suggested by [defendant]."]; *Wendell v. Johnson & Johnson* (N.D. Cal. 2013) 2013 WL 1741704, at *4 ["[T]he *O'Neil* court's holding rests on the particular circumstances in that case, which did not warrant extending the duty of due care. Plaintiffs here have at least a reasonable argument that this case, unlike *O'Neil*, warrants an extension of the duty of due care given the brandname manufacturer's control over labeling."]; see also *Rosa v. Taser Int'l., Inc.* (9th Cir. 2012) 684 F.3d 941, 949 [holding, six months after *O'Neil*, that "under certain circumstances, California's negligence law may impose on a manufacturer a duty to warn individuals who, while not users of its products, could foreseeably rely on its warnings"].)

Indeed, *O'Neil* itself seemed to impliedly endorse the rationale behind the Court of Appeal's decision in this case when, in a footnote, it cited *Powell v. Standard Brands Paint Co.* (1985) 166 Cal.App.3d 357, a case in which the Court of Appeal mused that there may be some limited circumstances a company's inaccurate labeling could serve as a basis to assign liability to it

for to injuries caused by another company's "generically identical" product. (*O'Neil*, *supra*, at p. 352, fn. 7.)

2. The decisions in *Conte* and this case do not conflict with *Cadlo*.

Novartis also contends that the Court of Appeal's decision in this case (and the decision in *Conte*) directly conflicts with the decision in *Cadlo*, *supra*, 125 Cal.App.4th 513. But a close reading of *Cadlo* shows that, as with *O'Neil*, no such conflict exists.

Like *O'Neil*, *Cadlo* involved sailor—Anthony Cadlo—who was exposed to "Kaylo," an asbestos-containing product, while serving on a naval warship. Although *Cadlo*, was not exposed to Kaylo until 1965, he sued Owens-Illinois, which ceased manufacturing Kaylo in 1958. Among other things, the plaintiff accused Owens–Illinois of misrepresentation and concealment for issuing advertisements that under-represented the dangers associated with Kaylo. The First District ultimately held that Owens–Illinois could not be held liable for the plaintiff's injuries.

As a threshold matter, nothing in *Cadlo* challenges the general rule that a tortfeasor who disseminates misinformation to the public is liable for the foreseeable consequences of those misrepresentations. Nor does *Cadlo* stand for the simplistic proposition that one company can never be liable for a tort where the plaintiff's injuries were attributable to a product made by another.

To the contrary, *Cadlo* actually entertained the plaintiff's concealment claims against Owens–Illinois even though Owens-

Illinois did not manufacture the Kaylo to which the plaintiff was exposed. (*Cadlo*, *supra*, 125 Cal.App.4th at pp. 519–520 ["For pleading purposes, the Cadlos satisfactorily alleged that Owens–Illinois knowingly misrepresented that Kaylo was a safe product …."].)

Indeed, the only reason that claim did not succeed in *Cadlo* was because Cadlo failed to establish that he relied on the representations Owen–Illinois issued about Kaylo before it stopped selling the product. (*Id.* at p. 520.) But again, Plaintiffs here, like the plaintiffs in *Conte*, *are* able to establish reliance on Novartis's label due to the unique operation of federal drug law.

Thus, at most, *Cadlo* stands for the proposition that, barring an atypical set of facts, it will be difficult for a plaintiff injured by one company's product to show that his injury was related to another company's misrepresentations, past or present, about its own products.

Plaintiffs do not doubt that proposition and, contrary to the "sky is falling" arc of Novartis's petition, suspect that almost all such cases will fail due to an inability to plausibly plead reliance on the declarant–defendant's representations, let alone the foreseeability of such "slant" reliance. Indeed, it is perhaps no coincidence that the *only* two cases where such claims have succeeded—*Conte* and this one—were both drug cases.

III. Public policy supports asserting liability against brand-name manufacturers who shirk their responsibility to timely update drug labels regarding serious health hazards.

In *O'Neil*, this Court—citing *Rowland v. Christensen* (1968)

69 Cal.2d 108, among other authorities—reiterated that, "[i]n some cases," imposing liability for a negligent act would impose such "an intolerable burden on society" that, "'a cause of action should not be sanctioned no matter how foreseeable the risk.'" (*O'Neil*, *supra*, 53 Cal.4th 335 [quoting *Elden v. Sheldon* (1988) 46 Cal.3d 267, 274].)

Seizing on that concept, Novartis advances a number of doomsday scenarios it predicts will befall California unless this Court abrogates the Court of Appeal's decisions in this case and in *Conte*. But as discussed below, Novartis's prophecies are overblown, and public policy militates heavily in favor of *Conte* and the decision in this case.

A. Without the ability to assign liability to brand-name manufacturers for fraudulent drug labels, there will be no recourse for victims of mislabled drugs.

At present, most state laws allow, if not require, pharmacists to fill a prescription with a generic equivalent if one exists. California is no exception. (See, e.g., Bus. & Prof. Code, § 4073 ["A pharmacist filling a prescription order for a drug product prescribed by its trade or brand name may select another drug product with the same active chemical ingredients of the same strength, quantity, and dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients."].) As a consequence, at least 75 percent of all drugs consumed in the United States are generic drugs. (*See Mensing*, *supra*, 564 U.S. at pp. 627–628 (dis. opn. of

Sotomayor, J.). Moreover, "[n]inety percent of drugs for which a generic version is available are now filled with generics." (*Ibid.*)

But juxtaposed with the fact that 75 to 90 percent of the drugs consumed in the United States are generic drugs is the fact that generic drug manufacturers are, with perhaps the narrowest of exceptions, essentially immune from tort liability for injuries caused by their drugs. This is because federal drug law—which requires generics to mimic the brand-name form of their drugs in both formulation and labeling—has been interpreted to preempt any state-tort suit against a generic-drug manufacturer for deficiencies in formulation or labeling. (*See, e.g.*, *Mutual Pharmaceutical Co. v. Bartlett* (2013) 133 S.Ct. 2466; *Mensing*, *supra*, 564 U.S. 604.)

The result of the above is that, for at least 75 percent of the drugs consumed in the United States, there is virtually no civil recourse if the drug or its labeling proves unreasonably dangerous to the consumer. This is an anomalous result given that Congress regarded state tort suits as a very necessary adjunct to the regulatory power of the FDA in ensuring that the nation's drugs are reasonably safe for the consuming public. (E.g., *Wyeth v. Levine* (2009) 555 U.S. 555, 574.)

California courts—specifically the First District in *Conte* and the Fourth District here—have responded to this problem in the most sensible way: If generic drug manufacturers are virtually immune from lawsuits for deficient labeling on account of the fact that they have no choice but to adopt the label in use by brand-name manufacturers (*Mensing*, *supra*, 564 U.S. at p.

613), then the brand-name manufacturers—which have the means and the responsibility to update the labels (21 C.F.R. § 201.80(e); *id.* § 314.70(c)(6)(iii)(A))—should bear the burden of any misrepresentations therein. In so holding, the Court of Appeal has given the millions of California citizens who rely on generic drugs the only means to seek redress in the event those drugs prove unreasonably dangerous.[2]

B. Novartis derived a pecuniary benefit from the continued sale of Brethine after it divested the brand rights in December 2001.

In *O'Neil*, this Court mused that it would be "unfair to require manufacturers … to shoulder a burden of liability when they derived no economic benefit from the sale of the products that injured the plaintiff." (*O'Neil*, *supra*, 53 Cal.4th at p. 363.) However true that statement is in the abstract, it is irrelevant here because Novartis derived a pecuniary benefit from the

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[2] In response, Novartis will surely point out that Plaintiffs have claims against Global Pharmaceuticals/Impax Laboratories, the manufacturer of the generic medication that Plaintiffs' mother consumed. But Plaintiff's claims against those entities are predicated on a narrow exception to the general rule. In particular, Plaintiffs have alleged that Impax/Global violated federal law prohibiting a drug company from promoting the off-label use of a drug when, among other things, it shipped boxes of generic Brethine to the "Sharp Mary Birch Hospital for Women and Newborns," the facility where Plaintiffs' mother was treated. Plaintiffs contend that Global/Impax thus knew or should have known that the pills it was furnishing to that facility were going to be consumed for a nonapproved use. But, of course, there is no guarantee that claim will succeed at trial. More importantly, the unique facts that *might* permit Plaintiffs to assert claims against Global/Impax are unlikely to exist for the overwhelming majority of persons who consume, and are injured by, generic drugs.

continued sale of Brethine after it sold the brand rights in December 2001.

Again, by December 2001, most of Brethine's profit potential stemmed from its popularity in managing preterm labor *not* its FDA-approved use as an asthma drug. (AA 040–041.) It therefore follows that it was the likelihood of continued Brethine sales that motivated aaiPharma to buy the brand rights from Novartis in the first place. Indeed, if there were no market for Brethine, Novartis would not have any buyers for those brand rights or at least would not have fetched as high a price for them.

Of course, if one agrees that Novartis would not have been able to sell the Brethine brand rights at all or only for much less had the Brethine label contained a warning regarding risks to fetal health, it follows that Novartis derived a pecuniary benefit by failing to update the label with such a warning. The only distinction is that Novartis reaped that benefit the moment it sold the brand rights rather than on a going-forward basis.

C. Novartis could have insulated itself from future tort exposure by simply updating Brethine's label.

Long ago, in *United States v. Carrol Towing Co.* (1947) 159 F.2d 169, Judge Learned Hand articulated the now elementary calculus of negligence in which the burden sought to be imposed is weighed against the likelihood of harm multiplied by the degree of harm. This formula tells us that when a tremendous amount of harm could have been prevented by a minimally burdensome act, the failure to do so is negligent in the extreme.

Here, Novartis's failure to update the Brethine label is alleged to have resulted in severe cognitive deformities in thousands of children. It is further alleged that preventing that harm would have taken nothing more than drafting an update to Brethine's warning label and filing it with the FDA.

It perhaps suffices to say that, from a policy perspective, the fact that so much harm could have been prevented with such a minimal burden weighs heavily in favor of imposing liability on Novartis. (*Randi W.*, *supra*, 14 Cal.4th at p. 1078 [noting that policy supports assigning liability to a defendant that "had alternative courses of conduct to avoid tort liability" at its disposal].)

D. The Court of Appeal's decisions in *Conte* and in this case will enhance, not diminish, the public's access to necessary medications.

Novartis next argues that *Conte* and the Court of Appeal's decision in this case will put medications out of reach for most Californians.

For example, Novartis implies that it and other pharmaceutical companies might stop innovating and selling brand-name drugs if doing so would expose companies like Novartis to tort suits from individuals harmed by generic drugs. (E.g., Novartis Pet. at pp. 24–25.)

But the veiled threat that drug companies might stop producing or marketing drugs unless this Court reverses the Court of Appeal's decisions in this case and in *Conte* is difficult to take seriously from a defendant whose parent corporation, Novartis AG, reported $8.27 **billion** in net profit in 2015 alone.

(Novartis Annual Report 2015, p. 245 <https://www.novartis.com/sites/www.novartis.com/files/novartis-annual-report-2015-en.pdf> [as of May 7, 2016] [reporting 8.041 billion net income in Swiss Francs for 2015].).

For these same reasons, it is also hard to take seriously Novartis's assertion that tort suits like Plaintiffs' may put necessary medications out of the hands of low-income Californians as drug companies mitigate the financial burden of such tort suits by passing the costs through to the consumers in the form of higher-priced medications.

As a threshold matter, it strikes Plaintiffs as a touch disingenuous for a company whose parent corporation sees $8.27 billion in annual net profit to suggest that its *real* motive in this case is ensuring that low-income citizens have access to medications.

In any event, again, the massive profits in the pharmaceutical industry make it hard to believe that companies like Novartis could not absorb the impact of any such suits without having to raise drug prices to the point that they are out of reach of all but the most wealthy Californians.

This, of course, is to say nothing of the fact that this scenario is entirely artificial: For Novartis to incur liability to a patient who is injured by a generic form of Novartis's drug, there would necessarily have to be low-cost generics available to the public. Thus, in any case where Novartis might encounter liability due to a victim's consumption of a generic drug, the

medicine-consuming public will be able to avoid the high prices Novartis threatens it will use to offset its liability in such cases.

Moreover, in arguing the Court of Appeal's decisions in *Conte* and in this case will cause drug companies to stop making drugs or to charge more for them, Novartis overlooks one significant benefit that the decisions in *Conte* and in this case confer on the drug-consuming public: As discussed above, at least 75 percent of the drugs consumed in the United States are generic drugs. But if Novartis has its way, then both brand-name *and* generic drug manufacturers will be virtually immune from any tort suits for injuries caused by generic forms of unreasonably dangerous drugs.

Of course, consumers' realization that they have virtually no recourse if their drugs prove unreasonably dangerous—and the broader realization that the lack of civil liability means there is essentially no check on drug companies to ensure that their labeling is accurate and up to date—could eventually diminish the public's confidence in drugs. This may cause drug companies to lose profits and, more importantly, patients to opt to forego necessary medication.

E. The Court of Appeal's decisions in *Conte* and in this case would have limited application outside drug cases.

Novartis asserts that, although the decisions *Conte* and in this case both involved mislabled drugs, the decisions will inevitably have a trickle-down effect on tort law in general. Accordingly, Novartis vaguely predicts an economic slowdown as

companies consider whether to do business in California. (Novartis Pet. at pp. 33–35.)

But *Conte* has been good law since 2008. In the eight years since, this case is the only appellate decision in California to cite it as a basis for assigning liability to one company for harm caused by another company's product. If the past eight years are any indication, then, Novartis's doomsday prophecies are overblown.

Indeed, it is no coincidence that the three cases assigning liability to one manufacturer company where the instrument of injury was another company's product—this case, *Conte*, and this Court's opinion in *Sindell v. Abbott Laboratories, Inc.* (1980) 26 Cal.3d 588—have all been pharmaceutical cases. This fact, coupled with the contrary outcomes in *O'Neil* and *Cadlo*, all but confirms that the results in *Conte* and in this case will rarely, if ever, be seen in the context of conventional products.

IV. California is at the forefront of tort law insofar as it recognizes the critical importance of foreseeability in the context of tortious misrepresentation cases.

In its petition, Novartis—armed with an impressive string cite—notes that the Court of Appeal's decisions in *Conte* and in this case put California in rare company among the courts to consider whether a brand-name manufacturer can be held liable for injuries caused by a generic drug.

Plaintiffs will spare this Court a case-by-case break down of each out-of-state authority listed in Novartis's voluminous string cites. Instead, it perhaps suffices to assure this Court that, when one analyzes those decisions, it becomes clear that they are based

on either a flawed understanding of federal drug law or more fundamental differences in other state's tort laws that transcend this specific issue. In that regard, Novartis's cited authorities all fall into one of three camps:

One camp consists of courts that more or less blindly follow the Fourth Circuit's decision in *Foster v. American House Products Corp.* (4th Cir. 1994) 29 F.3d 165 (*Foster*), which was perhaps the first published decision to address this precise issue. In *Foster*, the Fourth Circuit, applying Maryland law, held that a brand-name manufacturer does not owe a duty of care to users of a generic medication. *Foster* is notable because it The courts that simply parrot *Foster* obviously includes those sitting within the Fourth Circuit's footprint (e.g., *Stoddard v. Wyeth, Inc.* (E.D.N.C. 2009) 630 F.Supp.2d 631, 633–634; *Meade v. Parsley* (S.D. W. Va. 2009), 2009 WL 3806716), but also some courts outside that jurisdiction.

But *Foster*'s conclusion that brand-name manufacturers were not responsible for injuries caused by a generic drug was predicated in large part on the *Foster* court's mistaken belief that generic manufacturers could unilaterally update their warning labels. (*Foster*, *supra*, 29 F.3d at p. 169 ["[M]anufacturers of generic drugs approved pursuant to ADNAs may alter a drug's labeling '[t]o add or strengthen a contraindication, warning, precaution or adverse reaction' or '[t]o delete false, misleading or unsupported indications for use or claims for effectiveness' without prior FDA approval," quoting 21 C.F.R. §§ 314.70(c)(2), 314.97].)

Of course, after *Foster* was decided, the U.S. Supreme Court confirmed that federal law requires generic drug manufacturers to copy the brand-name label verbatim. (See *Mensing*, *supra*, 564 U.S. at p. 613; see also 21 U.S.C. § 355(j)(2)(A)(v).) Because, for reasons discussed above, the correct interpretation of federal law renders it both highly foreseeable that a consumer of generic drug will rely on a brand-name manufacturer's instructions and deprives consumers of generic drugs of virtually any civil recourse against generic-drug manufacturers, the *Foster* court's fundamental misunderstanding of federal drug law renders the decision void of any persuasive authority.

A second camp consists of courts sitting in, or applying the tort law of, states that—unlike California—have not yet adopted sections 310 and 311 of the Restatement (Second) of Torts. (See, e.g., *Burke v. Wyeth, Inc.* (S.D. Tex. 2009) 2009 WL 3698480, at *2-3 [tortious misrepresentation in Texas limited by Restatement section 552]; *Moretti v. Wyeth, Inc.* (D. Nev. 2009), 2009 WL 749532, at *3-4 [declining to apply *Conte* because Nevada had not yet adopted Restatement sections 310 and 311].)

In fact, California is one of few states that have formally adopted sections 310 and 311 of the Restatement (Second) of Torts and therefore condition liability for tortious misrepresentation on foreseeability. (Robert K. Wise & Heather E. Poole, *Negligent Misrepresentation in Texas—The Misunderstood Tort* (2008) 40 Tex. Tech. L. Rev. 845, 849–852.)

The majority of other states have either adopted the common-law rule of "near privity" or Restatement section 552. Under either standard, a lawsuit for tortious misrepresentation cannot be maintained absent a relationship between plaintiff and defendant. (*Ibid.*; Martin A. Ramey, Conte v. Wyeth*: Caveat Innovator and the Case for Perpetual Liability in Drug Labeling* (2010) 4 Pitt. J. Envtl Pub. Health L. 73, 98–101.) But because California follows sections 310 and 311 of the Restatement (see *Randi W.*, *supra*, 14 Cal.4th at pp. 1070, 1077, 1081; *Garcia*, *supra*, 50 Cal.3d at pp.735–736)—an conclusion that preceded *Conte* by at least a decade—there is no such impediment to tortious misrepresentation claims in California.

A third and final camp consists of courts that view any tort claim involving a product as a strict-products-liability case even if the plaintiff alleged tortious misrepresentations claims. And because they view any tort claim involving a product as a "product-liability case," courts in this camp simply default to the common-law, strict-products-liability rule that—as was also set forth in *O'Neil*—a company cannot be held strictly liable for injuries caused by another company's product.

But, once again, California is in the minority of states which do not view every tort case as a "products case" simply because the instrument of injury was a "product." To the contrary, California courts recognize that whether a case is a "products case"—and thus whether the general rule against holding one company strictly liable for the products of another applies—depends on the theory of liability asserted, *not* whether

the injury-producing instrumentality was a "product." (See *Saller v. Crown Cork & Seal Co., Inc.* (2010) 187 Cal.App.4th 1220, 1239 ["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."]; see also *Kellogg v. Wyeth, Inc.* (D. Vt. 2010) 762 F.Supp.2d 694, 704 (*Kellogg*) ["To date, however, Vermont has not eliminated common law actions for negligence or fraud merely because they involve products. … Neither the Vermont courts nor the Vermont legislature have collapsed negligence actions into strict liability actions where products are involved."]; *Dolin v. SmithKline Beecham Corp.* (N.D. Ill. 2014) 62 F.Supp.3d 705, 713 (*Dolin*) ["Nothing in Illinois common law compels a court to construe Plaintiff's common law negligence claims as product liability claims either."].)

In short, the minority status of Court of Appeal's decisions in *Conte* and in this case are the direct result of the fact that (1) California courts correctly understand federal drug law and (2) is in the minority in more fundamental aspects of tort law that both transcend and long pre-date the cases addressing who should bear liability for mislabeled drugs.

This, of course, is not to mention that being in the "minority" is simply part and parcel of California's status as an innovator of tort law in the United States. (Novartis Pet. at p. 13 ["California has long been in the forefront of nationwide issues of product liability law."].) Of course, California did not achieve its

status as the innovator of American tort law by playing it "safe" and sticking with the majority.

Indeed, to take but a few of many possible examples, California was among the first states, if not *the* first state, to articulate and apply the concept of market-share liability (*Sindell*, *supra*, 26 Cal.3d 588), comparative negligence (*Li v. Yellow Cab Co.* (1975) 13 Cal.3d 804), burden-shifting in cases where the defendant's negligent act deprived the plaintiff of the ability to establish causation (*Haft v. Lone Palm Hotel* (1970) 3 Cal.3d 756), and the collateral-source rule (*Helfend v. Southern California Rapid Transit District* (1970) 2 Cal.3d 1).

Most, if not all, of these decisions were (and, in some cases, still are) heavily criticized by courts and commentators outside of California. But neither criticism nor the specter of intellectual solitude has deterred this Court from staking out sensible principles of tort law that, in time, have garnered more widespread—if not universal—acceptance.

Someday, courts in jurisdictions across the United States may scarcely remember a time when brand-name manufacturers were *not* deemed liable for injuries caused by their misleading labeling regardless of whether the victim was injured by a brand-name or generic form of the drug. But for those that *do* remember such a time, they will also undoubtedly remember that, as has been true so many times in the past, California's courts were the first.

CONCLUSION

For the foregoing reasons, Plaintiffs pray this Court will **deny** Novartis's petition for review.

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CERTIFICATE OF COMPLIANCE

Pursuant to rule 8.504(d)(1) of the California Rules of Court, I certify that, according to the word-count feature in the word-processing program used to generate this brief, this Answer to Petition for Review contains **8,216** words, including footnotes, but excluding the content identified in rule 8.504(d)(3).

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PROOF OF SERVICE

I, the undersigned, say: I am over 18 years of age, employed in the County of San Diego, California, and not a party to the subject cause. My business address is 2550 Fifth Avenue, Suite 1100, San Diego, California, 92103.

On May 9, 2016, I served the attached **Answer to Petition for Review**, of which a true and correct copy of the document filed in the cause is affixed by placing a copy thereof in a separate envelope for each addressee named hereafter, addressed to each such addressee respectively as follows:

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Each envelope was then sealed, and with the postage thereon fully prepaid, deposited in the United States mail by me at San Diego, California, on May 9, 2016.

I declare under penalty of perjury that the foregoing is true and correct, and this declaration was executed at San Diego, California, on May 9, 2016.

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Diane DeCarlo