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 Brief on the Merits

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2. If so, does a manufacturer that attempts to maximize its profit from an illegally mislabeled drug by selling that drug to another company instead of adding warnings required by federal law remain potentially liable for subsequent, foreseeable injuries caused by the mislabeled drug?

INTRODUCTION

As this Court recently reaffirmed, there is a "substantial body of California law aimed at protecting consumers from the potential dangers posed by prescription medication, including warnings about serious side effects and prohibiting false and misleading labeling." (*Bristol Myers Squibb Co. v. Superior Court* (Cal. Aug. 29, 2016) 2016 WL 450617, at *16.)

In keeping with that "substantial body of California law," Plaintiffs seek to hold Novartis responsible for marketing and selling for use by pregnant women a prescription drug ("Brethine") that poses a risk of serious injury to the developing fetal brain—a risk that was not disclosed on the drug's label.

In 2001, when the risk became too obvious for Novartis to continue to ignore, rather than update the Brethine label to warn of the risk (as federal drug laws required it to do), Novartis simply sold the mislabeled drug to another company (aaiPharma) for a tidy profit and went on its way.

But, predictably, because Brethine's market value was dependent on its continued sales to pregnant women, aaiPharma *also* failed to update the Brethine label, leaving the original, Novartis label intact.

A few years later, when Plaintiffs' mother became pregnant with twin boys, her doctor prescribed a generic version of Brethine to control her pre-term labor. Because federal law requires generic drugs to bear the same labels as their brand-name equivalents, her doctor, in prescribing the drug to Plaintiffs' mother, relied on the same, dangerously inaccurate label that was written by Novartis before it sold the drug to aaiPharma in 2001. Because that label said nothing about the drug's risk to unborn children, the doctor saw no problem with prescribing the drug to Plaintiffs' mother to control her pre-term labor.

Plaintiffs were born with brain damage, and it happened as a direct result of Novartis's original refusal to update its label to disclose the risk it knew about back in 2001—the risk it chose to ignore when it chose profit over the health of American families.

Novartis nonetheless asks this Court to grant it total immunity for its negligent—possible intentional—failure to update its label, claiming that (a) brand-name drug companies can't be sued at all for injuries caused by generic versions of their drugs; and (b) even if they could, *this* lawsuit must fail because

Novartis had already sold its inadequately labeled drug to another company by the time the Plaintiffs' injuries occurred.

Novartis's argument fails on both counts. First, the lower court's ruling that brand-name companies can be held liable for negligently misrepresenting the dangers of generic drugs is fully consistent with one of the most basic 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. (See, e.g., *Randi W. v. Munroc Joint Unified School Dist.* (1997) 14 Cal.4th 1066, 1077.)

Here, the "foreseeable reliance" is a function of the fact that federal law *requires* generic drug labels to be identical to the labels written for biologically equivalent brand-name drugs. As a result, where—as here—a consumer is injured by an inadequately labeled generic drug, the fault for the misrepresentation is that of the brand-name manufacturer, not the generic. It therefore makes perfect sense, and is perfectly in keeping with California tort law, to hold brand-name manufacturers liable for injuries caused by inadequately labeled generic drugs.

It is also perfectly in accordance with California tort law to allow liability to extend to "former" brand-name manufacturers, in cases where—as here—the divestiture of the drug to a successor company does not break the chain of causation between the original drug company and the injured party. It is well established that "[a]n originally negligent actor generally remains liable although a third person negligently fails to…prevent[ ] the harm *if the third person's conduct is reasonably foreseeable*." (*Cline v. Watkins* (1977) 66 Cal.App.3d 174, 179 [emphasis added].)

Here, because Brethine's market value depended on its continued sales to pregnant women, it was more than "reasonably foreseeable" to Novartis that aaiPharma would, just like Novartis, violate its duty to update the drug's label to warn of its serious risks to the fetal brain—it was a virtual certainty. Thus, under California law, Novartis should remain potentially liable for its misrepresentation even though it did not own the drug at the time Plaintiffs sustained their injuries.

And the rule advocated by Novartis—a bright-line rule of immunity for all former manufacturers of brand-name drugs—would represent the worst sort of public policy. Novartis's

proposed rule would create a powerful disincentive for brand-name manufacturers to update their labels when serious hazards emerge in the post-approval marketplace, thereby directly undermining the most important public-policy factor behind the imposition of tort liability: the prevention of future harm. (See *Rowland v. Christian* (1968) 69 Cal.2d 108, 113.)

Under Novartis's approach, a brand-name company with a mislabeled drug could get off scot-free by simply selling its drug to another company without first changing the label, leaving consumers entirely at the mercy of the successor company as to whether (and, if so, when) the label is ever updated—or not, as occurred in this case. And where, as here, the drug's market value is dependent on the label *not* being updated to disclose the risk, the incentives to simply toss the "hot potato" of a dangerously mislabeled drug without first changing the label are especially powerful. The risk of potential tort liability provides a necessary deterrent to this type of life-threatening corporate misconduct.

For all these reasons, this Court should reject Novartis's invitation to immunize brand-name pharmaceutical manufacturers at the expense of public health and safety.

STATEMENT OF FACTS

A. Federal Regulation of Drug Labeling.

All prescription drugs sold in this country require the approval of the U.S. Food and Drug Administration (FDA) before they may be marketed. (21 U.S.C. § 355(a).) To obtain approval for a new drug, a brand-name manufacturer must submit a "New Drug Application" (NDA) demonstrating the drug's safety and effectiveness through clinical trials. (21 U.S.C. §§ 355(b), (d).)

NDA applicants must also propose labeling for the drug, which must identify, among other things, appropriate use of the product, contraindications, warnings, precautions, and adverse reactions. (21 C.F.R. § 201.56.) In particular, the drug's label must bear "such adequate warnings against use… where its use may be dangerous…as are necessary for the protection of users." (21 U.S.C. § 352(f)(2).)[1]

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[1] Under federal law, the term "label" includes not only the fine print on a bottle or box containing the medication, but also any printed material inside the container, any marketing materials, and the drug's corresponding entry in the *Physician's Desk Reference*, an exhaustive compendium of drug labels that physicians consult to educate themselves regarding drug information. (See 21 U.S.C. § 321(m); 21 C.F.R. § 202.1(l)(2). Consistent with federal law, this brief uses the term "label" broadly to encompass all these items.

"Originally the same rules applied to all drugs." (*PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 613.) In 1984, however, Congress passed the Drug Price Competition and Patent Term Restoration Act ("Hatch–Waxman") which allows an applicant to file an abbreviated NDA—an "ANDA"—for a new generic drug. (21 U.S.C. § 355(j)(2)(A).) In return, Hatch–Waxman extended patent protection for brand-name drug manufacturers to account for the time spent in the FDA's drug approval process. (35 U.S.C. §156(a)(4).)

Under Hatch–Waxman, generic drugs can obtain FDA approval simply by showing (1) equivalence to a brand-name drug that has already been approved by the FDA (*PLIVA, supra*, 564 U.S. at p. 612 [citing 21 U.S.C. § 355(j)(2)(A)]); and (2) that the generic drug's label "is the same as the labeling approved for the [brand-name] drug." (*Ibid.* [citing 21 U.S.C. §§ 355(j)(2)(A)(v), 355(j)(4)(G)].)

Once a drug is approved by the FDA, all manufacturers of that drug—brand-name and generic alike—must use the label approved by, and on file with, the FDA. (See 21 C.F.R. § 314.70(b)(2)(v).) The label's content, however, is not set in stone. Rather, FDA regulations provide that approved drug

labeling "*shall* be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug[.]." (*Id.* § 201.80(e) [emphasis added].)

Typically, necessary label changes are made through a "supplement" submitted by the manufacturer to FDA for the FDA's pre-approval. (See 21 C.F.R. §§ 314.70, 314.71, 314.90.)

But under the "changes being effected" (CBE) regulation, *brand-name* manufacturers can unilaterally update their labels without the FDA's express prior authorization where that "[brand-name] manufacturer is changing a label to 'add or strengthen a contraindication, warning, precaution, or adverse reaction.'" (*Wyeth v. Levine* (2009) 555 U.S. 555, 568.) In such cases, the brand-name manufacturer "may make the labeling change upon filing its supplemental application with the FDA; *it need not wait for FDA approval*." (*Ibid.* [emphasis added].)

But, notably, *generic* drug manufacturers are *not* permitted to add to or strengthen their labels in any way without prior FDA approval, no matter how inadequate the warning may be. This is because the FDA's regulations require generic drug labels to be *identical* to the label used by the brand-name manufacturer of the drug, regardless of what new risks are discovered during the

post-marketing period. (See 57 Fed. Reg. 17,961 (1992); *PLIVA, supra,* 564 U.S. at p. 613.) As a result of this so-called "duty of sameness," if a generic manufacturer "believes that new safety information should be added" to its drug's labeling, it must "provide adequate supporting information to FDA, and the FDA will determine whether the labeling for the generic and [brand-name] drug should be revised." (57 Fed. Reg. 17,950, 17,951 (1992).) Until then, it is powerless to change the drug label.[2]

B. Different Tort Liability for Brand-Name and Generic Drug Manufacturers.

The differences between brand-name and generic manufacturers' ability to update an inadequate warning label under the FDA's regulations have, naturally, given rise to two different approaches to their respective liability for mislabeled drugs.

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[2] In November 2013, the FDA introduced a proposed rule that would enable generic-drug manufacturers to unilaterally update their labels, even if the revised labeling differs from its brand-name counterpart. (78 Fed. Reg. 67,985 (2013).) The rule's publication date was delayed to April 2017. (STAT, *FDA Again Delays Rule to Allow Generic Drug Makers to Change Labels*, https://www.statnews.com/pharmalot/2016/05/19/fda-generic-drugs-safety/ [as of Oct. 9, 2016].) In light of issues about its legality, some question whether the proposal will ever become reality. (*Ibid.*)

In *Wyeth*, *supra*, 555 U.S. 555, the U.S. Supreme Court held that, consistent with federal law, brand-name drug manufacturers can be held liable under state law for failing to warn about known hazards of their drugs. (*Id.* at p. 558.) The Court relied heavily on the fact that, under the FDA's regulatory scheme, Wyeth—a brand-name manufacturer—had the authority to strengthen its own warning labels without first obtaining FDA approval. (*Id.* at pp. 568–569.) Accordingly, the Court held, there was no tension between federal drug law and state tort law—both permitted, and indeed *compelled*, drug manufacturers to update their labels as soon as a deficiency in the warnings was identified. (*Id.* at p. 573.)

Two years later, however, in *PLIVA, supra,* 564 U.S. 604, the Court held that federal law *does* preempt state-law claims against *generic* drug manufacturers for failing to warn about known hazards (*Id.* at p. 624.) The Court reasoned that, because the FDA's regulations "demand[ ] that generic drug labels be the same at all times as the corresponding brand-name drug labels...," it would be "impossible for the [Generic] Manufacturers to comply with both their state-law duty to change the label and

their federal-law duty to keep the label the same." (*PLIVA*, *supra*, 564 U.S. at p. 618.)

Under *PLIVA*, consumers injured by inadequately labeled generic drugs—which make up over 80 percent of all prescription drugs taken in this country (78 Fed. Reg. 67,989 (2013))—have no recourse against the manufacturer of the drug that injured them.

C. Novartis's "Off-Label" Promotion of Brethine.

This case involves a drug that was aggressively marketed by Novartis and its corporate predecessors for an "off-label" use—that is, a use that was never approved by the FDA and thus never found to be safe or effective for that particular purpose.[3]

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[3] As one court recently explained, "[t]he FDA has long taken the position that a drug manufacturer that markets or promotes an approved drug for an unapproved use violates federal law." (*Amarin Pharma, Inc. v. FDA* (S.D.N.Y. 2015) 119 F.Supp.3d 196, 203.) Prior to 1997, drug manufacturers were explicitly prohibited from promoting their drugs for any unapproved use. (See O'Reilly & Dalal, *Off-Label or Out of Bounds? Prescriber and Marketer Liability for Unapproved Uses of FDA-Approved Drugs* (2003) 12 Annals of Health Law 295, 301 (hereafter *Off-Label-or Out of Bounds?)*.) In 1997, drug manufacturers were given a limited right to advertise off-label uses, contingent on approval of a supplemental new drug application. (See *id.* at p. 297.) But absent such approval, "the FDA's position is that a manufacturer who markets or promotes an off-label drug risks criminal liability for 'misbranding' under 21 U.S.C. § 331(A)…'" (*Amarin*, *supra*, 119 F.Supp.3d at p. 203.)

Specifically, Plaintiffs' mother was prescribed an FDA-approved asthma drug for the "off-label" purpose of preventing her from going into preterm labor (also known as "tocolysis"). The drug's active ingredient was terbutaline sulfate, one of several drugs known as "beta-agonists" or "beta-mimetics" that were released in 1970 for use as asthma medications. Terbutaline was approved to treat asthma by the FDA in 1974 under the brand name "Brethine." (AA022–027.)[4]

Brethine never achieved much success as an asthma drug. This was largely because the market for asthma drugs was fiercely competitive, with doctors favoring branded and generic forms of albuterol for asthma treatment. As a consequence, Brethine had disappointing sales figures as an asthma treatment. (AA040.)

But new "hope" for Brethine emerged in 1976, when a Swedish physician with ties to a pharmaceutical company published the results of a study which suggested that terbutaline had an acute "tocolytic" effect, meaning that it appeared to

[4] References to the Appellants' Appendix are abbreviated as "AA."

temporarily blunt labor contractions when given for a single 48-hour period. (AA022.)

Based on that data, Ciba-Geigy—the corporate predecessor to Novartis—acquired the exclusive right to market Brethine in the United States. Then, in the mid-1980s, Ciba-Geigy began to promote Brethine off-label for tocolytic use, even though there was no data on either the effectiveness *or* the long-term health effects of tocolytic therapy on the fetus. (AA022.)

These promotional efforts continued in the 1980s and 1990s, even as data began to mount that terbutaline not only had questionable efficacy as a tocolytic, but even worse, had dangerous consequences for fetal health, particularly for the fetal brain. (AA022–033.)

In the mid-1990s, the NDA for Brethine passed into Novartis's hands when Ciba-Geigy and Sandoz merged to form Novartis.[5] Novartis picked up where its corporate predecessor left off and actually took the promotional efforts to another level when it began promoting Brethine for so-called "maintenance tocolysis," which entails prolonged, regular Brethine

[5] Novartis, "Company History," <https://www.novartis.com/about-us/who-we-are/company history> [as of Oct. 9, 2016].

consumption—the type of consumption that can dramatically boost profits.

These promotional efforts paid off: Between the mid-1990s and late 2001, the use of Brethine for maintenance tocolysis had become well engrained with obstetricians throughout the United States. (AA042.) As a consequence, the once-fledgling asthma drug was, by 2000, posting $23 million in annual sales, most of which was owed to its tocolytic use.[6]

But while Novartis was making millions promoting and selling Brethine as a maintenance tocolytic, data throughout the 1980s, 1990s, and early 2000s, showed that beta-mimetics like Brethine were not only ineffective as a maintenance tocolytic, but actually caused serious damage to the fetal brain, particularly when used for long-term, maintenance tocolysis. (AA022–035.)

By 2001—the year Novartis sold Brethine to another company—this data was sufficiently clear that a team of German doctors found that "motor, socio-emotional, and cognitive—especially verbal—development was impaired in a group of term

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[6] See SEC, Form 8-K/A Report for aaiPharma, Inc. (Aug. 17, 2001), at p. F-2 <http://www.sec.gov/Archives/edgar/data/1013243/000095014402002153/g74591e8-ka.txt> [as of Oct. 9, 2016].)

children exposed to tocolytic treatment" using drugs like Brethine. (AA034.) These findings were echoed by researchers from Duke Medical Center who, by October 2001, concluded "that there are long-term liabilities of tocolysis with [Brethine], including…impaired school performance, and subsequent cognitive impairment and psychiatric disorders." (AA035.)

None of these risks were disclosed on Brethine's label. Instead, as of 2001, other than "increased fetal heart rate" and "hypoglycemia," the label merely warned of the potential risks of tocolytic use to the *mother,* thereby deceptively implying that Brethine posed no risks to fetal health.[7]

D. Novartis's 2001 Sale of Brethine to aaiPharma.

By 2001, Novartis faced a difficult choice. In light of the mounting scientific research, Novartis could no longer deny the risks of Brethine to the fetal brain. Disclosing those risks, however, would dramatically cut into Novartis's profits, because

[7] See FDA Response to Citizen's Petition (Feb. 17, 2011), at pp. 3–4, <http://www.fda.gov/downloads/drugs/drugsafety/ucm243797.pdf> [as of Oct. 9, 2016] [describing precautions sections of labeling for terbutaline, unchanged since Novartis's ownership of the drug in 2001].

the company was earning over $20 million in annual sales from Brethine, half of which were from its use as a tocolytic. (AA41.)

This somewhat unusual dilemma was a function of the fact that Brethine's principal market happened to be the very thing for which it was most dangerous: long-term tocolytic use. That, in turn, was a function of the fact that the drug was being prescribed "off-label" for a use for which it had never been found to be either safe or effective by the FDA.

If Novartis did what federal law required by adding warnings to the Brethine label regarding the potential hazards to fetal health, it would kill its "golden goose." On the other hand, every day it continued to market Brethine without adequate warnings, Novartis's tort exposure increased.

Novartis chose a third option. Rather than update Brethine's label *or* continue to market the drug with an inadequate label, Novartis sold Brethine, warts and all, to another drug company, aaiPharma, for $26.6 million in December 2001.[8]

[8] Despite selling the brand rights to the drug, Novartis retained an on-going interest in future Brethine sales by agreeing to manufacturer and supply the actual medication for aaiPharma

E. Post-Divestiture Events Relating to Brethine.

Virtually everything that Novartis might have predicted when it sold Brethine to aaiPharma without updating the label came true.

First, in the years immediately following Novartis's sale of Brethine to aaiPharma, additional studies continued to show that terbutaline posed series risks to fetal health. (AA034–039.)

Second, as Novartis also could have predicted, despite the additional evidence that terbutaline damaged the fetal brain when used as a tocolytic, aaiPharma continued to manufacture Brethine without updating the label to warn about Brethine's risks to fetal health. This was surely no surprise given that aaiPharma's willingness to pay $26.6 million for Brethine's brand rights was predicated on its sales potential as a tocolytic.

F. This Lawsuit.

This lawsuit was filed on behalf of fraternal twins who were injured in utero by their mother's off-label use of generic Brethine.

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through the end of 2004. (See aaiPharma, Inc. Form 10-K (Apr. 2005), at p. 7, < http://edgar.sec.gov/Archives/edgar/data/1013243/000095014405004448/g93882ke10vk.htm> [as of Oct. 9, 2016] [describing "interim supply agreement" requiring Novartis to supply aaiPharma with Brethine through Dec. 13, 2004].)

In early September 2007, the twins' mother was hospitalized due to concerns she might go into premature labor. As was convention at the time, her physician prescribed Brethine for maintenance tocolysis. When the twins were almost three, their pediatrician indicated they had developmental delay and they were ultimately diagnosed with autism in 2012. (AA043.)

The twins' sued Novartis, among others, for negligence, intentional misrepresentation, concealment, and negligent misrepresentation. Novartis demurred, arguing it had no duty to the twins because it did not manufacture the medication consumed by their mother and had no responsibility for the label in 2007 since it sold the rights to Brethine six years earlier. The trial court sustained the demurrer.

On appeal, Plaintiffs argued that, under longstanding California tort law, those who disseminate misinformation to the public are liable for injuries caused by foreseeable reliance on that misinformation. Applying that principle to this case, Plaintiffs argued that Novartis can be held liable for the causal role its misconduct played in Plaintiffs' injuries because:

- Prior to divesting the drug in December 2001, Novartis was (or should have been) aware of the substantial data showing that Brethine

posed risks of serious birth defects when administered to pregnant women.

- In light of that data, prior to divesting the drug in December 2001, Novartis had a duty, under federal law, to update Brethine's label with a warning regarding the potential risks to fetal health.

- Because drug manufacturers may unilaterally *add* or *strengthen* warnings on drug labels but cannot *remove* warnings without prior FDA approval, had Novartis updated the Brethine label prior to divesting the drug in December 2001 with a warning regarding risks to fetal health, that warning more likely than not would have remained on the Brethine label—brand-name *and* generic—indefinitely.

- Had the Brethine label warned of risks to fetal health, Plaintiffs' mother would not have taken Brethine while pregnant with Plaintiffs.

The Court of Appeal agreed, holding that if Plaintiffs can "in good faith" allege that (1) "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," and (2) "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," then "their claims for negligence and negligent misrepresentation can survive demurrer based on California law." (*Ibid.*)

ARGUMENT

Before addressing what this case *is* about, it is important to clarify what it is *not*. Contrary to Novartis' arguments:

- Plaintiffs do *not* contend Novartis is liable merely by virtue of having "innovated" Brethine;
- Plaintiffs do *not* contend Novartis is liable merely by virtue of its status as a "former" Brethine manufacturer; *and*
- Plaintiffs do *not* contend Novartis is liable for doing—or failing to do—anything after December 2001.[9]

Rather, Plaintiffs simply seek to assign liability to Novartis for the foreseeable, downstream consequences of its failure to discharge its federally mandated duty to update Brethine's label *while it still owned Brethine* (i.e., *prior to* December 2001).

With that in mind, it becomes clear that this case presents just two questions for this Court's consideration:

1. Can a brand-name manufacturer that knew or should have known that its drug was mislabeled ever be held liable for injuries caused by a generic version of the drug?

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[9] Novartis attempted this same distortion in the Court of Appeal, which saw it for the mischaracterization it was and squarely rejected it. (See *T.H. v. Novartis Pharmaceuticals Corp.* (2016) 245 Cal.App.4th 589, 601.)

2. If so, does a manufacturer that attempts to maximize its profit from an illegally mislabeled drug by selling that drug to another company instead of adding warnings required by federal law remain potentially liable for subsequent, foreseeable injuries caused by the mislabeled drug?

As discussed in Part I below, the answer to the first question is "Yes." Where (1) a brand-name manufacturer breaches its federal duty to update a drug label with necessary warning information; and (2) a patient is injured by a generic drug in reliance on that inaccurate label; then (3) California tort law strongly supports imposing liability on the brand-name manufacturer.

As Part II explains, the answer to the second question is also "Yes." Where (1) a "former" brand-name manufacturer breaches its federal duty to update a drug label with necessary warning information; (2) the update would have prevented a plaintiff's exposure to the drug; and (3) the former brand-name manufacturer could reasonably have foreseen that its successor would not update the label either; then (4) the former brand-name manufacturer also bears liability for injuries caused in reliance on the inaccurate label.

I. Longstanding Tort Principles Support Imposing Liability on Brand-Name Drug Companies for Injuries Caused by Generic Drugs.

Holding brand-name manufacturers liable for injuries caused by generic versions of their drugs is consistent with the long-standing rule that those who disseminate misinformation to the public are liable for physical harm to third parties resulting from foreseeable reliance on those misrepresentations.

A. Under California Law, Those Who Disseminate Misinformation to the Public Are Liable for Physical Harm Resulting from Foreseeable Reliance on Those Misrepresentations.

This principle was first articulated in Section 311 of the *Restatement (Second) of Torts*, which provides that "[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 . . . *to such third persons as the actor should expect to be put in peril by the action taken*." (*Id*. [emphasis added].)

Hanberry v. Hearst Corp. (1969) 276 Cal.App.2d 680, was among the first cases to expressly apply this intuitive principle. There, a consumer sued *Good Housekeeping Magazine* for giving a 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 liable for negligently misrepresentation. Citing the *Restatement*, the Court of Appeals agreed, noting that the magazine "ha[d] placed itself in the position where public policy impose[d] upon it 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.)

This Court relied on this sensible principle in *Garcia v. Superior Court* (1990) 50 Cal.3d 728, where a parole officer dissuaded a parolee's prior victim from taking security 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.) Citing *Hanberry* and Section 311 of the *Restatement*, this Court held that, once the parole officer elected to speak, he bore a duty to provide accurate information and could be held accountable for

any harm caused by the inaccuracy of that information. (*Id.* at pp.735–736.)

Garcia created an important exception to the "ordinary rule" that liability for negligent misrepresentations is limited to "those who supply information for business purposes in the course of a business or profession." (*Id.* at p. 735 [citation omitted].) *Garcia* held that, where physical harm is involved, "there may be liability for the negligence even though the information is given gratuitously and the actor derives no benefit from giving it." (*Ibid.* [citation omitted].)

Then, in *Randi W. v. Munroc Joint Unified School Dist.* (1997) 14 Cal.4th 1066, 1077, this Court extended *Garcia* to hold that "one who negligently provides false information to another can owe a duty of care to a *third person* who did not receive the information and who has no special relationship with the provider of the false information." (*Id.* [emphasis added].) *Randi W.* specifically ruled that a school district's misrepresentations about a former employee in a letter of recommendation could render the school district liable for the employee's molestation of a student at his new school. "[C]onsistent with Restatement Second of Torts sections 310 and 311," this Court held, the writer

of the recommendation owed a duty not to misrepresent the relevant facts if the misrepresentations would present a foreseeable and substantial risk of harm to a third party. (*Id.* at p. 1081.)

B. *Conte* is Deeply Rooted in California Tort Law.

Hanberry, *Garcia*, and *Randi W.* inexorably led to the decision in *Conte v. Wyeth* (2008) 168 Cal.App.4th 89, where the Court of Appeal—citing each of the above authorities—applied common-law principles of duty and foreseeability to conclude that a brand-name drug manufacturer could be held liable under a negligent-misrepresentation theory for injuries caused by a generic version of its drug. (*Id.* at p. 109.)

Conte began by dismissing the brand-name manufacturer's argument—the same argument Novartis advances here—that it was immune from suit because it did not manufacture the actual pills that injured the plaintiff. While the court agreed that a defendant generally cannot be held liable in *products liability* absent a showing that it made the offending product, the court held that this rule did not bar the plaintiff's suit because the plaintiff had alleged a negligent-misrepresentation claim against

the brand-name manufacturer, *not* a strict-liability claim. (*Id.* at p. 101.)

Conte then addressed "whether a name-brand prescription drug manufacturer…owes a duty of care to patients who take a generic version of the drug pursuant to a prescription written in reliance on the name-brand maker's information." (*Id.* at p. 103.) *Conte* observed that, "[a]s in *Garcia* and *Randi W.*, in this case our duty analysis must look primarily to the foreseeability of physical harm." (*Id.* at p. 104.) The court observed:

> In California, as in most states, pharmacists have long been authorized by statute to fill prescriptions for name-brand drugs with their generic equivalents unless the prescribing doctor forbids the substitution… It is therefore highly likely that a prescription for Reglan written in reliance on Wyeth's product information will be filled with generic metoclopramide. And, because by law the generic and name-brand versions of drugs are biologically equivalent…, it is also eminently foreseeable that a physician might prescribe generic metoclopraminde in reliance on Wyeth's representations about Reglan.

(*Id.* at 105.) "In this context," *Conte* concluded, "we have no difficulty concluding that Wyeth could reasonably perceive that there could be injurious reliance on its product information by a patient taking generic metoclopramide." (*Ibid.*)

That conclusion is hardly exotic or revolutionary, given that federal law *requires* generic drug label to be *identical* to brand-name drug labels. And *Conte*'s recognition that brand-name manufacturers' duty of care extends to consumers of generic drugs is in lockstep with *Randi W.*'s holding that "the writer of a letter of recommendation owes to third persons a duty not to misrepresent the facts…if [doing so] would present a substantial, foreseeable risk of resulting physical injury…" (*Randi W., supra*, 14 Cal.4th at p. 1081.)

In fact, far from an extreme expansion of California tort law, *Conte* is actually a *more conservative* ruling than both *Garcia* and *Randi W.* insofar as those cases imposed liability for negligent misrepresentations "even though the information was given gratuitously and the actor derive[d] no benefit from giving it." (*Garcia*, *supra*, 50 Cal.3d at p. 375.)

C. *O'Neil* Strongly Supports Plaintiffs, Not Novartis, by Endorsing *Conte*'s Approach to Negligence Claims.

Notwithstanding *Conte*'s consistency with *Garcia* and *Randi W.*, Novartis contends that this Court implicitly overruled *Conte* in *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335. Novartis is

wrong. In fact, *O'Neil* strongly supports and affirms *Conte* and, thus, the decision below.

1. O'Neil*'s Holding that Manufacturers Can Only Be Sued for Injuries Caused by Their Own Products Only Applies to Strict Liability Claims.*

As a threshold matter, the holding in *O'Neil* that is championed by Novartis—that product manufacturers may not be held liable for harm caused by another manufacturer's product—only applies to *strict-liability claims*, not negligence claims, and thus has nothing to do with this negligent-misrepresentation case.

We know this for two reasons. First, *O'Neil* contained both strict-liability claims *and* negligence claims, and virtually all of *O'Neil*'s broad statements to the effect that manufacturers cannot be sued for injuries caused by another manufacturer's product are couched entirely in terms of strict products liability.[10]

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[10] (See, e.g., *O'Neil*, *supra*, 53 Cal.4th at p. 348 ["From the outset, *strict products liability* in California has always been premised on harm caused by deficiencies in the defendant's own product"]; *ibid.* ["We have never held that *strict liability* extends to harm from entirely distinct products that the consumer can be expected to use with, or in, the defendant's non-defective product. Instead, we have consistently…requir[ed] proof that the plaintiff suffered injury caused by a defect in the defendant's own product."]; *id.* at p. 349 ["the mere foreseeability of injury to users of a defective product [has never been] sufficient justification for

Second, the Court's actual *holding* that a product manufacturer can only be sued for injuries caused by its own products only related to the strict-liability claims in that case. The Court's language is crystal clear on this point. It states "that a product manufacturer generally may not be held *strictly liable* for harm caused by another manufacturer's product." (*Id.* at p. 362 [emphasis added].) This holding is plain on its face. It contains no reference to negligence claims, and thus Novartis's attempt to graft it onto this lawsuit—a negligent-misrepresentation case that has nothing to do with strict liability—fails right out of the starting gate.

If there were any remaining doubt as to the limits of *O'Neil*'s holding, it would be dispelled by the fact that this Court then went on to separately analyze the plaintiff's *negligence*

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imposing *strict liability* outside the stream of commerce."] [emphases added to all quotes].)

The only exception is a stray quote from the beginning of the decision—which Novartis seizes upon in its brief (see OBOM at p. 18)—that is couched in broader terms. (See *id.* at p. 342 [stating that "product manufacturers may not be held liable in strict liability or in negligence for harm caused by another manufacturer's product."].) The actual holding of *O'Neil*, however, is far narrower, as this brief explains.

claims by applying the policy factors set forth in *Rowland v. Christian* (1968) 69 Cal.2d 108, 113, to determine whether the cause of action should be permitted to proceed. (*Id.* at p. 365.) Although *O'Neil* ultimately determined that the defendant was not negligent, that conclusion was *not* predicated on the bare fact that the defendant had not manufactured the product that injured the plaintiff; rather, it was because the Court felt that, for a variety of reasons, imposing liability on that defendant would not be appropriate under *Rowland*.[11]

If, as Novartis contends, *O'Neil* intended to erect a blanket prohibition against negligence claims against manufacturers for injuries caused by products they did not produce, then there would have been no need for *O'Neil* to conduct a *Rowland* analysis at all. Yet not only did the *O'Neil* Court analyze the asserted negligence claims under *Rowland*, but—as explained

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[11] For example, *O'Neil* relied on the fact that the connection between the defendants' conduct and the plaintiff's injury was extremely remote because the plaintiff "did not work around defendants' pumps and valves until more than 20 years after they were sold, and he did not develop an injury from the replacement parts and surrounding insulation until nearly 40 years after his workplace contact"—circumstances that "attenuate the connection between the defendants' products and the alleged injury." (*Id.* at p. 365.)

below (see Part I.D.)—all of those factors weigh heavily in favor of *Plaintiffs* here.

2. O'Neil*'s Separate Treatment of Strict Liability and Negligence Claims Vindicates and Reaffirms* Conte*—and Thus Supports the Lower Court's Ruling in This Case.*

The foregoing is more than sufficient to render Novartis's reliance on *O'Neil* wholly inapposite. But there's more, because, contrary to Novartis's claim that "*Conte* rests upon legal arguments soundly rejected by this Court in *O'Neil*" (OBOM at p. 10), *O'Neil*'s analysis actually reaffirms *Conte*'s entire analytical approach.

First, *O'Neil*'s separate treatment of the plaintiff's strict-liability claims and negligence claims endorses *Conte*'s crucial foundational premise that "[n]egligence 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." (*Conte*, *supra*, 168 Cal.App.4th at p. 101.)

This matters because, as discussed below (see Part I.E.), many of the out-of-state cases that refused to hold brand-name manufacturers liable for injuries caused by generic drugs have

rejected this foundational premise, and thus treat all lawsuits involving injuries caused by a product as "product-liability actions," even if the claims are rooted in negligence. And, because in most jurisdictions—as in California—a defendant generally cannot be held liable for "products liability" unless it made or sold the offending product, courts that ignore negligence claims in "products" cases have declined to hold brand-name manufacturers liable for injuries caused by generic drugs simply because the brand-name manufacturer did not manufacturer the product in question.[12]

Seen against this backdrop, *O'Neil*'s separate treatment of the plaintiff's strict-liability *and* negligence claims is a vitally important confirmation of *Conte*'s recognition that California courts do *not* treat all claims the same simply because they happen to involve a defective product. (*Conte*, *supra*, 168 Cal.App.4th at p. 101; see also *Saller v. Crown Cork & Seal Co., Inc.* (2010) 187 Cal.App.4th 1220, 1239 ["Negligence and strict

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[12] See Victor E. Schwartz et. al, *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects* (2013) 81 Fordham L. Rev. 1835, 1861 (collecting cases; hereafter *Shifting Liability*).

product 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."].)[13]

Second, *O'Neil* affirmed and endorsed *Conte* by subjecting the plaintiff's negligence claims to a *Rowland* analysis, rather than simply dismissing them on the ground that a manufacturer can only be sued for injuries caused by its own product. (*O'Neil, supra,* 53 Cal.4th at pp. 364–366.) This, of course, is *exactly* what the Court of Appeals did in *Conte*, *supra*, 68 Cal.App.4th at p. 105–107, and it is exactly the approach that Novartis implausibly argues that *O'Neil* overruled.

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[13] As *O'Neil* recognized, there is good reason to treat strict-products liability and negligent-misrepresentation claims differently, particularly in the context of pharmaceutical drugs. The entire policy rationale behind strict products liability—that is, liability without fault—"is to insure that the costs of injuries resulting from defective products *are borne by the manufacturers that put such products on the market* rather than by the injured persons who are powerless to protect themselves." (*O'Neil*, *supra*, 53 Cal.4th at p. 348 [emphasis added].) By contrast, in the context of a negligent-misrepresentation claim, the need to establish fault by the defendant obviates the need to strictly limit liability to those who made or sold the offending product. (See, e.g., *Hanberry*, *supra*, 276 Cal.App.2d at p. 686.)

This is especially important because *Rowland* established the crucial policy of this state, applicable in all negligence actions, that "although it is true that some exceptions have been made to the general principle that a person is liable for injuries caused by his failure to exercise reasonable care in the circumstances,…no such exception should be made unless *clearly supported by public policy*." (*Id.* at p. 112 [emphasis added].) By applying the *Rowland* test to the plaintiff's negligence claims, *O'Neil* reaffirmed that this principle—that liability is the rule unless *Rowland* "clearly" requires an exception—still applies with full force in negligent-misrepresentation cases involving defective products, like *Conte* and this case, regardless of whether the defendant actually manufactured the offending product.

3. O'Neil *is Factually Distinguishable Because Novartis Bears Direct Responsibility for Plaintiffs' Injuries.*

Finally, *O'Neil* involved a situation in which a *morally blameless* manufacturer was being sued for injuries caused by a product that was used in conjunction with *entirely different products* that caused the plaintiffs' injuries. (*O'Neil*, *supra* 53 Cal.4th at p. 342.) By contrast, this case involves a manufacturer that breached its *own* duty of care with regard to its *own*

product—a breach that ended up causing the plaintiff's injuries because the second product happened to be identical to the defendant's own.

The unique twist of cases like this one—and the key fact that makes it different from *O'Neil* and the cases cited in *O'Neil*—is that even though Plaintiffs were injured by another manufacturer's product, Novartis is being sued for breaching its *own* independent duty of care with regard to its *own* product—a fact that makes all the difference in the *Rowland* analysis, to which we now turn.[14]

[14] Novartis' reliance on *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063, and *Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588, is just as misguided as its reliance on *O'Neil,* and for similar reasons. Like *O'Neil*, these cases involve strict-product-liability claims, not negligent-misrepresentation claims, and thus have no bearing here. *Brown*, moreover, *embraced* the propriety of holding prescription drug manufacturers under theories of negligence and failure to warn. (See *Brown, supra*, 44 Cal.3d at p. 1069, fn. 12 ["Our conclusion does not mean, of course, that drug manufacturers are free of all liability for defective drugs. They are subject to liability for manufacturing defects, *as well as under general principles of negligence, and for failure to warn of known or reasonably knowable side effects*."].)

D. The *Rowland* Factors All Strongly Favor Imposing Liability on Brand-Name Manufacturers for Injuries Caused by Generic Drugs.

Rowland held that where, as here, a manufacturer has breached a duty of care, no exceptions to liability may be made "unless *clearly supported* by public policy." (*Rowland*, *supra*, 69 Cal.2d at p. 112 [emphasis added].) Novartis has not even come close to making any such showing here.

1. Foreseeability and Causation.

As *Conte* recognized, it does not take a crystal ball for a brand-name manufacturer to predict that misstatements in its label could ultimately cause injuries to consumers of a generic version of that same drug. (*Conte*, *supra*, 168 Cal.App.4th at pp. 104–105.) As explained above, the FDA requires that generic drugs bear the same labels as their brand-name counterparts. (See 57 Fed. Reg. 17,961 (1992) ["[T]he [generic drug's] labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for [generic drug] approval"); *PLIVA, supra,* 564 U.S. at p. 613.) Thus the brand-name manufacturer provides the only prescribing information that doctors receive about a drug. And, in California, once a doctor has prescribed a drug, based on the information the brand-name

manufacturer provides, pharmacists are authorized to fill that prescription with a generic drug unless the prescribing doctor forbids the substitution. (*Conte*, *supra*, 168 Cal.App.4th at p. 105.) Therefore, there is no question that it is foreseeable to a brand-name manufacturer that its misinformation will mislead consumers of generic drugs just as much as consumers of brand-name drugs.[15]

2. Moral Blame Attached to Defendant's Conduct.

Moral blameworthiness is also straightforward. Plaintiffs allege that Novartis illegally promoted Brethine for off-label use in pregnant women and then affirmatively breached its duty, under federal law, to update its label to warn of the serious risk that Brethine posed to the fetal brain. They allege, moreover, that Novartis prioritized profits over the safety of unborn children when it sold the drug to aaiPharma without updating the drug's label to warn of that risk. Because Novartis could have prevented those injuries by simply updating the label, the fact that the medication that injured the Plaintiffs was a generic

[15] The causation and foreseeability issues related to Novartis' 2001 sale of the Brethine NDA to another drug company are addressed *infra* in Part II.

version of Novartis's product does not diminish Novartis's blameworthiness in the slightest.

3. Prevention of Future Harm.

Another easy one. The question of whether imposing tort liability on brand-name drug companies for misrepresenting the hazards of their drugs will prevent future harm was answered by the U.S. Supreme Court in *Wyeth, supra,* 555 U.S. 555. There, in holding that federal law does not preempt state-law failure-to-warn claims against brand-name drug manufacturers, the Court stated that state-tort liability plays a crucial role in terms of protecting consumer from the dangers of unsafe drugs. (*Id.* at pp. 578–579.)

The incentives created by tort liability on brand-name manufacturers are particularly important for generic drugs. As explained above, generic-drug companies do not have the authority to update their labels to disclose newly discovered risks without prior FDA approval; only brand-name manufacturers do. (See *PLIVA*, *supra*, 564 U.S. at p. 618.) And a brand-name drug manufacturer's incentive to police its labels drops precipitously the minute its drug goes generic, because the market for a brand-name drug will generally plummet once a generic equivalent

enters the marketplace.[16] As a result, unless a brand-name drug company knows it can be held liable for injuries caused by mislabeled generic copies of its drugs, brand-name manufacturers have little incentive to ensure that its drug labels remain accurate.

But if a brand-name manufacturer were to know it might face tort liability for injuries caused by generic versions of its drugs, it would have a much stronger incentive to ensure that its labels remain accurate.

This is particularly important when it comes to off-label uses. Although the FDA "believes permitting off-label promotion undermines its authority by allowing drug manufacturers to bypass its strict review and approval process," *Off-Label or Out of Bounds?*, *supra*, at p. 306, the practice goes dramatically under-regulated by the FDA. (*Id.* at p. 323 ["Off-label use is now so widespread that it is virtually impossible for the regulatory process to keep up with the pace of innovation."].) Because

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[16] See 78 Fed. Reg. 67,985, 67,988 (2013) ["After the introduction of a generic drug, the market share of the 'brand name' drug…may drop substantially. Among drugs for which a generic version is available, approximately 94 percent are dispensed as a generic."]

proscriptive regulation of off-label drug use is largely ineffective, the deterrent effect of state-tort claims represents an especially important tool to protect public health.

4. Burden on the Defendant.

Notably, it would not present *any* additional burdens on drug companies if this Court were to impose liability on brand-name manufacturers whose negligent failure to update their drug labels with necessary warnings played a causal role in a victim's harmful exposure to a generic version of their drug.

This is because avoiding such liability would require nothing more than "updating the warning label." (*Dolin v. SmithKline Beecham Corp.* (2014) 62 F.Supp.3d 705, 715.) Of course, drug companies *already have* the burden under federal law to update their labels "to include a warning as soon as there is reasonable evidence of a…serious hazard with a drug." (21 C.F.R. § 201.80(e).) Thus, imposing liability in cases of this sort would not saddle Novartis or its competitors with a burden they do not already have under federal law.

Even so, Novartis may counter that it simply isn't "fair" to make brand-name companies shoulder the liability for generic-

drug companies who (in Novartis's world-view) have swooped in and "stolen" their product.

But that argument rests a false premise: that imposing liability on brand-name manufacturers for injuries caused by generic drugs is akin to making the brand-name companies "insurers" for the entire drug industry. The reason that's false is because lawsuits like this one do not seek to hold brand-name manufacturers liable for the misconduct of *other* companies. To the contrary, this lawsuit seeks to hold Novartis liable for the consequences of its *own* misconduct.

5. Consequences to the Community.

a. No Compensation to Victims.

At the same time, Novartis's approach would strip generic-drug victims of their ability to seek compensation for their injuries from the pharmaceutical companies that misrepresented the dangers of their drugs. Under the U.S. Supreme Court's rulings in *PLIVA*, *supra*, 564 U.S. at p. 618, and *Mutual Pharmaceutical Co. v. Bartlett* (U.S. 2013) 133 S.Ct. 2466, 2470, generic-drug manufacturers are largely immune from tort liability. Novartis now seeks to make sure that brand-name manufacturers are also immune from liability for generic-drug

injuries, even though they are responsible for the content of all drug labels and prescribing information, brand-name and generic.

Novartis doesn't speak to this at all, except to suggest that it isn't fair to require brand-name manufacturers to pay for injuries caused by generic drugs, even though it is the brand-name drug companies that are principally responsible for the content of the drug labels, and even though keeping them up-to-date is already their duty under federal law. Why, one might ask, is that more unfair than preventing consumers of dangerously mislabeled drugs from receiving any compensation at all, simply because their pharmacy happens to have filled their prescription with a generic version of the drug? Short answer: it isn't.

The longer answer is that, as *Conte* pointed out, "California law is well established that concurrent tortfeasors whose separate acts contribute to an injury are each liable,… and we see nothing novel or unjust in recognizing application of the rule

under the present circumstances." (*Conte*, *supra*, 168 Cal.App.4th at pp. 109–110 [citation omitted].)[17]

b. Innovation Will Not Be Stifled.

Novartis's other main theme is that, if brand-name drug manufacturers can be sued by injuries caused by generic drugs, innovation will be stifled and "grave health policy implications" will ensue. (OBOM at p. 20.) This argument fails on multiple fronts.

First, this Court has *already* rejected this argument, in a case that Novartis fails to even mention. In *Carlin v. Superior Ct.* (1996) 13 Cal.4th 1105, this Court allowed strict liability failure-to-warn claims against prescription-drug manufacturers

[17] In this case, Plaintiffs asserted a claim against the generic drug company that manufactured the drug that injured Plaintiffs, Global Pharmaceuticals/Impax Laboratories, which survived the demurrer in the trial court predicated on a fact pattern unique to this case. In particular, Plaintiffs alleged that Impax/Global violated the federal laws that prohibit the promotion of off-label uses when it shipped boxes of generic Brethine—an FDA-approved asthma drug—to the "Sharp Mary Birch Hospital for Women and Newborns," the facility where Plaintiffs' mother was treated for pre-term labor. Plaintiffs contend that Global/Impax knew or should have known that the pills it was furnishing to that facility would be put to a non-approved use. Whether or not Plaintiffs succeed on this unusual claim does not alter the fact that, in the vast majority of cases, plaintiffs injured by generic drugs have no recourse against the generic manufacturer.

and affirmatively *rejected* the argument that imposition of tort liability on brand-name manufacturers will deter innovation in the pharmaceutical industry.

Carlin held that there was simply "no clear or sufficient basis for concluding that research and development will inevitably decrease as a result of imposing strict liability for failure to warn of *known or reasonably scientifically knowable* risks." (*Id.* at 1117; emphasis in original.) "Indeed," *Carlin* concluded, "requiring manufacturers to internalize the costs of failing to determine may instead *increase* the level of research into safe and effective drugs." (*Ibid.* [emphasis in original].) Based on these findings, *Carlin* ultimately *allowed* strict-liability failure-to-warn claims to proceed against a pharmaceutical company. (*Id.* at p. 1117.)

Carlin is devastating to Novartis in two respects. First, it puts the lie to Novartis's contention that this Court has "cautioned against expansive theories of liability" against prescription-drug manufacturers. (OBOM at p. 21.) Second, it thoroughly debunks Novartis's argument that the imposition of tort liability will somehow wreak havoc on the pharmaceutical

industry. Both arguments have already been presented to—and rejected by—this Court.

Second, Novartis's doomsday predictions defy common sense given that brand-name drug companies make enormous profits during the "extended periods of government protected monopoly privileges" in the period before generics are able to come onto the market. (*Dolin*, *supra*, 62 F.Supp.3d at p. 715.) It is hard to believe that drug companies would stop innovating drugs, and thus completely forego the enormous financial windfall that comes with having a monopoly on an otherwise successful drug, just because drug companies who negligently fail to update their warning labels might face tort exposure from individuals who consume generic copies of those drugs after generics eventually hit the market.

Third, the logic of Novartis' innovation-stifling arguments is wholly inapplicable to the situation here, where Plaintiffs sued Novartis for *off-label* promotion of Brethine. Drugs are only ever prescribed off-label after they have been approved by the FDA for a different, often unrelated use. Off-label use thus has little to do with innovation and instead is a means for companies to reap

increased profits without having to go through the rigors of FDA approval. (See *Off-Label or Out of Bounds?*, *supra*, at p. 300.)

Fourth, if the past eight years is any indication, suits like this one are fairly rare. *Conte* has been on the books since 2008. But in the eight years since the decision was published, the lower court's ruling is the *only* published appellate decision assigning liability to a brand-name manufacturer for injuries caused by a generic drug. Given that fact, there is no reason to think a reversal is necessary to hold back a tidal wave of litigation. (Cf. *Loeffler v. Target Corp*. (2014) 58 Cal. 4th 1081, 1142 [dis. opn., Liu, J.].)

Finally, Novartis has cited no evidence—none—to support its theory that imposition of tort liability would stifle innovation, despite the fact that, as a drug company, it is in the best position to have such evidence. And it asks this Court to immunize *all* brand-name manufacturers from *all* liability from *all* injuries caused by generic drugs based on this phantom evidence. Novartis should not be permitted to immunize itself—and all brand-name manufacturers along with it—based on such self-serving, conclusory assertions.

E. Cases from Other Jurisdictions Are Unpersuasive or Distinguishable.

Aside from its misguided reliance on *O'Neil* and its "sky-will-fall" policy rhetoric, Novartis—armed with an impressive string cite (see OBOM at pp. 32-33)—also argues that *Conte* just can't be right because a whole bunch of courts from other states have said it's wrong. Those decisions are either unpersuasive or inapplicable.

One camp consists of courts that more or less blindly followed the Fourth Circuit's decision in *Foster v. American House Products Corp.* (4th Cir. 1994) 29 F.3d 165, which was premised on the mistaken belief that "as an expert, a manufacturer of generic products is responsible for the accuracy of labels placed on its products." (*Id.* at 170.)[18] As the Alabama Supreme Court recently observed, however, *Foster* is no longer persuasive authority in light of the holding in *PLIVA*, *supra,* 564 U.S. at p. 613, that exclusive authority for generic drug labels lies

[18] See, e.g., *Schrock v. Wyeth, Inc.* (10th Cir. 2013) 727 F.3d 1273, 1284–1285; *Guarino v. Wyeth, LLC* (11th Cir. 2013) 719 F.3d 1245, 1252.

with brand-name manufacturers. (See *Wyeth, Inc. v. Weeks* (2014) 159 So.3d 649, 669–670.)

A second camp consists of courts applying the law of the 25 states that—unlike California—have statutory product-liability laws that treat any lawsuit involving injuries caused by a product as a "product-liability action," even if the claim is stated as one for negligent misrepresentation. (See *Shifting Liability*, *supra*, 81 Fordham L. Rev. at p. 1861 [collecting cases].) In such cases, the courts have held that "product-liability actions" may be asserted only against the manufacturer or seller of the product that harmed the plaintiff.

These rulings have no bearing here because, as noted above in reference to *O'Neil*, California does not lump all tort cases into one category simply because the instrument of injury was a "product." To the contrary, as *O'Neil* itself confirmed, whether a case is a "products case"—and thus whether the general rule against holding one company liable for the products of another applies—depends on the theory of liability asserted, *not* whether the injury-producing instrumentality was a "product."

A third camp consists of courts sitting in, or applying the tort law of, states that—unlike California—have not yet adopted

Section 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], *aff'd*, *Moretti v. Wyeth, Inc.* (9th Cir. 2009) 579 F.Appx. 563.)

These holdings have no bearing here, because California is one of only a few states that have formally adopted Section 311 of the Restatement of Torts and therefore allow claims for negligent misrepresentation based on foreseeability, without regard to privity. (See 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.)

A fourth and final camp consists of courts that simply predict, as the Sixth Circuit did in *In re Darvocet, Darvon, and Propoxphene Products Liability Litig.* (6th Cir. 2014) 656 F.3d 917, that state courts might reject brand-name manufacturer liability for injuries caused by generic drugs on public policy grounds. (See *id.* at p. 945 [citing, *inter alia,* the "grave policy consequences associated with recognizing brand manufacturer

liability," such as "few innovative drugs"].) That conclusion is wholly unconvincing for all the reasons set forth above—in reality, public policy strongly *favors* imposing tort liability on brand-name manufacturers for injuries caused by inadequately labeled generic drugs.

II. California Law Supports Imposing Liability on "Former" Drug Manufacturers Whose Negligence is a Legal Cause of the Plaintiff's Injuries.

The only remaining question is whether Novartis, as a "former" brand-name manufacturer of Brethine, should be absolved of liability for Plaintiffs' injuries merely because another company owned the rights to Brethine in 2007, when the Plaintiffs sustained their injuries. As discussed below, the answer is clearly "no."

Part "A" below explains why Novartis's failure to update the Brethine label was a legal cause of Plaintiffs' injuries, notwithstanding the fact that a subsequent tortfeasor—aaiPharma—*also* failed to update the Brethine label after it purchased the NDA in 2001.

Part "B" then explains why a bright-line rule immunizing "former" brand-name manufacturers for injuries caused by generic drugs would seriously undermine the public-policy factors

set forth in *Rowland*—in particular, the policy against prevention of future harm.

A. Novartis's Failure to Update the Brethine Label was a Legal Cause of Plaintiffs' Injuries.

Under California law, an actor's acts or omissions constitute a legal cause of injury if they played a "substantial factor" in causing the injuries. In the context of a negligent *omission* (as opposed to a negligent *act*), the omission is the legal cause of injuries if those injuries would, more likely than not, have been avoided had the omission been replaced by conduct in conformity with the standard of care. (See, e.g., *Saelzler v. Advanced Group 400* (2001) 25 Cal.4th 763, 778–779.)

In this case, the actionable omission is Novartis's failure to update its label to warn of the dangers Brethine posed to fetal health when used as a tocolytic to prevent pre-term labor in pregnant women. Plaintiffs specifically allege (a) that they suffered severe neurological damage as a result of their prenatal exposure to Brethine; and (b) that their mother's physician would not have prescribed Brethine had the label warned of potential hazards to fetal health. These allegations must be taken as true at the demurrer stage. (E.g., *Randi W.*, *supra*, 14 Cal.4th at p.

1078.) Accordingly, this Court must assume that Plaintiffs would not have been harmed had the Brethine label contained a warning regarding risks to fetal health.

1. If Novartis Updated the Label in or Before 2001, the Label Would Have Still Contained the Warning in 2007.

Against this backdrop, the primary causation question is whether the Brethine label would have still contained a warning regarding the risks to fetal health in 2007—when Plaintiffs' mother took the drug—had Novartis added such a warning prior to December 2001. The answer is "yes," for four related reasons.

First, when Novartis sold Brethine to aaiPharma in December 2001, aaiPharma—which held the NDA for Brethine until 2007—was required by federal law to use the operative Brethine warning label that Novartis left on file with the FDA. (See 21 U.S.C. § 355; 21 C.F.R. § 314.105(b).)

Second, while brand-name NDA holders can unilaterally *add or strengthen* warnings on a drug label in order to warn of a serious hazard with the drug, federal law *prohibits* NDA holders from removing (or watering down) an existing warning without the express authority of the FDA. (See *Wyeth*, *supra*, 555 U.S. at p. 568; 21 C.F.R. § 314.70(c)(6)(iii)(A)–(C).)

Thus, had Novartis added a warning to the Brethine label regarding hazards to fetal health, that warning would have persisted *indefinitely* unless (a) the FDA, after analyzing the new warning and the data on which it was based, ultimately decided to reject it (a highly unlikely event, as discussed below); or (b) aaiPharma sought and received the FDA's authority to remove it (something that would never have occurred in the real world for the additional reason that had Novartis actually added such a warning to Brethine, aaiPharma never would have purchased it in the first place).

Third, at this stage of the litigation, Plaintiffs are entitled to an inference that the FDA would not have disturbed a warning on the Brethine label regarding risks to fetal health had Novartis fulfilled its duty to add one while it still held the Brethine NDA. Although "the FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application" (*Wyeth*, *supra*, 555 U.S. at p. 571), Novartis will have the burden at trial to provide "clear evidence that the FDA would not have approved a change to [Brethine's] label." (*Ibid.*)

Whether Novartis can actually meet this burden is a highly fact-specific inquiry inappropriate for resolution at this stage. But in light of the numerous studies demonstrating the dangers of using terbutaline as a tocolytic that emerged throughout the 1980s and 1990s, it seems more likely the FDA would have *embraced* such a warning had Novartis actually fulfilled its duty to add one.

Fourth, and finally, federal drug laws required all generic Brethine manufacturers to copy, verbatim, the operative label used by the brand-name manufacturer. (*PLIVA, supra,* 564 U.S. at p. 614.) This means that even the labels on generic Brethine would have had to include a warning regarding risks to fetal health had Novartis fulfilled its duty to add one before it sold the Brethine NDA to aaiPharma in December 2001.

In short, at this stage of the litigation, Plaintiffs are entitled to two inferences that, together, show that Novartis is legally responsible for Plaintiffs' injuries: (1) if the label had contained a warning regarding risks to fetal health, it would have prevented Plaintiffs' injuries; and (2) if Novartis had updated the label with such a warning prior to selling the drug in 2001, it would have remained in effect in 2007, when Plaintiffs' mother

was prescribed and ingested generic Brethine, resulting in Plaintiffs' injuries.[19]

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[19] This fact readily distinguishes this case from *Cadlo v. Owens–Illinois*, Inc. (2004) 125 Cal.App.4th 513, which Novartis champions in its brief. (See OBOM at p. 29). There, a plaintiff contracted mesothelioma from exposure to asbestos known as "Kaylo." At the time of his exposure, Kaylo was manufactured by Owens-Corning Fiberglass ("OCF"). However, prior to 1958, Kaylo was manufactured by a legally distinct company, Owens–Illinois. The plaintiff sued Owens–Illinois alleging that it concealed information regarding Kaylo's hazards.

The chief distinction between *Cadlo* and this case is that, even if Owens–Illinois had fully disclosed Kaylo's hazards on its product information, there is no reason to believe OCF would have necessarily continued to adopt those warnings when it took over the product line in 1958. This was implicit in the *Cadlo* court's conclusion that, even if Owens–Illinois communicated misinformation about the hazards of Kaylo to OCF, it was not foreseeable that OCF would necessarily parrot that information to subsequent Kaylo users once OCF took over the product line. (*Cadlo*, *supra*, 125 Cal.App.4th at p. 521.) As such, in *Cadlo*, there was no true causal nexus between Owens–Illinois' failure to warn prior to selling the Kaylo product line and the plaintiff's resulting injuries. (E.g., *Cadlo*, *supra*, 125 Cal.App.4th at p. 520 ["Consequently, any misrepresentations about Kaylo's safety on which he might have relied would have been made by OCF."].)

The same is not true here because, absent proof that the FDA would have removed a warning regarding risks to fetal health, aaiPharma—and any subsequent Brethine manufacture, brand-name or generic—would have been forced to adopt that same warning by operation of federal drug law had Novartis fulfilled its duty to add such a warning to the Brethine label.

2. aaiPharma's Failure to Update the Label Does Not Absolve Novartis for its Own Failure to Update the Label.

The next question is whether the fact that aaiPharma *also* failed to update the Brethine label was a superseding cause that absolves Novartis of liability for Plaintiffs' injuries. The answer is clearly "no."

Under California tort law, "[an] originally negligent actor generally remains liable although a third person negligently fails to discharge a duty to take affirmative action which would have prevented the harm if the third person's conduct is reasonably foreseeable." (*Cline v. Watkins* (1977) 66 Cal.App.3d 174, 179.) In such cases, liability will shift from a former to a subsequent tortfeasor as a matter of law "only in exceptional circumstances." (*Ibid.*) More specifically, "[a]n independent, intervening act is a superseding cause relieving the actor of liability for his negligence only if the intervening act is highly unusual or extraordinary and hence not foreseeable." (*Ibid.* [citation omitted]; see also *Vesely v. Sager* (1971) 5 Cal.3d 153, 164 ["[A]n actor may be liable if his negligence is a substantial factor in causing an injury, and he is not relieved of liability because of the

intervening act of a third person if such act was reasonably foreseeable at the time of his negligent conduct."].)

This thus begs the question: Was aaiPharma's own failure to update the Brethine label so thoroughly unforeseeable to Novartis that Novartis should be absolved of liability for the causal role that its own failure to update the label played in Plaintiffs' harmful exposure to Brethine? Again, the answer—particularly at this stage of the case—is "no."

As a general matter, Novartis—having failed to discharge its *own* duty to update Brethine's label with a warning regarding the risks to fetal health despite ample evidence of that fact—can hardly claim surprise that aaiPharma similarly failed to do so.

More specifically, the facts of this case suggest that, far from being surprised by aaiPharma's failure to update the Brethine label, Novartis actually had reason to *anticipate* that aaiPharma would not update the label.

At the time Novartis sold the drug to aaiPharma, at least half of Brethine's approximate $20 million in annual sales—and, thus, much of its market value—resulted from its use as a tocolytic, *not* its FDA-approved use as an asthma drug. (AA041.) It is thus logical to infer that a significant—if not the

predominant—factor in aaiPharma's interest in acquiring the Brethine product line was its sales potential as a tocolytic. Nothing would have threatened Brethine's popularity as a tocolytic more than a warning on its label that it may cause serious birth defects. Therefore, Novartis knew or should have known that aaiPharma—like Novartis itself—had a powerful financial disincentive to update the Brethine label with a warning regarding risks to fetal health and was thus unlikely to do so.

Of course, because foreseeability is a question of fact, it will ultimately be for the jury to determine whether Novartis could have foreseen that aaiPharma would fail to fulfil its own duty to update the Brethine label. (E.g., *Bigbee v. Pacific Tel. & Tel. Co.* (1983) 34 Cal.3d 49, 56.) But the point at this juncture is that the mere fact that aaiPharma *also* failed to prevent Plaintiffs injuries does *not* absolve Novartis of liability for its own negligent failure to do the same.[20]

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[20] This is not to suggest that aaiPharma is not liable for its own negligent failure to update the Brethine label; on these facts, aaiPharma is at least as culpable as Novartis. But California law recognizes that multiple defendants may be responsible for the same injury and thus holds that a defendant "cannot avoid responsibility just because some other person, condition, or event

B. Arbitrarily Limiting Tort Liability to "Concurrent Manufacturers" Would Run Counter to Public Policy as Embodied in the *Rowland* Factors.

Novartis does not seriously attempt to debate any of the foregoing. Instead, it asks this Court to adopt a rule that would arbitrarily limit liability to "concurrent" brand-name manufacturers (i.e., aaiPharma in this case) and would thus categorically absolve "former" brand-name manufacturers (i.e., Novartis), even where, as here, there is a causal nexus between the former manufacturer's negligent failure to update a drug's warning label and the plaintiff's resulting harm.

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was also a substantial factor in causing [the plaintiff's] harm." (CACI No. 432 ["Causation: Multiple Causes"].) It is thus not an "either/or" scenario; *both* Novartis *and* aaiPharma are liable for Plaintiffs' injuries.

In fact, in this case, Plaintiffs filed claims against Novartis *and* aaiPharma alleging that both companies violated their federal duty to timely update the Brethine label with a warning regarding the potential hazards to fetal health. Unfortunately, as it turns out, aaiPharma is insolvent, having filed for bankruptcy in May 2005 (see BusinessWire, *aaiPharma Files Chapter 11 Plan for Reorganization* (Nov. 7, 2005) <http://www.businesswire.com/news/home/20051107005470/en/AAIPharma-Files-Chapter-11-Plan-Reorganization> [as of Oct. 10, 2016]), in part due to shareholder suits alleging the company defrauded its shareholders. (See *SEIU Pension Plans Master Trust v. aaiPharma, Inc.* (E.D.N.C. Feb. 11, 2005) No. 7:04-CV-27-FL.)

But public policy—as embodied in this Court's *Rowland* factors—strongly disfavors Novartis's position.

1. Foreseeability and Causation.

The first *Rowland* factors—causation and foreseeability—are actually case-specific factors that need to be determined on an individual basis. In this case, as explained above, both of these factors weigh strongly in favor of liability. This is a function of the unusual facts of this case: in particular (a) the substantial evidence that Brethine causes serious damage to the fetal brain when used as a tocolytic drug; (b) the fact that Novartis knew—or at least should have known—of that evidence and yet chose to market the drug anyway without updating the label; and (c) the fact that Novartis had good reason to know that aaiPharma would not update the label because much of its value was dependent on its continued use as a tocolytic. None of these facts is likely to appear in a typical drug case—let alone a conventional tort case—but they all argue strongly in favor of liability here.

Where Novartis goes wrong is by arguing for a per se rule of liability that forbids *any* former manufacturer from *ever* being held liable for any injuries caused by generic drugs, regardless of the specific facts of the case. While there may be good reasons

not to impose liability in a particular case—where, for example, the former manufacturer had no reason to update the label prior to selling the drug, or where it was not foreseeable that the subsequent owner would fail to fulfill its duty to update the label after purchasing the drug—there is no reason to impose a blanket prohibition on such claims.

2. Moral Blame Attached to Defendant's Conduct.

And there are powerful reasons not to. First, a blanket prohibition on holding former manufacturers liable for injuries after they sell their rights to the drug can cause perverse results, by shifting liability from a *more culpable* drug manufacturer with more opportunities to avoid liability to a *less culpable* one with comparatively fewer opportunities to avoid liability.

Consider, for example, a case not unlike this one, where a manufacturer (Company A) holds onto a drug for years, knowing that it is dangerously mislabeled, and then sells it to Company B without changing the label. Two months after the sale, an unsuspecting person consumes a generic version of the drug and experiences the exact same harmful effects that Company A knew about but did not address in a label update.

According to Novartis, it is Company B, *not* Company A, that should bear liability for the mislabeled drug in that scenario. But Company A is the *far more* culpable of the two drug companies in the above hypothetical: Company A sat on its hands for *years* whereas Company B had mere *months* to detect the need for a warning and draft appropriate language. Yet under Novartis's proposal, all the liability would fall on the least culpable party.

And that's the best-case scenario for the consumer. On the above facts, the more likely outcome is that the concurrent manufacturer won't be held liable either, because it had not owned the drug long enough at the time of the Plaintiff's injuries to justify the imposition of liability. In that scenario, the blameworthy defendant gets off scot-free while the injured victim gets no compensation at all.

3. Prevention of Future Harm.

Novartis's proposed bright-line rule limiting tort liability to concurrent manufacturers would also undermine the "the policy of preventing future harm" (*Rowland*, *supra*, 69 Cal.2d at p. 113) by creating a strong incentive for brand-name manufacturers to *delay* the adoption of necessary warnings and then profit from

their misconduct by selling the rights to the drug at a price inflated by consumers using the drug because they don't realize its dangers.

To understand why, consider a scenario where a drug company like Novartis sells a mislabeled drug to a successor brand-name drug company. When that occurs, there are two possible outcomes:

First, as this case shows, one possibility is that, like aaiPharma here, the successor will prove to be a negligent steward of the label and, as such, will also fail to update the label for a prolonged period of time if at all. In such a case, it follows that many individuals will be harmed by consumption of a dangerous drug they would have otherwise avoided had the label been updated.

The second possibility is that the successor is a diligent, responsible drug manufacturer. But even in this best-case scenario, numerous individuals will still be needlessly harmed because, as was hinted at in the hypothetical in the preceding section, there is simply no telling how long it would take even a diligent drug company to recognize the deficiency in the label and put a new label into action.

But while no one can predict for certain whether a successor manufacturer will be negligent or diligent in handling a mislabeled drug (or even when a diligent manufacturer will cure the deficiency in the drug's label), one thing is certain: A drug company looking to sell an NDA to a mislabeled drug can render all of that moot by simply curing the deficiencies in the drug label *before* selling the NDA to a successor.

And as between the two proposed rules before this Court—one that allows imposition of liability on former manufacturers and one that arbitrarily limits liability to concurrent manufacturers—*only the first rule would encourage drug manufacturers to update deficient labels before they sell the brand rights to the drug to a successor manufacturer*. Under the latter rule, drug manufacturers who plan to sell their NDA to another company have a strong disincentive to update their label, because they know they won't be held liable for any injuries that may occur after the NDA passes to a new owner and adding a warning label before the sale would cause the purchase price to drop.

Second, making matters worse, a rule that categorically insulates former manufacturers from liability for injuries caused by a mislabeled drug actually gives drug companies an

affirmative *incentive* to sell the brand rights to the drug rather than update the drug's label.

This would be particularly true where, as here, the needed warning would significantly affect the drug's profitability. In such a case, from a financial perspective, the existing NDA holder would be better off selling the drug to a successor than damaging the drug's market value by updating the label.

This, too, would have a tendency to result in lag: Once the decision to sell the rights to a mislabeled drug has been made, a drug company would have little incentive to update the label before the brand rights are actually sold. Again, updating the label might impair the value of the brand rights and, with a sale imminent, there would be little fear of future tort exposure. Accordingly, if former manufacturers were categorically immune from liability for their negligent failures to update a drug label while they held the NDA, brand-name manufacturers of mislabeled drugs would have an incentive to refrain from updating the label while they put the brand rights up for sale, and then "punt" the problem to a successor manufacturer, whether negligent or diligent, by selling the NDA.

In the meantime, an untold number of individuals would be needlessly injured in the period immediately before the NDA is transferred to the successor manufacturer. And, as noted earlier, many more would be injured for at least some period thereafter.

4. Burden on the Defendant.

Imposing tort liability on "former" manufacturers would not increase their legal burdens at all; to avoid tort liability, they would simply need to fulfill their federally mandated duty to ensure that their labels are accurate while they still control the drug.

Beyond that, soon-to-be-former manufacturers could insulate themselves from liability by entering into agreements with the buyer of the NDA in which the buyer agrees to assume the liability for any actions arising after the sale date. (See, e.g., *Cline*, *supra*, 66 Cal.App.3d. at p. 179 ["In some circumstances, responsibility may be shifted by agreement between the actor and the third person."].) For example, a seller could ask the buyer to indemnify it if the seller is ever successfully sued for a deficient label.

Ostensibly, such agreements would affect the price the buyer is willing to pay for the brand rights, particularly in the

case of a long-mislabeled drug with serious health hazards like Brethine. But even so, the conclusion that a mislabeled drug will make it more expensive to secure an indemnity agreement from a prospective purchaser will provide an economic incentive for drug companies to keep their labels up to date, thereby promoting the public policy in favor of adequate drug labeling.

5. Consequences to the Community.

Novartis's bright-line rule is only good for one segment of the community: Big Pharma. If Novartis has its way, it is inevitable that a good number of culpable former manufacturers will be let off the hook, leaving hundreds, perhaps thousands, of uncompensated victims in their wake. And to what end? There is no reason not to allow former-manufacturer liability to be determined on a case-by-case basis, just as the tort system works in other contexts.

Novartis's only response is to suggest that allowing former manufacturers to be sued will open a Pandora's Box of "perpetual liability" that will end up backfiring on consumers by driving up prices and stifling innovation. This argument is wholly unrealistic in at least two respects.

First, as a threshold matter, it is difficult to imagine a scenario in which a brand-name manufacturer is sued an extended period of time (e.g., 20 years) after it divested a drug. For such a scenario to come to pass, two seemingly mutually exclusive things would have to come true: First, the drug would have to be sufficiently obviously mislabeled at the time the manufacturer sold the drug that it was negligent for not providing a warning. And second, the mislabeled nature of the drug would have to essentially fly under the radar for several more decades without anyone, including the FDA, taking notice.

But even if such an improbable scenario did come to pass, a former manufacturer facing liability for a drug it last sold 20 years prior would almost certainly face minimal tort exposure thanks to the fact that California juries have the ability to allocate fault among the various defendants. (See note 20, *supra*.) Inherently, for every "former" manufacturer, there will be at least one "subsequent" manufacturer of the drug. Indeed, the longer the drug remains mislabeled the more "subsequent" manufacturers there will likely be. Of course, a jury can and will allocate fault among each of those manufacturers.

Accordingly, it stands to reason that the more "perpetual" the liability for any one manufacturer, the less actual liability that manufacturer will bear. The idea that the mere risk of such liability would be sufficient to impact the pharmaceutical industry in any serious way is fanciful.

C. Novartis's "Former-Manufacturer" Authority is Easily Distinguishable.

Novartis has no actual case law to support its theory that allowing "former" prescription-drug manufacturers to be held liable for injuries caused by generic drugs would up-end the settled tort law of this state.

Novartis argues, oddly, that *O'Neil* rejected imposition of liability on the "former manufacturer" defendants (see OBOM at p. 26), but in reality *O'Neil* had nothing to do with whether the defendants were "former" manufacturers; rather, as explained above, the strict-liability ruling hinged on the fact that the defendants did not manufacture the product that injured the plaintiff.

Novartis's other flagship case is *Cadlo v. Owens–Illinois*, Inc. (2004) 125 Cal.App.4th 513, which has no bearing here because—as explained above at note 19—there was no true

causal nexus between the *Cadlo* defendant's failure to warn and the plaintiff's resulting injuries, whereas here the causal nexus is clear by virtue of the unique interplay between the facts of this case and the federal drug labeling laws.

The only other cases Novartis cites (see OBOM, pp. 28–29 & fn. 10) have no bearing here because none of those cases involved a negligent-misrepresentation claim and, in fact, dealt only with products-liability claims. As such, they all stand for a proposition with which no one, including Plaintiffs, disagrees—absent the exceptions identified in *O'Neil,* a manufacturer cannot be held liable in products liability for injuries caused by a product it did not make.

* * *

At bottom, Novartis is left with a bare proposition that lacks any real support in law or logic: that "former" drug manufacturers should receive total immunity from tort liability under *all* circumstances simply because the imposition of liability in *some* circumstances might not be fair or reasonable, even if a defendant's past misconduct bore a causal nexus to the plaintiff's injuries. That proposition is utterly at odds with the way the tort system is designed to—and actually does—work in the real world.

Juries are perfectly capable of sorting out the fact-specific intricacies of "former-manufacturer" liability in prescription drug cases, just as in other areas of the law. That the stakes are higher in the prescription-drug area in terms of public health and safety is a reason to *allow* tort liability, not to permit the type of total immunity sought by Novartis.

CONCLUSION

For the foregoing reasons, Plaintiffs pray this Court will affirm the decision below and remand this case for further proceedings.

Dated: October 11, 2016

By: /s/ Leslie A. Brueckner
Leslie A. Brueckner, Esq.

By: /s/ Benjamin I. Siminou
Benjamin I. Siminou, Esq.

CERTIFICATE OF COMPLIANCE

As required by California Rules of Court, rule 8.520(c)(1), I certify that, according to the word-count feature in Microsoft Word, this "Answer Brief on the Merits" contains words **13,948**, including footnotes, but excluding any content identified in rule 8.520(c)(3).

Dated: October 11, 2016

By: /s/ Benjamin I. Siminou
Benjamin I. Siminou, Esq.

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 Ave., Ste. 1100, San Diego, California, 92103.

On October 11, 2016, I served the attached **Answer Brief on the Merits**, 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 October 11, 2016.

I declare under penalty of perjury that the foregoing is true and correct, and this declaration was executed at San Diego, California, on October 11, 2016.

_____
Diane DeCarlo