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

Leslie A. Brueckner, Esq.
PUBLIC JUSTICE, P.C.
555 12th Street, Suite 1230
Oakland, California 94607
Tel: (510) 520-6205
Fax: (510) 622-8155

Benjamin I. Siminou, Esq.
THORSNES BARTOLOTTA MCGUIRE LLP
2550 Fifth Avenue, 11th Floor
San Diego, California 92103
Tel: (619) 236-9363
Fax: (619) 236-9653

Attorneys for Plaintiffs and Appellants
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Benjamin I. Siminou, Esq.
THORSNES BARTOLOTTA MCGUIRE LLP
2550 Fifth Avenue, 11th Floor
San Diego, California 92103
Tel: (619) 236-9363
Fax: (619) 236-9653

Attorneys for Plaintiffs and Appellants
T.H., a Minor, et al.

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STATEMENT OF ISSUES

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?

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

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[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]

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[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