No.: S233898

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

T.H., etc., et al.,
Plaintiffs and appellants,

vs.

NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant and respondent.

Court of Appeal,
Fourth Appellate District, Division 1
No.: D067839

San Diego County Superior Court
No.: 37-2013-00070440-CU-MMCTL

On Review of a Judgment of Dismissal following an Order Sustaining a Demurrer
Honorable Joan Lewis, Presiding

APPLICATION TO FILE AND AMICUS CURIAE BRIEF OF CONSUMER ATTORNEYS OF CALIFORNIA AND AMERICAN ASSOCIATION FOR JUSTICE IN SUPPORT OF PLAINTIFFS T.H.

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CERTIFICATE OF INTERESTED ENTITIES OR PERSONS

This is the initial certificate of interested entities or persons submitted on behalf of Amici curiae for appellants T.H. et al., Consumer Attorneys of California, American Association for Justice in the case number listed above.

The undersigned certifies that there are no interested entities or persons that must be listed in this Certificate under California Rules of Court, rule 8.208.

Dated: November 30, 2016 By: _____

Alan Charles Dell'Ario

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AMICUS CURIAE BRIEF

BRIEF IN SUPPORT OF T.H., a minor, by CONSUMER ATTORNEYS OF CALIFORNIA and AMERICAN ASSOCIATION FOR JUSTICE

APPLICATION TO FILE AMICUS BRIEF

Consumer Attorneys of California and the American Association for Justice request that the attached amicus brief submitted in support of plaintiffs T.H., a minor, et al. be accepted for filing in this action. Counsel are familiar with all of the briefing filed in this action to date. The concurrently-filed amicus brief addresses fundamental public policy issues not otherwise considered or argued by the parties and amici believes the brief will assist this Court in its consideration of the issues presented. In particular, this brief discusses the common-law foundations of the defendant's tort liability, its relationship to federal drug regulation and California principles of concurrent causation in the context presented by the case.

No party to this action has provided support in any form with regard to the authorship, production or filing of this brief.

STATEMENT OF INTEREST

Consumer Attorneys of California [CAOC] is a voluntary membership organization representing over 6,000 associated consumer attorneys practicing throughout California. The organization was founded in 1962. Its membership consists

primarily of attorneys who represent individuals who are injured or killed because of the negligent or wrongful acts of others, including victims of mislabeled drugs. CAOC has taken a leading role in advancing and protecting the rights of Californians in both the courts and the Legislature.

As an organization representative of the plaintiff's trial bar throughout California, including many attorneys who represent plaintiffs injured or killed as the result of negligence, CAOC is interested in the significant issues presented by the court of appeal's decision in this case, particularly with respect to the determination of what duty is owed by brand-name drug manufacturers to consumers who ingest generic forms of their drugs. State law requires generic equivalents be available to patients even where brand-name drugs are prescribed. (Bus. & Prof. Code, § 4073.)

The American Association for Justice [AAJ] is a voluntary national bar association whose trial lawyer members primarily represent plaintiffs in personal injury lawsuits, civil rights and employment rights actions, and small business litigation. AAJ's mission is to preserve the constitutional right of access to the courts for redress of wrongful injury as well as the Seventh Amendment right to trial by jury in civil cases. AAJ is concerned that the broad immunity Novartis seeks in this case will remove the right to compensation for those wrongfully injured by pharmaceutical manufacturers' misrepresentations along with a powerful financial incentive for safety that protects all Americans. AAJ firmly believes that the court of appeals'

decisions in that case as in this one were correct as a matter of law and reflect sound public policy that benefits Californians and, persuasively, all Americans.

ARGUMENT

"[C]ommon sense and the common law of California" recognize that drug manufacturers have a duty, sounding in negligence, to furnish adequate warnings of the known risks of their drugs.[1] The ultimate decision to take terbutaline sulfate lay with the T.H. twins' mother.[2] Without an adequate warning of the drug's risks, mother could not give her informed consent to ingest it.[3]

Federal and state law require generic drug manufacturers to mimic, on pain of tort liability, the warnings provided by the brand-name manufacturers. [BNMs][4] This mandate and traditional California tort analysis require that a brand-name manufacturer not be relieved of its "general duty to use due care in disseminating product information to those it knows or should

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1 Slip opn. at p. 14; e.g., *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 64–65 *(Stevens).*

2 "[I]t is the prerogative of the patient, not the physician, to determine for himself the direction in which he believes his interests lie."(*Cobbs v. Grant* (1972) 8 Cal.3d 229, 242 *(Cobbs).*)

3 *Cobbs, supra,* 8 Cal.3d at p. 245.

4 *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 613 *(PLIVA)* ["generic drug manufacturers have an ongoing federal duty of 'sameness.'"]; *Teva Pharm. USA, Inc. v. Superior Court* (2013) 217 Cal.App.4th 96, 112 [breach of "sameness" duty creates liability].

know are likely to be harmed as a result of their physician's reliance on that information" including consumers who ingest generic, biologically-equivalent versions of its drugs.[5]

Likewise, a brand-name manufacturer cannot be relieved of liability for negligent failure to warn merely because it sold the rights to the drug unless the manufacturer establishes the victim's injury was the result of a superseding cause. California law has long been "well settled that an 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."[6] Because Novartis negligently failed to revise its label when obliged to do so, it cannot escape liability merely by pointing out it no longer owned the brand when mother took terbutaline.

Neither the court of appeal here nor the *Conte* court has departed from traditional, well-settled principles of California law. The Court should affirm.

I. The court of appeal's conclusions are rooted in well-settled California and national negligence law as applied to prescription drug manufacturers.

Novartis characterizes the court of appeal's opinion an "extraordinary expansion[] of traditional tort law" (OBM 9), and a dismantling of "boundaries established over decades of product

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[5] *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89, 111 *(Conte)*; Slip Opn. at p. 18.

[6] *Stevens*, *supra*, 9 Cal.3d at p. 69.

liability law." (RBM 10.) The company decries *Conte*, on which the court of appeal heavily relied, as "impos[ing] a new and infinite duty upon a prescription drug manufacturer." (OBM 31.) *Conte* is "anomalous," has "gained little traction," and "has failed the test of time," says Novartis. (OBM 25, 31, 33). But Novartis is wrong. As both the court of appeal and the *Conte* court recognized, the principle that a drug manufacturer may be liable for negligently failing to warn or negligently misrepresenting its drug's dangerous side effects is rooted in California law and common sense. (*Conte*, *supra*, 168 Cal.App.4th at p. 102; Slip opn. at p. 14.)

A. For over 40 years, this Court has recognized the drug manufacturer's negligence-based duty to warn of its drug's dangers.

In 1973, the Court recognized that prescription drug manufacturers have a duty, sounding in negligence, to provide adequate warnings of the dangerous side effects of their drugs. (*Stevens*, *supra*, 9 Cal.3d at pp. 64–65.) Drug manufacturers must "exercise reasonable care to inform [users] of its [drug's] dangerous condition or of the facts which make it likely to be dangerous." (*Id.* at p. 64.) The question was not novel, even then, for the Court relied on the Restatement, 2d, Torts, section 388 and earlier decisions such as *Tingey v. E.F. Houghton & Co.* (1947) 30 Cal.2d 97, 102.[7] (*Stevens*, *supra*, at pp. 64–65.)

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[7] "[A] manufacturer must give an appropriate warning of any known dangers which the user of his product would not ordinarily discover."

In *Brown v. Superior Court* (1988) 44 Cal.3d 1049 *(Brown)*, the Court rejected a strict-liability failure-to-warn duty that extended to unknown drug risks. (*Id.* at p. 1069.) But the Court made clear that manufacturers "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." (*Id.* at p. 1069 fn. 12.)

The Court again spoke on this issue in *Carlin v. Superior Court* (1996) 13 Cal.4th 1104. "Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about." (*Id.* at p. 1112.) No question exists that drug manufacturers have a duty to furnish adequate warnings of known drug risks.

B. Traditional tort law recognizes negligent misrepresentation resulting in physical harm as a distinct cause of action.

The cause of action for physical harm caused by reasonable reliance on defendant's misrepresentations is a separate and independent cause of action well within the mainstream of negligence law. The tort of misrepresentation has its origins in the ancient common-law "writ of deceit known as early as 1201." (W. Prosser, et al., Prosser and Keeton on the Law of Torts (5th ed. 1984) 727 (Prosser).) This writ was later "superseded by an action on the case in the nature of deceit, which became the general common law remedy for fraudulent or even non-

fraudulent misrepresentation resulting in actual damage." *(Id. at p. 728.)* That cause of action evolved into the tort of misrepresentation:

> There is a duty not to make a false representation to those to whom a defendant intends, for his own purposes, to reach and influence by the representation; to those to whom he has a public duty created by statute or pursuant to a statute; and to those members of a group or class that the defendant has special reason to expect to be influenced by the representation.

(W. Prosser, *Misrepresentation and Third Persons* (1966)19 Vand. L.Rev. 231, 254.) Prosser and Keeton catalogue cases recognizing the tort of misrepresentation resulting in physical harm or injury dating back to at least 1905.(Prosser, *supra*, at p. 726, n.15.)

The tort of misrepresentation in its modern form is set out in Restatement (Second) of Torts § 310 and § 311. Section 311(1) provides:

> (1) One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results (a) to the other, or (b) to such third persons as the actor should expect to be put in peril by the action taken.

Section 310 restates a similar rule applicable to conscious misrepresentation. The comments and reporter's notes to both sections make clear that these torts apply to foreseeable third-party injuries like those alleged here:

> A misrepresentation may be negligent not only toward a person whose conduct it is intended to influence but also toward all others whom the maker should recognize as likely to be imperiled by action taken in reliance upon his misrepresentation.

(Restatement (Second) of Torts § 310, comment c and *id.* § 311, comment d.) Novartis's misrepresentations were directed at pregnant women and their doctors, imperiling the unborn children.

The tort of misrepresentation "finds particular application where it is a part of the actor's business or profession to give information upon which the safety of the recipient or a third person depends." (*Id.* at § 311(1), comment b.) The duty imposed on Novartis in this case was not that of an "innovator" or even a "former manufacturer." It was the duty of one whose business was to supply information to physicians on which the safety of their patients depends.

One of the earliest cases recognizing liability for negligent misrepresentation involved a medicinal product. In *Thomas v. Winchester* (1852) 6 N.Y. 397, defendant manufactured medicinal extracts, "putting up and falsely labeling the jar of belladonna as the extract of dandelion." *(Id.* at p. 398.) The consumer plaintiff who ingested the product was seriously injured. The court rejected defendant's privity argument and held that the defendant could be liable on the separate ground of negligent mislabeling. (*Id.* at p. 408.)

A cause of action "for negligent misrepresentation or misstatement . . . is now recognized by nearly all courts where tangible injury to person or property results." (V. Schwartz et al.,

Prosser, Wade and Schwartz's Torts (10th ed. 2000) 1010; see also F. Harper, et al., Harper, James & Gray on Torts (2006) § 7.6 ["Where misrepresentations entail the foreseeability of physical harm and such harm in fact results, the ordinary rules of negligence have for some time been applied."].)

As plaintiffs have demonstrated, this cause of action is firmly supported by California precedents, which establish that those who disseminate misinformation may be liable for physical harm caused by foreseeable reliance on that information. Those precedents do not depend on the defendant's duty as the maker or marketer of an injury-producing product. (ABM 23–25.)

State courts from around the country likewise recognize the tort of negligent misrepresentation resulting in physical injury, as set out in Restatement (Second) of Torts § 311, as a cause of action entirely separate from a product supplier's failure to warn. For example, in *Lawhon v. Ayres Corp.* (Ark. Ct. App. 1999) 992 S.W.2d 162, a pilot was killed in a crash that was allegedly caused by a defective airplane wing. His widow was allowed to pursue not only products liability claims against the manufacturer, but also misrepresentation claims against the company that serviced the aircraft. (*Id.* at pp. 163–164.) Similarly, in *Gerrity v. R.J. Reynolds Tobacco Co.* (Conn. 2003) 818 A.2d 769, the court allowed plaintiff to pursue both consumer product-liability claims for injuries caused by defective tobacco products and Unfair Trade Practices Act claims for injuries caused by defendant's misrepresentations. (*Id.* at pp. 774–775.)

In *Thompson v. Hardy Chevrolet-Pontiac-Buick, Inc.* (Ga. Ct. App. 1992) 417 S.E.2d 358, the court ruled that defendant auto dealership could be held liable for injuries a passenger sustained

in an auto accident caused by brake failure, not because the dealership was the seller of the vehicle, but because "Hardy Chevrolet negligently informed [the buyer] that the brakes on the vehicle she purchased had been inspected and were in good working order," citing Restatement (Second) of Torts §311. (*Thompson v. Hardy Chevrolet-Pontiac-Buick, Inc.*, *supra*, at pp. 360–61.)

Maryland first recognized the tort of negligent misrepresentation in *Virginia Dare Stores, Inc. v. Schuman* (Md. 1938) 1 A.2d 897. A cleaning company sent its employee to a store to wash walls. Although the store manager assured him that a dress case was safe to stand on, the case gave way, causing the worker to fall and suffer injury. Following "the weight of authority in other jurisdictions," the court upheld the cause of action for negligent misrepresentation. (*Id.* at p. 899.)

In each of these examples, defendant was not held to any expanded duty for the manufacturer or supplier of the injury-producing product. The defendant instead was held responsible as a negligent supplier of incorrect information in circumstances where foreseeable reliance on that information placed the plaintiff in peril.

The policies served by strict products liability make clear why the defendant's liability in that circumstance is tethered to its status as the supplier of the injury-causing product. This Court explained in *Greenman v. Yuba Power Prods., Inc.* (1963) 59 Cal.2d 57, "A manufacturer is strictly liable in tort when an article *he places on the market*, . . . proves to have a defect that causes injury to a human being." (*Id.* at p. 62 (emphasis added).) "The purpose of such liability 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." (*Id.* at p. 63, emphasis added.)

Thus, the policy under-girding strict products liability demands:

> [T]hat the burden of accidental injuries caused by products intended for consumption *be placed upon those who market them*, and be treated *as a cost of production* against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are *those who market the products*.

(Restatement (Second) of Torts § 402A (1965) comment c, emphasis added.)

Misrepresentation, by contrast, looks to the conduct of the defendant in disseminating dangerous misinformation. Both policies protect the public, but in distinct ways.

C. Novartis's contrary argument confuses negligence and strict liability.

Novartis's entire argument rests upon the incorrect notion that its tort responsibility is measured solely by the law of products liability, specifically the manufacturer's duty to warn of the dangers associated with the products it places into the stream

of commerce. Indeed, many of the (largely federal[8]) decisions the company relies upon proceed upon the premise that misrepresentation claims against drug makers are simply product liability claims in poor disguise. For example, one federal court predicted that all 22 states whose law would be applicable to the misrepresentation claims before it would construe those claims as product liability claims, either because the claims were subsumed under state product liability statutes, or because the court's *Erie*[9]-prediction of state common law reached that result, or because state law did not recognize a separate duty to use due care to avoid misrepresentation. (*In re Darvocet, Darvon, & Propoxyphene Prod. Liab. Litig.* (6th Cir. 2014) 756 F.3d 917, 941–954; see also *Johnson v. Teva Pharm. USA, Inc.* (5th Cir. 2014) 758 F.3d 605, 615 [The Louisiana Products Liability Act provides an exclusive remedy and claimants "may not recover from a manufacturer for damage caused by a product on the basis of any theory of liability that is not set forth in this Chapter," quoting La. Rev. Stat. Ann. § 9:2800.52]; *Fullington v. Pfizer, Inc.* (8th Cir. 2013) 720 F.3d 739, 744 [misrepresentation claims are essentially "product liability claims" governed by Arkansas Product Liability Act and its requirement that the injury-causing product be identified as defendant's]; *Schrock v. Wyeth, Inc.* (10th

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[8] Federal decisions no more than advisory in this Court. (*Bank of Italy Nat. Trust & Sav. Assn. v. Bentley* (1933) 217 Cal. 644, 653.)

[9] *Erie R. Co. v. Tompkins* (1938) 304 U.S. 64, 77–78 [federal courts in diversity cases must apply state law].)

Cir. 2013) 727 F.3d 1273, 1283 [finding no duty under Oklahoma law to warn or avoid misrepresentation between parties not in a contractual relationship].)

Novartis invents other terms, "former manufacturer" duty (OBM 9) and "drug innovator" duty (OBM 10), to argue that products liability principles should not be expanded to impose liability under the circumstances here. (RBM 13–22.) But the court of appeal imposed no new products-liability duties. In 2001, when Novartis owned the New Drug Application[10] [NDA] for Brethine, federal law required it to supply information to prescribing physicians concerning the risks associated with the drug. (21 C.F.R., § 201.80, subd. (e).) Whether Novartis is liable for a doctor's reliance in 2007 on Novartis's incomplete and inaccurate labeling that was still in force is, as the court below recognized, a factual question for the jury. (Slip opn. at p. 19.)

The court of appeal held that Novartis could be liable, not merely because it supplied prescription drugs, but because it supplied information intended to be relied upon by prescribing physicians, and ultimately, the consumers such as the mother here. Plaintiffs do not allege that the company should be liable for a defect in either Brethine or terbutaline. Rather, they claim that Novartis should be accountable for its own conduct in distributing misinformation concerning the drug. Novartis seeks a radical change in the law: absolute immunity for itself from liability for physical harm that was caused by its distribution of misinformation knowing that prescribing physicians would rely

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[10] The NDA application is the vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.

upon it, regardless of whether their patients would ultimately use Brethine or its identical generic equivalent. Novartis's status as a product supplier does not insulate it from liability as a misinformation supplier.

D. Pharmaceutical manufacturers are not entitled to immunity from liability for negligent misrepresentation.

Novartis nonetheless argues that Restatement of Torts (Second) § 311 and the tort of negligent misrepresentation do not apply to pharmaceutical manufacturers of prescription medicines. First, Novartis contends that the court of appeal imposed "new" duties based solely on foreseeability. (RBM 12.) To the contrary, the duty to supplement label warnings to reflect newly discovered dangers is imposed by federal law. 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." (21 C.F.R., § 201.80, subd. (e) [emphasis added].) The appellate court's discussion of reasonable foreseeability was in the context of whether it was reasonably foreseeable that plaintiff's prescribing physician would rely on Novartis's 2001 labeling information in 2007. (Slip opn. at pp. 19–20.) The court of appeal did not determine the scope of Novartis's duty based on foreseeability of harm. That duty was imposed by federal law. The court of appeal simply determined that reasonably foreseeable reliance by the treating physician could support a jury finding of causation. (*Id.* at p. 20.)

Second, Novartis relies on "the overwhelming judicial rejection of the Court of Appeal's additional proposed duty on innovator