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

manufacturers." (RBM 11.) But most of the decisions cited by Novartis are from federal courts and do not bind any state court. (See *United States v. DeGasso* (10th Cir. 2004) 369 F.3d 1139, 1145 ["It is axiomatic that state courts are the final arbiters of state law."].) And almost all those federal decisions are based on an *Erie* prediction that state courts would construe misrepresentation claims as *de facto* product liability claims. California tort law, on the other hand, recognizes negligent misrepresentation as an entirely separate cause of action from products liability.

As the court of appeal observed, many of those decisions follow *Foster v. Am. House Prods. Corp.* (4th Cir. 1994) 29 F.3d 165, which held that generic drug manufacturers were solely responsible for negligent misrepresentations in their warning labels. (*Id.* at p. 169.) *Foster* and the decisions that follow it do not withstand scrutiny in light of the Supreme Court's subsequent conclusion that generic drug makers have no authority to alter label warnings furnished by the BNMs. (*PLIVA*, *supra*, 564 U.S. at p. 613.)

Amici submit that those decisions which agree with the reasoning of the court of appeals in *Conte*, though fewer in number, are far more persuasive. The foremost comes from the Supreme Court of Alabama in *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649 *(Weeks)*. Its issues mirror the issues before this Court.

Danny Weeks was afflicted with tardive dyskinesia, an irreversible neurological disorder of involuntary movements caused by long-term use of the prescription drug metoclopramide, which is the generic form of the brand-name drug Reglan. Weeks

brought suit in federal district court, alleging liability on the part of the makers of Reglan for misrepresentation of the dangers associated with the drug, including its generic equivalent. The federal court certified to the Alabama Supreme Court the question whether a drug company may be liable under Alabama law "based on statements it made in connection with the manufacture or distribution of a brand-name drug," where the plaintiff claims "physical injury from a generic drug manufactured and distributed by a different company." *(Weeks*, *supra*, 159 So.3d at p. 653.)

The court first rejected defendants' assertion that Weeks' fraudulent misrepresentation claims, however pled, were in fact products liability claims. As with California's common-law principles, Alabama's products liability statute "did not subsume a common-law negligence or wantonness claim." (*Weeks*, *supra*, 159 So.3d at p. 656.) And as did the court of appeal here, the Alabama court rejected defendants' reliance on pre-*PLIVA* decisions. (*Id.* at pp. 664–666.)

The court was skeptical of Wyeth's contention that it had no duty because it lacked privity or other direct relationship with Weeks. "The Weekses are not arguing that Wyeth owed them a duty. Instead, they are arguing that Wyeth owed Danny Weeks's physician a duty and that, under the learned-intermediary doctrine, the Weekses are entitled to rely on the representations made to Danny's physician." (*Weeks*, *supra*, 159 So.3d at p. 664.)

> A prescription-drug manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug. . . . However,

> if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient. . . . The substitution of a generic drug for its brand-name equivalent is not fatal to the Weekses' claim because the Weekses are not claiming that the drug Danny ingested was defective; instead, the Weekses' claim is that Wyeth fraudulently misrepresented or suppressed information concerning the way the drug was to be taken and, as discussed, the FDA mandates that the warning on a generic-drug label be the same as the warning on the brand-name-drug label.

(*Weeks*, *supra*, 159 So.3d at pp. 673–674.)

The court concluded.

> [I]t is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce because the manufacturing process is irrelevant to misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies, when those alleged misrepresentations were drafted by the brand-name manufacturer.

(*Weeks*, *supra*, 159 So.3d at p. 677.)

Kellogg v. Wyeth (D. Vt. 2010) 762 F.Supp.2d 694 *(Kellogg)*, also followed *Conte*, imposing liability on a brand-name manufacturer for misrepresentation under Vermont law. The district court stated:

> [It] is reasonably foreseeable that a physician will rely upon a brand name manufacturer's representations--or the absence of representations--about the risk of side effects of its drug, when

> deciding to prescribe the drug for a patient, regardless of whether the pharmacist fills the prescription with a generic form of the drug.

(*Kellogg*, *supra*, 762 F.Supp.2d at pp. 708–709.)

"A reasonable jury could conclude that inadequate, misleading and inaccurate information provided by [defendants] was a proximate cause of [Kellogg's] injury." (*Id.* at p. 702.)

As did the court of appeal here, these cases acknowledge that a cause of action for misrepresentation does not automatically render the brand-name manufacturer liable. In such cases, "the plaintiffs have significant hurdles to overcome," including whether reliance on older warnings is both foreseeable and reasonable. (*Bd. of Educ. of City of Chicago v. A, C & S, Inc.* (1989) 131 Ill.2d 428, 456; *Lyman v. Pfizer, Inc.* (D. Vt. July 20, 2012) 2012 WL 2970627, at *17–18 [similar in prescription drug case].) Those questions of reasonableness and foreseeability are questions of fact for the jury.

E. The Court's *O'Neil* decision does not aid Novartis.

Novartis relies heavily on *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335 *(O'Neil)* but *O'Neil* does not even address the issues this case presents. The Court was facing the question of whether Crane Co., who made pumps used in navy ships, could be liable for "a wrongful death allegedly caused by asbestos released from external insulation and internal gaskets and packing, all of which were made by third parties and added to the pumps and valves post sale." (*Id.* at p. 342.) In other words, beyond producing a

product into which asbestos-containing parts could be added later, Crane had nothing to do with the injury-causing agency. Not surprisingly, the Court declined to extend product liability in that context.

An appellate decision is only authority on points "actually involved and decided." (*Santisas v. Goodin* (1998) 17 Cal.4th 599, 620.) The *O'Neil* court was not faced with a situation analogous to this one. Its opinion does not even mention *Conte*. And Crane Co. did not stand in the type of relationship as do generic manufacturers with their federally-mandated duty to mimic the BNM-authored warnings. (*PLIVA*, *supra*, 564 U.S. at p. 616.)

Moreover, the Court did conclude that liability attached where "the defendant participated substantially in creating a harmful combined use of the products." (*O'Neil*, *supra*, 53 Cal.4th at p. 342.) This is exactly what Novartis has done. It authored the warnings used for its products and the generic equivalents. It participated substantially in the harm by crating the inadequate, misleading warnings. The court of appeal recognized this distinction. (Slip opn. at pp. 23–24.) Nothing in the *O'Neil* opinion dilutes *Conte's* and court of appeal's duty analysis.

II. Federal labeling law compels a conclusion that the manufacturer's duty of care extends to patients who take generic equivalents.

Consumers of prescription drugs receive information about them from various sources, including brand-name manufacturers, generic manufacturers, pharmacies and physicians. In the case of a brand-name drug with generic equivalents, the ultimate source of that information is the same–the brand name manufacturer.

"[A] central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times. It is charged both with crafting an adequate label and with ensuring that its warnings remain adequate as long as the drug is on the market. (Citation.)" (*Wyeth v. Levine* (2009) 555 U.S. 555, 570–571 *(Wyeth)*.)

Manufacturers of generic equivalents have a duty to follow the brand-name manufacturers. That is, they have "an ongoing federal duty of sameness regarding their warning labels" and may not take unilateral disclosure of additional perceived risks associated with a particular drug. (*PLIVA*, *supra*, 564 U.S. at p. 616.) Any failure to discharge this duty by the subjects them to liability to injured patients. (*Teva Pharm. USA, Inc. v. Superior Court*, *supra*, 217 Cal.App.4th at p. 112.)

The BNMs obtain approval from the Federal Drug Administration to market a new prescription drug. (21 U.S.C. § 355.)

> Approval of the New Drug Application will be denied if clinical testing data and other information do not show that the drug is safe and effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, or if based on a fair evaluation of all material facts, such labeling is false or misleading in any particular. (21 U.S.C. § 355(d).)

(*Conte*, *supra*, 168 Cal.App.4th at pp. 97–98.)

Brand-name manufacturers have a duty to supply the FDA with "postmarketing reports," which include reports of any serious and unexpected adverse reactions suffered by a user of a

drug. (21 C.F.R., § 314.80.) The brand-name manufacturer also must submit annual reports to the FDA on significant information, including information that might affect the safety, effectiveness, or labeling of the product. (21 C.F.R. § 314.81.) Likewise, a generic manufacturer is required to submit these reports to the FDA. (21 C.F.R. §§ 314.92, 314.98.) But they may not issue any new or different information about the drug. (*PLIVA*, *supra*, 564 U.S. at p. 616.)

In *Conte,* the court of appeal undertook an exhaustive duty analysis of BNMs vis-a-vis consumers who took their generic equivalents. (168 Cal.App.4th at pp. 103–107.) Like T.H.'s mother, Elizabeth Conte had taken a generic equivalent of the prescribed drug. The court saw no reason not to employ California's well-settled duty principles. (168 Cal.App.4th at p. 103.) Starting with foreseeability, the court held, "we have no difficulty concluding that Wyeth [the BNM] should reasonably perceive that there could be injurious reliance on its product information by a patient taking [the] generic [equivalent.]" (*Conte*, *supra*, 168 Cal.App.4th at p. 105.)[11] Then court explored

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[11] After all, California pharmacists may fill a prescription with a generic equivalent whenever requested unless the physician expressly orders otherwise. (Bus. & Prof. Code, § 4073.) As reported on National Public Radio, in 2016, more than half of all people with insurance will have some brand-name medications excluded from coverage. (A. Kodjak, *Fight To Lower Drug Prices Forces Some To Switch Medication* (N.P.R. 2016) http://www.npr.org/sections/health-shots/2016/01/25/463809474/fight-to-lower-drug-prices-forces-some-to-switch-medication (as of 11/28/2016).)

in detail the other *Rowland*[12] factors the Court has established as the framework for duty analysis. After assessing those other factors, the court concluded:

> [W]e find the conclusion inescapable that Wyeth knows or should know that a significant number of patients whose doctors rely on its product information for [the brand name] Reglan are likely to have generic [equivalent] metoclopramide prescribed or dispensed to them.
>
> . . .
>
> We hold that Wyeth's duty of care in disseminating product information extends to patients who are injured by [the] generic [equivalent] as a result of prescriptions written in reliance on [the brand-name drug manufacturer's] product information for [its brand-name drug]."

(*Conte*, *supra*, 168 Cal.App.4th at p. 107.)

Novartis owed this same duty of care to all the patients who ingested generic versions of its drugs.

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[12] *Rowland v. Christian* (1968) 69 Cal.2d 108.

III. Federal labeling law is a floor, not a ceiling, on a drug manufacturer's liability.

A. Both this Court and the U.S. Supreme Court have rejected the premise that FDA labeling law provides the sole limit of liability.

Just as it recognized a drug manufacturer's duty to warn, the Court long ago rejected the notion that federal labeling law placed a ceiling on that duty.

> [M]ere compliance with regulations or directives as to warnings, such as those issued by the United States Food and Drug Administration here, may not be sufficient to immunize the manufacturer or supplier of the drug from liability. The warnings required by such agencies may be only minimal in nature and when the manufacturer or supplier knows of, or has reason to know of, greater dangers not included in the warning, its duty to warn may not be fulfilled.

(*Stevens*, *supra*, 9 Cal.3d at p. 65.)

The Court presaged the U.S. Supreme Court by nearly 40 years. As the high court would later hold, a major premise of the Federal Food, Drug, and Cosmetic Act[13] [FDCA], is that "[s]tate tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information." (*Wyeth*, *supra*, 555 U.S. at p. 579.)

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[13] 21 U.S.C. § 301, et seq.

The high court observed, "If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history." (*Wyeth*, *supra*, 555 U.S. at p. 574 & n.7.) Yet, Congress has expressly and repeatedly rejected proposals to do just that, and has instead preserved state tort remedies. (See also *Consumer Fed'n of Am. v. Upjohn Co.* (D.C. 1975) 346 A.2d 725, 731 [explaining that a private right of action was omitted from the FDCA because "it would create an unnecessary federal action duplicative of state remedies"]; R. Adler, et al., *Preemption and Medical Devices: The Courts Run Amok,* (1994) 59 Mo. L. Rev. 895, 924 & n.130 [Congress intended to preserve existing common-law causes of action for injury caused by prescription drugs)].)

"Evidently," the Supreme Court concluded, Congress "determined that widely available state rights of action provided appropriate relief for injured consumers. (*Wyeth*, *supra*, 555 U.S. at p. 574.) This "is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness." (*Id.* at p. 575.) The *Wyeth* Court continued:

> In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that the FDA traditionally regarded state law as a complementary form of drug regulation. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety

> risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. Thus, *the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation.*

(*Wyeth*, *supra*, 555 U.S. at pp. 578–579 [emphasis added]; see also *Bates v. Dow Agrosciences LLC* (2005) 544 U.S. 431, 451 [state tort suits "can serve as a catalyst" for federal agency action by aiding in the exposure of new dangers and prompting a manufacturer or the federal agency to decide that a revised label is required].)

One instance of this "layer of consumer protection" emerged after the Court's *Wyeth* decision. Diana Levine, the victim, had developed gangrene, and her forearm had to be amputated when a physician's assistant injected her artery with the anti-nausea drug Phenergan by using the "IV push" method of intravenous injection. Subsequently, the FDA's analysis of "post marketing reports of severe tissue injury" with respect to promethazine (the generic form of Phenergan) led the FDA to require a boxed warning against injection by this method, which so tragically affected Ms. Levine. (See FDA, Information for Healthcare Professionals - Intravenous Promethazine and Severe Tissue Injury, Including Gangrene (2009) http://www.fda.gov/Drugs/DrugSafety/

PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm182169.htm (as of 11–27-2016).)

FDA regulation depends heavily upon reporting of adverse events by drug manufacturers themselves. State tort law holding drug companies accountable for their negligence in promoting their products in no way conflicts with Congress's plan for FDA regulation. To the extent that potential tort liability supplies a financial incentive for brand-name drug companies to provide prompt and accurate reports of adverse events to prescribing physicians, private causes of action protect the public from unanticipated dangers posed by prescription drugs.

B. The drug manufacturers, not the FDA, have the responsibility for monitoring for adverse events that emerge post-marketing.

In its reply brief Novartis contends for the first time[14] that imposing liability on brand-name drug manufacturers for misrepresentations that harm users of the generic version must not "stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." (RBM 30.) Novartis further claims that liability for misrepresentation would "nullify federal law policy judgments governing the regulation of prescription drugs." (*Ibid.*) Novartis proposes instead that its

[14] This conflict-preemption argument was not raised in Novartis' Opening Brief on the Merits and should be deemed waived. "It is axiomatic that arguments made for the first time in a reply brief will not be entertained because of the unfairness to the other party." (*People v. Tully* (2012) 54 Cal.4th 952, 1075.)

responsibility be limited to the FDA's administrative requirements. That is, Novartis argues any responsibility for failure by an NDA holder to revise the drug label to warn of hazards discovered post-marketing, as required by 21 C.F.R., § 201.80, subd. (e), ends when the owner sells its NDA, even where the owner's prior failures to revise the label have resulted in serious injury. (RBM 23 ("A subsequent drug manufacturer is solely responsible for the safety and labeling of its drug *from the moment it purchases the NDA*.") (emphasis in original).) In Novartis's view, immunity from any broader private right of action is warranted because "courts are not institutionally qualified to balance the complex, interrelated, and divergent policy considerations in determining labeling and liability obligations of brand and generic pharmaceuticals." (RBM 31.)

But imposing tort liability in this context does not conflict with Congress' objectives or with FDA labeling regulation. Indeed, Congress, the FDA and the U.S. Supreme Court view private tort litigation as a necessary complement to the efforts of the FDA. (*Wyeth*, *supra*, 555 U.S. at p. 579.)

As a former FDA Commissioner has observed, pre-approval testing of prescription drugs generally is incapable of detecting adverse effects that occur infrequently, have long latency periods, or affect sub-populations not adequately represented in the studies, including pregnant women. (D. Kessler, et al., *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims* (2008) 96 Geo. L.J. 461, 471.) Commentators cite estimates that "as many as half of all new drugs have at least one serious adverse effect that is unknown at the time of drug approval." (B. Evans, *Seven Pillars of a New Evidentiary*

Paradigm: The Food, Drug, and Cosmetic Act Enters the Genomic Era (2010) 85 Notre Dame L. Rev. 419, 430, citing B. Furberg, et al., Evaluating Clinical Research 8 (2d ed. 2007).)

Indeed, experts believe that only one to ten percent of adverse events are reported to FDA, and the quality of those reports is poor. (J. Mann, *FDA Adverse Event Reporting System: Recruiting Doctors to Make Surveillance A Little Less Passive* (2015) 70 Food & Drug L.J. 371, 380–84, see also U.S. Gen. Accounting Office, GAO/T-HEHS-00–53 (2000) Adverse Drug Events: Substantial Problem But Magnitude Uncertain 6; T. Tiedt, *The Drug Safety System Conundrum* (2007) 62 Food & Drug L.J. 547, 551–55 [summarizing criticisms of the FDA's post-market oversight].)

The FDA faces serious challenges in addressing the mammoth workload before it. The Institute of Medicine of the National Academies (IOM) has concluded that FDA "lacks the resources to accomplish its large and complex mission today, let alone to position itself for an increasingly challenging future." (IOM, The Future of Drug Safety: Promoting and Protecting the Health of the Public (2007) 193, available at http://www.fda.gov/oc/reports/iom013007.pdf; see also E. Parasidis, *Patients over Politics: Addressing Legislative Failure in the Regulation of Medical Products* (2011) 2011 Wis. L. Rev. 929, 932 [FDA is "'an agency with expanded responsibilities, stagnant resources, and the consequent inability to implement or enforce its statutory mandates,'" quoting P. Hutt, *The State of Science at the Food and Drug Administration* (2008) 60 Admin. L. Rev. 431].)

Amici underscore a hard truth that was voiced on the Senate floor by the chief Senate sponsor of the 2007 FDCA Amendments--the FDA cannot be expected to assume exclusive responsibility for protecting the public.

> Clearly, the resources of the drug industry to collect and analyze post-market safety data vastly exceed the resources of the FDA, and no matter what we do, they will always have vastly greater resources to monitor the safety of their products than the FDA does. It is absurd to argue that the FDA, even with the enhanced resources and authorities provided by this legislation, commands the field when it comes to postmarket safety. The drug companies have the capacity to do a far more comprehensive job.

153 Cong. Rec. S11832 (daily ed. Sept. 20, 2007) (remarks of Sen. Ted Kennedy).

Congress has long relied on state tort causes of action to provide the financial incentive for drug companies to supply medical providers with prompt and accurate information concerning the risks associated with their products discovered post-marketing. Nothing about Novartis' status as the prior brand-name manufacturer alters that reliance.

IV. No special rules of superseding cause apply to a negligent drug manufacturer who sells its rights to the drug.

As the prior NDA holder, Novartis is like any other tortfeasor who claims that subsequent, third-party tortious conduct extinguished its liability. In *Stevens*, the Court confirmed the application of superseding cause analysis in cases of a negligent

drug company's failure to warn. The defendant had asserted that the negligence the prescribing doctor was a superseding cause who exonerated it from liability. (*Stevens*, *supra*, 9 Cal.3d at p. 67.) Rejecting the claim, the Court hewed to the general principles that govern when a tortfeasor contends that an intervening actor's conduct excuses its liability.

> It is 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. (Citations.) Moreover, if the likelihood that a third person may act in a particular manner is the hazard or one of the hazards which makes the actor negligent, such an act whether innocent, negligent, intentionally tortious or criminal does not prevent the actor from being liable for harm caused thereby." (Citation.)

(*Stevens*, *supra*, 9 Cal.3d at p. 69.)

Thus, even where the prescribing doctor testified that he was aware of the dangerous qualities of the drug, the jury could properly conclude that Parke, Davis's advertising overcame the warnings it gave. (*Stevens*, *supra*, 9 Cal.3d at p. 69)

In other words, before Novartis can be exonerated by any negligence of its subsequent NDA holder, it must plead and prove that the holder's negligence in not curing Novartis's defective warning is superseding cause. As the Court explained nearly 50 years ago:

> This issue is concerned with whether or not, assuming that a defendant was negligent and that

> his negligence was an actual cause of the plaintiff's injury, the defendant should be held responsible for the plaintiff's injury where the injury was brought about by a later cause of independent origin. This question, in turn, revolves around a determination of whether the later cause of independent origin, commonly referred to as an intervening cause, was foreseeable by the defendant or, if not foreseeable, whether it caused injury of a type which was foreseeable. If either of these questions is answered in the affirmative, then the defendant is not relieved from liability towards the plaintiff; if, however, it is determined that the intervening cause was not foreseeable and that the results which it caused were not foreseeable, then the intervening cause becomes a supervening cause and the defendant is relieved from liability for the plaintiff's injuries.

(*Akins v. Cnty. of Sonoma* (1967) 67 Cal.2d 185, 199.) "Normal, but negligent, intervening response will not supersede but an extraordinarily negligent response will supersede." (*Martinez v. Vintage Petroleum, Inc.* (1998) 68 Cal.App.4th 695, 701.) The T.H. plaintiffs have alleged facts that would support a finding that "it was foreseeable physicians and patients would continue to rely on Novartis's product label for adequate warnings." (Slip. opn. at p. 19.) Any negligence of the current NDA holder cannot be a superseding cause of plaintiffs' harm.

Moreover, whether a subsequent actor or force amounts to a superseding cause is an affirmative defense all elements of which must be proved by the defendant. (*Arreola v. Cnty. of Monterey* (2002) 99 Cal.App.4th 722, 760; see CACI 432.) This is not a matter which can be resolved on demurrer.

CONCLUSION

Neither the *Conte* court nor the court of appeal created new or novel theories of liability. Their holdings pose no threat to or conflict with federal drug regulation but instead compliment that regulation as Congress intended. Their conclusions are firmly grounded in the common law of California and common sense. The Court should affirm.

Respectfully submitted,

Dated: November 30, 2016 By: _____

Alan Charles Dell'Ario

Attorney for Amici curiae Consumer Attorneys of California and American Association for Justice

CERTIFICATE OF COMPLIANCE

This brief is set using **13-pt Century Schoolbook**. According to TypeLaw.com, the computer program used to prepare this brief, this brief contains **7,520** words, excluding the cover, tables, signature block, and this certificate.

The undersigned certifies that this brief complies with the form requirements set by California Rules of Court, rule 8.204(b) and contains fewer words than permitted by rule 8.520(c) or by Order of this Court.

Dated: November 30, 2016 By: _____

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IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

No. S233898

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