Case No. **S233898**

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IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

T.H., a Minor, etc., et al.,
Plaintiffs and Appellants,

vs.

NOVARTIS PHARMACEUTICALS CORPORATION,
Defendant and Respondent.

ON REVIEW FROM THE COURT OF APPEAL, FOURTH APPELLATE DISTRICT, DIVISION ONE, CASE NO. D067839; SAN DIEGO COUNTY SUPERIOR COURT, NO. 37-2013-00070440-CU-MM-CTL, THE HONORABLE JOAN M. LEWIS, JUDGE

AMICUS CURIAE BRIEF OF THE CIVIL JUSTICE ASSOCIATION OF CALIFORNIA IN SUPPORT OF DEFENDANT AND RESPONDENT

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IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

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INTRODUCTION: COMPLEXITY OF ISSUE AND INTEREST OF AMICUS

The court's phrasing of the issue is broad in scope:

> **May the brand name manufacturer of a pharmaceutical drug that divested all ownership interest in it be held liable for injuries caused years later by another manufacturer's generic version of that drug?**

Several specific subsidiary questions, however, are implicit in parsing and endeavoring to answer this one. To begin with, is this a "product liability" or "negligence" issue; and does or should it matter what label or theory is advanced for liability here? Next, what liability, if any, does the "generic manufacturer" of the drug the plaintiff's mother actually consumed have to plaintiffs harmed *in utero*? And what about the liability of the physician who prescribed the drug that injured plaintiffs?[1] Is the brand name drug company, Novartis, the *only* defendant legally liable in the situation posited by the statement of the issue to be decided? If so, does the answer to

[1] Plaintiffs' suit against the physician who prescribed the drugs, the hospital where plaintiffs were born and the manufacturers of the generic drugs used by their mother is still pending in the trial court.

that query convey anything about why liability should or should not be imposed by the Court in this case? What does it legally matter that here the brand name manufacturer sold all its interest in the drug years before the plaintiff was injured by consuming a generic version of the drug made by a different pharmaceutical company? If total divestiture by a company of an asset through its sale to a separate and independent company does not extinguish the seller's liability to future consumers injured by a copycat product made by a different manufacturer, what can a product manufacturer do to rid itself of future liability? Must the original manufacturer remain infinitely liable for copycat products made by others of ones it long ago ceased to make?

Moreover, when the phrasing of the question refers, as it does, to "injuries caused," are we to assume *causation en toto*, both "cause-in-fact" and "legal (what used to be "proximate") cause" is a given? If "legal causation" is presumed, can the "foreseeability" element necessary for determining "legal cause" be incorporated into and satisfy the "foreseeability" element of a negligent failure-to-warn claim or any negligence claim requiring proof of four elements: (1) a *duty* owed by the defendant to the plaintiffs; (2) a *breach* of that duty by defendant; (3) causation, both *legal* and *in-fact*, resulting in injury to plaintiffs; and (4) *recoverable damage* to plaintiffs? (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 500.) Is there a difference between the "foreseeability" element present in both "legal cause" and "duty" and, if so, what is that difference?

These implicitly subsumed questions reveal the complexity of addressing the larger one presented, and are central to the Civil Justice Association of California's (CJAC's) principal purpose — to educate the public about ways to make our civil liability laws more fair, certain, economical and efficient. Toward these ends, CJAC has

regularly petitioned government for the past 38 years when it comes to deciding who gets how much, from whom, and under what circumstances when the conduct of some occasions injury to others.

We welcome the opportunity[2] to do so again in this case, where the trial court answered "no" to the question now before us by sustaining the demurrer of the original (also referred to as the "innovator" or "pioneer") manufacturer, Novartis, to the complaint based on its failure to warn on its label that its drug Brethine, which it developed to treat asthma, had dangerous side effects to the fetus when consumed by a pregnant woman.

In reversing the trial court, the appellate opinion relied heavily, as do plaintiffs, on *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89 (*Conte*), which it described as applying "common law principles of duty and foreseeability to conclude a brand-name pharmaceutical manufacturer should 'shoulder its share of responsibility for injuries caused . . . by its negligent . . . dissemination of inaccurate information' even though the patient consumed a generic version of the medication manufactured by another company." (Slip Opinion, pp. 2-3, citing and quoting *Conte* at 103, 109-110.)

From *Conte*'s inception, "[v]irtually all of the reaction to [it] . . . has been intensely negative. Commentators have mercilessly lambasted the California court for concluding that a drug manufacturer could be liable for injuries suffered by someone who took another company's product. . . Likewise, other courts . . . have been nearly unanimous in condemning *Conte*'s reasoning." (Rostron, *Prescription for Fairness: a New*

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[2] By application accompanying the lodging of this amicus brief, CJAC asks the Court to accept it for filing.

Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers (2016) 60 *DUKE L.J.* 1123, 1126-1127.) Fortunately, this case now affords an opportunity to review the logic and impact of *Conte* with the benefit of hindsight over the eight years since it was decided.

CJAC is mindful of and appreciates the many pioneering advances in tort law by this Court's opinions, some of which we have been privileged to have participated in argument as amicus. (See, *e.g.*, within the past five years, *Winn v. Pioneer Medical Group, Inc.* (2016) 63 Cal.4th 148; *Richey v. Autonation, Inc.* (2015) 60 Cal.4th 909; *Verdugo v. Target Corp.* (2014) 59 Cal.4th 312; *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335; and *Howell v. Hamilton Meats & Provisions, Inc.* (2011) 52 Cal.4th 541.)[3] Notably, this Court's seminal opinions shaping tort law doctrine recognize that judicial expansion of liability and damages law are wisely and necessarily tempered by recognition of reasonable limits, that, for example, '[p]roducts liability is not absolute liability, . . . a manufacturer is not the insurer of the product," (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1121); "the societal benefits of certainty in the law, as well as traditional concepts of tort law, dictate limitation of bystander recovery of damages for emotional distress," (*Thing v. La Chusa* (1989) 48 Cal.3d 644, 648 (*Thing*)); and "it would be unfair to impose liability on the hiring person when the liability of the contractor, the one primarily responsible for the worker's on-the-job injuries, is limited to providing workers' compensation

[3] Besides the above opinions that are consistent with the position CJAC took as amicus, we have, in the interest of full disclosure, unsurprisingly also participated in others that were decided contrary to what our briefs argued. (See, *e.g.*, *Rose v. Bank of America* (2013) 57 Cal.4th 390; *People ex. Rel. Harris v. Pac Anchor Transp, Inc.* (2014) 59 Cal.4th 772; *Beacon Residential Community Assn. v. Skidmore, Owings & Merrill LLP* (2014) 59 Cal.4th 568; and *Horiike v. Coldwell Banker Residential Brokerage Co.*, 2016 WL 6833005.

coverage." (*Toland v. Sunland Housing Group, Inc.* (1998) 18 Cal.4th 253, 267.)

Most importantly, developments occurring since *Conte* was decided show that it is an "outlier" opinion that, unless trimmed or overruled, will continue to produce inequitable results, costly litigation, and unnecessary confusion by bench and bar.

Finally, as petitioner warns, plaintiffs' position premised on *Conte* and carried to the limits of its logic, imposes liability upon "any former manufacturer or manufacturer of a branded product, whether the product at issue is a prescription drug, a consumer good, a computer, a piece of software, a chemical, a petroleum product, or any number of products upon which the California economy depends. . . [A]ll that is required to impose a duty of care is some foreseeable scenario by which such product manufacturers 'bear at least some direct responsibility for the alleged harm.'" (Petition, p. 33, citing and quoting from the appellate opinion.)

LEGAL BACKGROUND TO THIS CASE

Federal law, statutory and judicial, strongly influence and inform this case.

We begin with the Drug Price Competition and Patent Term Restoration Act of 1984, commonly referred to as the "Hatch-Waxman Act."[4] Designed to ease the entrance of generic drugs into the pharmaceuticals market, the Hatch-Waxman Act relaxed the requirements for U.S. Food and Drug Administration (FDA) approval for those drugs. Instead of having to leap the same clinical hurdles as the original drug sponsor, generic manufacturers need only demonstrate that their product is "the same as" an existing brand drug, meaning that it is bioequivalent to its brand counterpart and

[4] Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355(j) and 35 U.S.C. §§ 156, 271(e)).

has the same active ingredient(s), route of administration, dosage form, and strength.[5] Other than routine information reflecting the different manufacturer or distributor, the generic drug also must have "the same" prescribing information, *i.e.* label, as the brand drug (*i.e.*, the reference listed drug) on which its approval was based.

Next, three Supreme Court opinions concerning the scope and application of federal preemption in lawsuits against drug manufacturers by consumers injured from use of the drugs they took were decided over the course of four years. The first was *Wyeth v. Levine* (2009) 555 U.S. 555 (*Levine*), holding that the FDA's approval of a *brand-name* drug's prescribing information did not preempt state-law failure-to-warn claims because the brand manufacturer had discretion under FDA's "changes being effected" (CBE) regulation to unilaterally strengthen a drug warning.

Levine was followed by *PLIVA v. Mensing* (2011) 131 S.Ct. 2567 (*Mensing*), which expanded the scope of "impossibility preemption," effectively immunizing generic drug manufacturers from state law failure-to-warn claims. (*Id.* at 2569.) There, two individuals who developed tardive dyskinesia, a severe abnormal and uncontrollable face movement disorder, were left without legal recourse.

Mensing was soon followed by *Mutual Co. Pharmaceutical v. Bartlett* (2013) 133 S. Ct. 2466, further expanding the reach of federal preemption. There the injured plaintiff purchased an affordable *generic* drug to treat her life threatening dermatologic disorder, but as a result of the Court's preemption interpretation, she was also left without legal recourse to address her debilitating injuries.

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[5] See 21 U.S.C. § 355(j)(2)(A) (describing the information required for abbreviated new drug applications).

As a result of these three Supreme Court decisions, the FDA's responsibility is subject to this bizarre lacuna preventing *generic* drug consumers from seeking legal recourse to address their injuries unless they can persuade Congress to plug the gap or, as is being attempted here, state courts to shift liability for their injuries over to the *brand-name* manufacturer of the generic equivalent that injured them. Hence, we are faced with this "hard case" that, as Justice Holmes warned, often makes for "bad law." (*Northern Securities Co. v. United States* (1904) 193 U.S. 197, 364.)

SUMMARY OF ARGUMENT

This Court should eschew plaintiffs' entreaty to impose a duty on the brand-name manufacturer of a drug for injuries they sustained *in utero* when their mother took a generic version of that drug made by a pharmaceutical competitor. The brand-name manufacturer, Novartis, had no relation whatsoever to plaintiffs. Years before plaintiff's mother used the generic version of that drug during her pregnancy, Novartis divested itself of all interests in its brand-name drug by selling it to another company and, in accordance with federal law, allowing other manufacturers to make and market their own generic equivalent of the brand-name drug.

California tort law should not be perverted to provide compensation for injured plaintiffs as a result of federal legislation and judicial opinions that create an anomalous hiatus affording no state law remedy for injured consumers of generic drug manufacturers while allowing state law remedies against brand-name drug makers by consumers injured from use of their drugs. Two wrongs, however, do not make a right; and the manufacturer of a particular product should not be liable for injuries caused by another's "copycat" version of that product.

The "duty" analysis plaintiffs seek to foist upon California will, if accepted by the Court, distort tort law and cause much mischief and confusion beyond pharmaceutical products. Indeed, the expansion of duty plaintiffs urge here has no logical stopping point; it's reliance on "foreseeability" for failure-to-warn cannot be reasonably cabined. Reliance on the reasoning of *Conte* to get to where plaintiffs wish this Court to go has been widely rejected by the vast majority of courts in other jurisdictions and soundly criticized by legal scholars. Shifting liability to former manufacturers for injuries caused by "knock-off" products made by competitors is unfair to the former manufacturers. The remedy for this present anomaly propelling plaintiffs to seek redress for their injuries against pharmaceutical companies that did not make the product that caused them harm because the company that is responsible is immune from state tort law, properly lies with Congress or the FDA, not this Court.

ARGUMENT

I. THE DUTY ANALYSIS URGED BY PLAINTIFFS HAS NO REASONABLE LIMIT AND, IF ADOPTED, PORTENDS VEXATIOUS CONSEQUENCES FOR PHARMACEUTICAL AND OTHER PRODUCT MANUFACTURERS.

Plaintiffs make much of the supposed distinction between actions for failure-to-warn sounding in negligence and product liability. Indeed, they claim any concern that *Conte*'s rationale for imposing a duty upon Novartis runs afoul of the well-settled principle that a defendant should not be held liable for harm caused by another manufacturer's product is misplaced because that principle "only applies to *strict-liability claims*, not negligence claims, and thus has nothing to do with this negligent misrepresentation claim." (Answer Brief on the Merits (ABOM), p. 29.) That assertion,

however, assumes a bright line distinction between strict products liability and negligence that does not exist when it comes, as here, to the products of others.

As petitioner explains, *O'Neil v. Crane Co.*, *supra*, 53 Cal.4th at 342 makes clear that "a product manufacturer may not be held liable in strict liability or negligence for harm caused by another manufacturer's product." (Respondent's Brief on the Merits, p. 14, quoting *O'Neil.*) "There is *no duty of care* to prevent injuries from another manufacturer's product." (*O'Neil*, 53 Cal.4th at 363; italics added.) In contravention of this unambiguous holding, plaintiffs, in reliance on *Conte*, seek to impose a *duty* on Novartis for its failure-to-warn about dangers from use of the generic drug that contained the active ingredient terbutaline, a different product from Novartis' brand name drug Brethine and one made by a different pharmaceutical company years after Novartis divested itself of all interest in Brethine by selling it to aaiPharma. Significantly, even *Conte* recognized that sale of a drug to another company reduced, if not extinguished, the former manufacturer's liability for injuries from that drug.[6]

Plaintiffs nonetheless urge this Court to impose a duty on Novartis to warn of dangerous side effects from consumption of a copycat drug made by a competitor. That knock-off generic drug was based on the brand-name drug Brethine that Novartis ceased making make years ago after selling all interest in it to another company. Plaintiffs claim this is copasetic because "it is *foreseeable* to a brand-name manufacturer that its misinformation will mislead consumers of generic drugs just as much as

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[6] In response to defendant Wyeth's argument that "innovator liability" imposed "permanent . . . liability . . . in perpetuity" upon it, the Court stated this was not the case because "Wyeth no longer has . . . responsibility for Reglan-related claims arising after March 31, 2002, the date Wyeth sold its interest in Reglan. (*Conte*, *supra*, 168 Cal.App.4th at 107.)

consumers of brand-name drugs." (ABOM, p. 38; italics added.) Indeed, plaintiffs' answer brief bristles 32 times with the term "foreseeable." But foreseeability alone is, as this Court has often reminded us, not enough to determine "duty;" especially when it comes to injury caused by another's product.

> [E]xpansion of the duty of care as urged here would impose an obligation to compensate on those whose products caused no harm. To do so would exceed the boundaries established over decades of product liability law. [S]ocial policy must at some point intervene to delimit liability even for foreseeable injury.

(*O'Neil, supra*, 53 Cal.4th at 365.)

Courts have long been aware that "foreseeability" is an elusive, open-ended touchstone under which everything is foreseeable and, hence, everyone owes a duty to everyone else. Hence, as a factor for ascertaining duty, "foreseeability" offers little guidance. That "duty" should not be determined by foreseeability of the risk of harm alone is underscored by *Thing*, *supra*, 48 Cal.3d 644, which cautioned when tightening the test for recovery by third parties for their negligently inflicted emotional distress that "there are clear judicial days on which a court can foresee forever and thus determine liability, but none on which that foresight alone provides a socially and judicially acceptable limit on recovery of damages for [an] injury." (*Id.* at 668.) This same concern was reiterated in *Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370: "Policy considerations may dictate that a cause of action should not be sanctioned *no matter how foreseeable* the risk . . . for the sound reason that the consequences of a negligent act must be limited in order to avoid an intolerable burden on society." (*Id.* at 399, quoting *Elden v. Sheldon* (1988) 46 Cal.3d 267, 274; emphasis added.)

A compelling reason for courts to eschew the equation of *foreseeability* with *duty* under negligence law is:

> If the foreseeability formula were the only basis of determining both duty and its violation, such activities as some types of athletics, medical services, construction enterprises, manufacture and use of chemicals and explosives, serving of intoxicating liquors, operation of automobiles and airplanes, and many others would be greatly restricted. Duties would be so extended that many cases now disposed of on the duty issue would reach a jury on the fact issue of negligence.

(Green, *Foreseeability in Negligence Law* (1961) 61 *COLUMB. L. REV.* 1401, 1417-18.) That, unfortunately, is the position plaintiffs urge happen here despite this Court's sound authority to the contrary. (See, *e.g.*, *Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 774-784 [rejecting claimed exception to duty of care for stopping alongside a freeway]; *Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456, 472-478 [recognizing exception to duty of care for normal operation of garbage truck near bridle path]; *Sharon P. v. Arman, Ltd.* (1999) 21 Cal.4th 1181, 1185 [operators of commercial parking garages had no duty to take precautions against criminal activity in the absence of similar crimes in the past, rejecting contention that a string of robberies was sufficiently similar to plaintiff's rape to impose a duty]; and *Nicole M. v. Sears, Roebuck & Co.* (1999) 76 Cal.App.4th 1238 [defendant owes no duty toward a patron who is victim of attempted assault in defendant's parking lot absent prior criminal attacks].) "[F]oreseeability may be present in cases in which there are good grounds nevertheless to deny liability . . . where for other reasons of policy, liability is foreclosed or limited." (Cardi & Green, *Duty Wars* (2008) 81 *S. CAL. L. REV.* 671, 678.) This is just such a case.

II. WIDESPREAD REPUDIATION OF *CONTE*'S "INNOVATOR LIABILITY" THEORY BY OTHER FEDERAL AND STATE COURTS STRONGLY CALLS INTO QUESTION THE WISDOM OF THIS COURT ADOPTING IT'S REASONING TO IMPOSE LIABILITY ON DEFENDANT.

Though "counting heads" amongst the panoply of jurisdictions that have considered and decided the same liability issue is not determinative of how this Court comes down on the issue, the "near unanimity of agreement by courts considering [and rejecting]" the negligent misrepresentation theory plaintiffs are urging here "suggests we should question the advisability of . . . allegiance" to *Conte*. (*Moradi-Shalal v. Fireman's Fund Ins. Companies* (1988) 46 Cal.3d 287, 298.) Many federal and several non-California *state* court opinions have cited and discussed *Conte* in the context of brand-name or generic drug manufacturer liability since that opinion was published in 2008; and the vast majority have rejected and severely criticized *Conte's* reasoning and conclusion.

A. Federal Courts that Have Considered *Conte*'s "Innovator Liability" Theory Have Resoundingly Rejected it.

Close to 50 federal courts, including six appellate circuits, have considered imposing liability on brand-name drug manufacturers for injuries sustained by consumers who took a generic equivalent of the brand-name drug made by a different pharmaceutical company. The vast majority of these courts have repudiated and refused to adopt *Conte's* innovator liability/negligent misrepresentation theory plaintiffs urge this Court to embrace. One of the most recent opinions to repel *Conte*'s reasoning is *In re Darvocet, Darvon, and Propoxyphne Products Liability Litigation* (6th Cir. 2014) 756 F.3d 917 (*In re Darvocet*). Though captioned as "product liability litigation," this multi-district class-action aggregation of lawsuits against a variety of brand-name and generic pharmaceutical companies, considered and analyzed state tort law claims sounding in

negligence and product liability against the defendant drug manufacturers. *In re Darvocet* noted that "an overwhelming majority of courts, in at least 55 decisions from 22 states, have rejected 'the contention that a brand name manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug." (756 F.3d at 938.) While acknowledging that a minority of states have, following *Conte*, held the opposite, *In re Darvon* found it significant that the vast majority of courts disagreed and found that "generic consumers . . . could not maintain an action against brand manufacturers, in line with the majority of courts nationwide." (*Id.* at 939.) The appellate opinion, "[a]fter conducting a state-by-state . . . analysis," concluded that "the highest courts in each of the 22 implicated states would not recognize plaintiffs misrepresentation claims under their respective state laws." (*Id.*)

Similarly, a different Sixth Circuit panel in *Strayhorn v. Wyeth Pharmaceuticals, Inc.* (6th Cir. 2013)737 F.3d 378 observed that "every federal court of appeals to consider this issue has held that brand name manufacturers are not liable to plaintiffs who are injured by a generic manufacturer's drug, whether under a state's product liability act or under general principles of duty." (*Id.* at 406.) *Schrock v. Wyeth, Inc.* (10th Cir. 2013) 727 F.3d 1273, 1284-86 also remarked that every federal circuit court has rejected brand name liability to plaintiffs injured by consumption of the equivalent generic drug made by a competing pharmaceutical company. See also *Guarino v. Wyeth, LLC* (11th Cir. 2013) 719 F.3d 1245, 1251-53 (noting the "overwhelming national consensus" on the issue and finding that "the cases denying recovery to plaintiffs bringing claims identical to those we confront in this case are legion, and this mountain of authority steels us in our determination that Florida law does not recognize a claim against the brand manufacturer of a prescription drug when the plaintiff is known to have

consumed only the generic form."); *Bell v. Pfizer, Inc.* (8th Cir. 2013) 716 F.3d 1087, 1092 (same); *Demahy v. Schwarz Pharma, Inc.* (5th Cir. 2012) 702 F.3d 177, 182-83 (*per curiam*). *Accord*: *Moretti v. Wyeth, Inc.* (9th Cir. June 17, 2014) __Fed.Appx.__, 2014 WL 2726886, at *1 (affirming summary judgment for brand defendants based on Nevada law); *Lashley v. Pfizer, Inc.* (5th Cir. 2014) 750 F.3d 470, 476–78 (affirming summary judgment for brand defendants because plaintiffs ingested only generic metoclopramide).

Federal district court opinions are also strongly arrayed against finding liability against a brand-name drug maker under an innovator liability or negligent misrepresentation theory for injuries to consumers who use a generic version of the drug made by another pharmaceutical company. In *Gardley-Starks v. Pfizer, Inc* (N.D. Miss. 2013) 917 F.Supp.2d 597, for instance, the court concluded that Mississippi, "consistent with the vast majority of courts to consider this issue, would not recognize a cause of action – *however styled* – against a brand manufacturer for injuries caused by use of its competitor's generic product." (Italics added.) See also *Levine v. Wyeth, Inc.* (M.D. Fla. 2010) 684 F. Supp.2d 1338, 1344 ("The holding in *Conte* . . . runs counter to the overwhelming majority of case law, including that of Florida.").

Metz v. Wyeth LL (M.D. Fla. 2011) 830 F.Supp.2d 1291 addressed the argument advanced by plaintiffs here that after *Mensing*, *supra*, 131 S.Ct. 2567 absolved generic drug manufacturers from liability under state tort law on preemption grounds, it became urgent to provide a state tort law remedy like *Conte* against the brand-name manufacturer of the generic equivalent. Otherwise, plaintiffs argue, they will be without any remedy for injuries they incurred from consumption of the generic drug. But *Metz* pointed out that *Mensing* "neither created nor abrogated any duty under [state] law with

regard to brand-name manufacturers;" and that, in any event, this is "a matter best addressed by the [state] legislature . . .." (*Id.* at 1294.)

The notion that one injured by a defendant's failure-to-warn of dangers from consumption of its copycat product because of federal preemption should then be able to foist liability on the original or innovator manufacturer of that product is, at bottom, a version of the principle that "for every wrong there is a remedy." (Civ. Code § 3523.) But this statutory maxim does not create substantive rights or an unbounded right to damages. (*County of San Luis Obispo v. Abalone Alliance* (1986) 178 Cal.App.3d 848, 865, 846 (*County of San Luis Obispo*).) The proposition that courts should strain to provide remedies for every "wrong" in the moral sense flies directly in the face of longstanding authority that only *legal* wrongs must be redressed. Indeed, California courts have explicitly rejected the concept of universal duty. "It must not be forgotten that 'duty' got into our law for the very purpose of combating what was then feared to be a dangerous delusion . . . *viz.*, that the law might countenance legal redress for all *foreseeable* harm." (*County of San Luis Obispo, supra,* 178 Cal.App.3d at 865, quoting *Dillon v. Legg* (1968) 68 Cal.2d 728, 734; italics added.) Instead, whether to recognize a new "legal wrong" or "tort" is often governed by policy factors. (See *Cedars-Sinai Medical Center v. Superior Court* (1998) 18 Cal.4th 1, 8.) In making these determinations, both the courts and the Legislature must weigh concepts of "public policy," as well as problems inherent in measuring loss, and "floodgates" concerns, in addition to the traditional element of foreseeability. (See *Elden v. Sheldon*, *supra*, 46 Cal.3d at 278.)

B. The Better Reasoned State Court Decisions Disavow *Conte*.

The most recent state supreme court to repudiate *Conte* is Iowa's, which found, contrary to the express holding in *Conte* and argument by the plaintiffs here, that the

brand name manufacturer owes no duty to consumers of *brand name drugs* but that the *generic manufacturer* could be held liable under that state's tort law. (*Huck v. Wyeth, Inc.* (2014) 850 N.W.2d 353.)[7] *Huck* called *Conte* an "outlier" opinion and stated that "a plaintiff seeking recovery for the side effects of a prescription who sues a pharmaceutical company under *any* theory, including misrepresentation, must prove she was injured by using the prescription drug manufactured or supplied by *that defendant*." (*Id.* at 374-375; italics added.) *Huck* concluded that to follow *Conte* and "expand tort liability to those who did not make or supply the injury-causing product used by the plaintiff involves choices and social engineering more appropriate within the legislative domain." (*Id.* at 376; internal citations omitted.) By the "appropriate legislative domain," *Huck* was referring to Congress, which it stated "has created a symbiotic relationship between brand and generic drug manufacturers," one where

> [n]ame brand manufactures undertake the expense of developing pioneer drugs, performing the studies necessary to obtain premarketing approval, and formulating labeling information. Generic manufacturers avoid these expenses by duplicating successful pioneer drugs and their labels. Name brand advertising benefits generic competitors because generics are generally sold as substitutes for name brand drugs, so the more a name brand drug is prescribed, the more potential sales exist for its generic equivalents.

(*Huck*, *id.*, quoting from *Foster v. Am. Home Prods. Corp.* (4th Cir. 1994) 29 F.3d 165, 170.)

Huck also remarked that the FDA responded to the *Mensing* preemption opinion that precludes injured consumers from suing the manufacturers of generic drugs that caused them harm by a proposed rule to allow generic manufacturers to update their

[7] The Court found *Mensing* did not preempt claims based on the generic manufacturer's failure to update its label warning with the language the FDA approved in 2004. (850 N.W.2d at 362.)

labeling on their own, regardless of the brand manufacturer labeling. (*Huck, supra*, 850 N.W.2d at 369, citing 78 Fed. Reg. at 67985.) This rule change, the opinion stated, "is the appropriate way to address the unfairness resulting from *Mensing*, rather than turning [state] tort law upside down." While acknowledging that courts "normally seek to find remedies for wrongs," *Huck* admonished that

> [T]he complexity and sheer size of the particular area of inquiry and the role that has been assumed by Congress in regulating and navigating through the area should make courts more than cautious to step in to create legal liability for brand-name manufacturers. The policies at play are currently being developed and shaped by Congress and include policies that militate against court intervention at this time.

(*Huck, supra*, 850 N.W.2d at 381-382.)

To be sure, not all state courts have repelled *Conte*. In fact, the rationale of *Conte* has recently been adopted by the Alabama Supreme Court in *Wyeth, Inc. v. Weeks* (2014) 159 So.3d 649 (*Weeks*; supplanted and reversed by statute, Ala. Code § 6-5-530 (2015)).[8] Echoing *Conte* and the arguments advanced by plaintiffs here, *Wyeth* found liability because "[a] brand-name manufacturer could reasonably foresee that a physician prescribing a brand-name drug (or a generic drug) to a patient would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version of the drug." (*Id.* at 670.) But amicus submits the dissent by Justice Murdock along with aforementioned authorities best explains why *Conte*'s

[8] Besides *Weeks*, two additional jurisdictions follow *Conte*: *Dolin v. SmithKline Beecham Corp.* (N.D. Ill. Feb. 28, 2014) 62 F. Supp.3d 705, 712 (explaining brand-name manufacturers' negligence foreseeable because state law mandates using generic version if available); and *Kellogg v. Wyeth* (D. Vt. 2010) 762 F. Supp.2d 694, 709.

"duty-to-warn" theory of liability should not be embraced by the Court. Justice Murdock recognized dual "bedrock principles" of American tort law. One is that the law "must protect the fruits of enterprise and create a climate in which trade and business innovation can flourish." The other countervailing principle is that "the law must justly allocate risks that are a function of that free trade and innovation." But in adopting *Conte's* rationale to impose liability based on "a duty to warn" of the brand name manufacturer, the law "must focus on the role of 'foreseeability' in the creation of a duty to the exclusion of [the] relationship . . . or nexus between the injured party and the defendant," a key factor in the determination of "duty." (159 So.3d at 685.) This, Justice Murdoch rightly warns, "poses danger for the prescription medicine industry and, by extension, for all industry." (*Id.*) That the Court's preemption decision in *Mensing*, *supra*, 564 U.S. 604 relieved generic drug manufacturers from state tort liability, however, "did nothing to undermine the essential rationale in the plethora of pre- and post-[*Mensing*] decisions holding that brand name manufacturers are not liable for injuries caused by deficient labeling of generic drugs they neither manufactured nor sold" (*Id.*)

> It does appear unfair . . . that a consumer harmed by a generic drug cannot seek compensation from the entity that manufactured and sold that drug. [H]owever, it is an unfairness created by Congress and the Food and Drug Administration in return for the perceived social benefit of less expensive generic drugs, or perhaps instead by the manner in which the United States Supreme Court subsequently has applied the preemption doctrine to the regulatory scheme structured by those entities. It is not an unfairness created by the brand-name manufacturer. The just answer then, if there is to be one, must come from a change of federal policy or preemption jurisprudence. It is not

> to come from ignoring age-old, elemental precepts of tort law in order to impose liability on an entity with whom the plaintiff has no relationship, in regard to a product that [it] . . . did not manufacture or sell.

(*Weeks*, *supra*, 159 So.3d at 685 (dissenting opinion by Justice Murdock).

In closing his dissent, Justice Murdock reminds us that *Mensing* "laid the blame for the unfairness at the feet of Congress and the FDA," but washed its own hands by asserting this was "not a problem for that Court to correct." (*Id.* at 686.) "If this is so," he concluded, neither is "it . . . a problem for this or any other state court to correct. And it is certainly not a 'wrong' that this or any court should attempt to correct with a second 'wrong.' " (*Id.)*

III. THE BREADTH OF SCHOLARLY CRITICISM LEVELED AT *CONTE*, LIKE THE FLOOD OF CONTRARY DECISIONS BY OTHER COURTS, SHOULD GIVE THE COURT SERIOUS PAUSE ABOUT ADOPTING IT.

This Court considers scholarly criticism of its opinions as well as those of intermediate appellate courts in determining their "continuing viability." (*Cianci v Superior Court* (1985) 40 Cal.3d 903, 921.) In the case of *Conte*, there is an abundance of critical scholarly commentary. Amicus shall, as we did with the preceding recitation of the plethora of cases repelling *Conte*'s innovator liability jurisprudence, refrain from citing them all ("let me count the ways"), but instead reference a few to illustrate the point.

An early and somewhat kind analysis of *Conte* nonetheless found it "startling" for having "reached the seemingly odd conclusion that the only manufacturer that could be held liable for plaintiff's injuries was one that did not make the drug that the plaintiff received." (*Rostron, supra*, 60 *DUKE L.J.* 1123 1126.) This same article

underscored, as mentioned, that "[v]irtually all of the reaction to . . . *Conte* . . . has been intensely negative. Commentators have mercilessly lambasted the California court for concluding that a drug manufacturer could be liable for injuries suffered by someone who took another company's product." (*Id.*) Another scholar characterized the opinion as offering "a plausible rationale" under tort law principles, but found its conclusion "ultimately dubious" (Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product* (2010) 45 *TORT TRIAL & INS. PRAC. L.J.* 673, 674, 694-95.)

Other commentators have described *Conte* as a "sea change" opinion that turns "products liability on its head" by permitting, "once an innovator's exclusive right to market a brand name drug expires and a competing manufacturer receives approval to market an identically labeled generic equivalent, the potential for perpetual liability . . .." (Ahmann & Verneris, *Brand Name Exposure for Generic Drug Use: Prescription for Liability* (2009) 32 *Hamline L. Rev.* 767, 788.); and as the worst judicial decision of 2008, an "anomaly" of "limited precedential value." (Beck & Herrmann, *Scorecard: Non-Manufacturer, Brand Name Defendants in Generic Drug Cases*, Drug and Device Law Blog (Nov. 12, 2009), http://druganddevicelaw.blogspot.com/search/label/Conte.) One scholar dubbed *Conte* a "radical departure" from the majority rule and reported that "subsequent opinions in [six states] expressly or implicitly rejected its holding." (Martin, *California Dreamin? Generic Drug Users Can Sue Brand Name Drug Manufacturers* (2010) 77 *DEF. COUNS. J.* 474, 483.)

These articles emphasize the extrapolation to the stars of *Conte*'s *foreseeability* analysis, the *unfairness* of saddling the brand name pharmaceutical manufacturer (the "innovator") with perpetual liability while the generic drug company escapes liability

due to federal preemption, and the staggering breadth of potential liability based on *Conte*'s peculiar spin on "failure- to-warn."

CONCLUSION

For all the reasons aforementioned, the Court of Appeal's opinion expanding a manufacturer's duty of care to injuries sustained by plaintiffs from use of another's product should be reversed.

Dated: December 8, 2016

Respectfully submitted,

/s/
Fred J. Hiestand
Civil Justice Association of California

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Date: December 8, 2016

/s/
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PROOF OF SERVICE

I, David Cooper, am employed in the city and county of Sacramento, State of California. I am over the age of 18 years and not a party to the within action. My business address is 3418 3rd Avenue, Suite 1, Sacramento, CA 95817.

On December 8, 2016, I served the foregoing document(s) described as: *Amicus Curiae* Brief of the Civil Justice Association of California in Support of Defendant and Respondent in *T.H., a Minor, Etc., et al. v. Novartis Pharmaceuticals Corporation,* S233898 on all interested parties in this action by placing a true copy thereof in a sealed envelope(s) addressed as follows:

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I declare under penalty of perjury under the laws of the State of California that the above is true and correct.

Executed this 8th day of December 2016 at Sacramento, California.

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