No. S233898

In the Supreme Court of California

T. H., A Minor, *etc.*, *et al.*,

Plaintiffs and Appellants,

vs.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant and Respondent.

APPLICATION OF PRODUCT LIABILITY ADVISORY COUNCIL, INC. FOR PERMISSION TO FILE AMICUS CURIAE BRIEF AND PROPOSED AMICUS CURIAE BRIEF SUPPORTING DEFENDANT AND RESPONDENT NOVARTIS PHARMACEUTICALS CORP.

On Review From a Decision in a Published Opinion of the
Court Of Appeal, Fourth Appellate District, Division One, No. D067839

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APPLICATION OF THE PRODUCT LIABILITY ADVISORY COUNCIL, INC. FOR PERMISSION TO FILE AMICUS CURIAE BRIEF

The Product Liability Advisory Council, Inc. ("PLAC") hereby applies to the Chief Justice of California for permission to file the attached proposed amicus curiae brief supporting Defendant and Respondent Novartis Pharmaceuticals Corp.

I. Issue Presented

The issue presented for review is this:

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

II. Interest Of Amicus Curiae

PLAC is a nonprofit association whose 94 corporate members are drawn broadly from American and international product manufacturers.[1] In addition, several hundred leading product liability defense attorneys are sustaining (non-voting) members of PLAC.

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[1] PLAC's corporate members are listed in the Appendix to its brief.

PLAC seeks improvement and reform of law affecting product liability in the United States and elsewhere. PLAC's point of view reflects its members' experience in diverse manufacturing industries. Since 1983, PLAC has filed almost 1200 briefs as *amicus curiae* in state and federal courts, including this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application of product liability law.

PLAC's interest derives from the Court of Appeal's dramatic departure from the rationale that this Court espoused when it created modern product liability – that the justification for holding product manufacturers liable for the cost of product-related injuries is, first and foremost, an obligation stemming from the profits they earn from selling their products. Product manufacturers also control the condition of the products they make, and are thus is in the best position to reduce product risks. The Court of Appeal's decoupling of liability for product-related injuries from these social policies, reiterated by this Court as recently as *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, raises fundamental jurisprudential concerns.

III. How The Proposed Amicus Curiae Brief Will Assist This Court In Deciding The Matter

This amicus curiae brief is respectfully submitted to the Court to address the public importance of these issues apart from and beyond the immediate interests of the parties to this case.

The Court of Appeal reached its result by placing form – the "negligence" label on the complaint – over substance – Plaintiffs' typical allegations of inadequate drug labeling. Although the claim against Novartis was substantively indistinguishable from a strict liability inadequate labeling claim, the Court of Appeal gave "negligence" a talismanic effect that exempted it from the bedrock product liability principle that liability follows the profits from product manufacture or marketing. Such a departure, however, was precluded by this Court's holding in *Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 478, that limitations on "product liability" actions cannot be evaded simply by "recasting" a product liability claim as something else.

Nor is liability necessary here to fill some gap in corporate governance. Imposing liability on a branded, or "innovator," company purportedly to prevent such companies from concealing product risks during corporate transactions is unnecessary. The "due diligence" routinely undertaken in such transactions, together with existing legal liability for misleading would-be buyers, avoids any need for the open-ended expansion of liability sought here.

PLAC's brief addresses the broader policy issues implicated by Plaintiffs' expansive liability theory on products other than prescription drugs, such as asbestos, motor vehicles, and high technology.

IV. Disclosure

No party, and no counsel for a party, in the matter pending before this Court has authored the proposed *amicus curiae* brief in whole or in part. Neither has any party, or any counsel for a party, in the pending matter made any monetary contribution intended to fund the preparation or submission of the brief.[2] No person or entity has made a monetary contribution intended to fund the preparation or submission of the brief, other than PLAC, its members, or its counsel in the pending matter.

V. Conclusion

For these reasons, PLAC respectfully requests permission to file the attached proposed amicus curiae brief.

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[2] Novartis, a member of PLAC since 2001, pays the same annual dues as any other PLAC member.

DATED: December 7, 2016

Respectfully submitted,

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PROPOSED AMICUS CURIAE BRIEF SUPPORTING DEFENDANT AND RESPONDENT NOVARTIS PHARMACEUTICALS CORP.

I. Introduction

The novel "innovator liability" theory – that the cost of injuries caused by generic drugs should be borne by companies holding FDA-approved New Drug Applications ("NDAs") for bioequivalent branded products[3] – as accepted by the Court of Appeal, is:

1. Contrary to foundational product liability principles dating back to the holding in *Greenman v. Yuba Power Products, Inc.* (1963) 59 Cal.2d 57, that liability follows from the profits made through the manufacture and sale of products to the public;

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[3] Because Plaintiffs' theory transfers liability for product-related injuries from generic manufacturers to entities that conducted the initial scientific research required to obtain FDA approval of the original new drug (or who acquired an NDA), it has come to be known as "innovator liability." See *Bartlett v. Mutual Pharmaceutical Co.* (D.N.H. 2009) 659 F.Supp.2d 279, 308 fn. 40 (coining "innovator liability"; noting that "brand-name" liability "for defects in [the] generic equivalent" is "rejected" by "[t]he vast majority of courts"); Weeks, *Picking Up the Tab for Your Competitors: Innovator Liability After PLIVA, Inc. v. Mensing* (Summer 2012) 19 Geo. Mason L.Rev. 1257, 1258 fn. 9 (discussing *Bartlett*).

2. Rejected by the overwhelming majority of courts nationwide, and by the latest Restatement of Torts;

3. Adopted without consideration of the policy and jurisprudential implications of expanding tort duties; and

4. An unpredictable and open-ended penalty upon research and innovation in development of new products that cannot be avoided even when the relevant product line has been sold.

The facts are fully described in the parties' briefs and the Court of Appeal's opinion. Briefly, Plaintiffs allege *in utero* exposure to a generic prescription drug, terbutaline, in 2007. Before divesting the NDA in 2001, defendant-respondent Novartis made the branded version, "Brethine," of the same drug. Plaintiffs' mother took terbutaline, not Brethine, to prevent preterm labor. That was an "off-label use" – not listed on the FDA-approved label. Also in 2001, the United States Supreme Court recognized off-label use as legal, "appropriate," and "generally accepted" medical practice.[4]

"[T]here are clear judicial days on which a court can foresee forever . . . ." *Thing v. La Chusa* (1989) 48 Cal.3d 644, 668 (*Thing*). It was error for the Court of Appeals to do so here.

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[4] *Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 350-351 (fn. omitted).

II. ARGUMENT: MANUFACTURERS SHOULD NOT BE LIABLE FOR INJURIES ALLEGEDLY CAUSED BY COMPETING PRODUCTS FROM WHICH THEY DERIVED NO ECONOMIC BENEFIT.

A. Traditional Product Liability Doctrine Properly And Sufficiently Addresses Inadequate Warning Claims Against Product Manufacturers.

This Court created modern product liability – not just for California but for the nation – nearly fifty years ago in *Greenman v. Yuba Power Products* (1963) 59 Cal.2d 57 (*Greenman*). *Greenman* cited a core principle of social responsibility to justify its creation of what it called "strict liability":

> 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 . . . .

59 Cal.2d at p. 63. In other words, manufacturers profit from the sale of their products. Therefore, it is just for them to answer for injuries caused by defects in those products.

Ever since *Greenman*, liability for injuries caused by allegedly defective products has been guided by this "paramount policy." *Price v. Shell Oil Co.* (1970) 2 Cal.3d 245, 251 (*Price*).

- "[T]he risk of injury can be insured by the manufacturer and distributed among the public as

a cost of doing business." *Ray v. Alad Corp.* (1977) 19 Cal.3d 22, 31.

- "Regardless of the identity of a particular defendant or of his position in the commercial chain the basis for his liability remains that he has marketed or distributed a defective product" *Daly v. General Motors Corp.* (1978) 20 Cal.3d 725, 739.

- A "manufacturer is in the best position to discover and guard against defects in its products and to warn of harmful effects; thus, holding it liable for defects and failure to warn of harmful effects will provide an incentive to product safety." *Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588, 611 (*Sindell*).

- "[T]he fundamental reasons underlying the imposition of [product] liability are to deter manufacturers from marketing products that are unsafe, and to spread the cost of injury from the plaintiff to the consuming public . . . ." *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1062 (*Brown*).

- "[W]e have consistently adhered to the *Greenman* formulation requiring proof that the plaintiff suffered injury caused by a defect in the defendant's own product. ¶ . . . . ¶ It is fundamental that the imposition of liability requires a showing that the plaintiff's injuries were caused by an act of the defendant or an instrumentality under the defendant's control."

O'Neil v. Crane Co. (2012) 53 Cal.4th 335, 348-349 (*O'Neil*).[5]

Contrary to the Court of Appeal, this Court has also recognized that "product liability" includes every legal theory implicating the social policies that underlay the doctrine's creation. In *Merrill v. Navegar* (2001) 26 Cal.4th 465 *(Merrill)*, the Court viewed a negligent entrustment claim as a form of "product liability" because plaintiffs sought damages for product-related personal injuries from product manufacturers. "Product liability" is no more – and no less – than "'the liability of those who supply goods or products for the use of others . . . for losses of various kinds resulting from so-called defects in those products.'" 26 Cal.4th at p. 478.[6] "Reformulating" product claims so that they sounded in "negligence" did not make them any less a form of "product liability":

> [T]his is a products liability action based on negligence, which asserts that the [product] was defective in design. . . . [I]mplicit in both the negligence and strict

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[5] Accord, *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1110 (*Carlin*) (following *Greenman*); *Cronin v. J.B.E. Olson Corp.* (1972) 8 Cal.3d 121, 133 (same); *Luque v. McLean* (1972) 8 Cal.3d 136, 145 (same); *Price, supra*, 2 Cal.3d at p. 251 (same); see also *Vandermark v. Ford Motor Co.* (1964) 61 Cal.2d 256, 262-263 (retailers subject to product liability because "[t]hey are an integral part of the overall producing and marketing enterprise that should bear the cost of injuries").

[6] Quoting Prosser & Keeton, Torts (5th ed. 1984) § 95, at p. 677.

> liability theories of products liability is that the defendant manufacturer was engaged in the business of distributing goods to the public. . . . [The plaintiffs' claim] is therefore simply a reformulated claim that the [product], as designed, fails the risk/benefit test [for defective design].

Id. at p. 481 (citations and internal quotation marks omitted).

Consistently, in *Peterson v. Superior Court* (1995) 10 Cal.4th 1185, this Court overruled prior precedent and rejected an analogy between product liability and real estate because an owner of property was "not a part of the manufacturing or marketing enterprise of the allegedly defective product that caused the injury in question." *Id.* at p. 1188. The existence of "'a continuous course of business [is] a condition to application of'" product liability. *Id.* at p. 1207 (citation omitted). Otherwise the "primary justification for shifting accident costs" is inapplicable. *Id.*

The Court recently revisited premises (and employer) liability in the asbestos context in *Kesner v. Superior Court* (Dec. 1, 2016, S219534, S219919) ___ Cal.4th ___ [2016 WL 7010174] (*Kesner*). In *Kesner* the Court held that "commercial users of asbestos" that "benefitted financially from their use" of itshould have foreseen the exposure of household members to fibers brought home on the persons of heavily exposed workers. 2016 WL 7010174, at *7. The cost of reasonable precautions (required by

existing standards[7]) was neither "unreasonably expensive" nor "impeded . . . an[y] activity with significant social utility." *Id.* at *8.

The Court distinguished *Kesner* from cases involving product liability defendants that "have no control over" exposure to their products "once the products containing those fibers are sold." *Kesner*, *supra*, 2016 WL 7010174, at *14. The duty analysis "differ[s] significantly [from] product liability cases" because of this lack of "control":

> [E]mployers or premises owners . . . had direct knowledge as to how fibers were being released and circulated within their facilities and failed to prevent those employees from leaving workplaces ***owned or controlled by the defendants*** . . . .

Id. (italics in original).

The duty sought here, by contrast, is even more attenuated than the typical product liability situation found "inapposite" in *Kesner*, *supra*, 2016 WL 7010174 at * 14. Here, the drug in question was not even Novartis' product. Branded manufacturers ***never*** have the requisite ownership or control over their competitors' generic products, or over their competitors'

[7] At the time of exposure, governmental and industry standards required precautions to "prevent employees . . . from contaminating their families." *Kesner*, 2016 WL 7010174, at *4-5.

marketing methods. Nor could Novartis, once it left the market, lawfully supplement the FDA-approved labeling provided to physicians who were prescribing drugs made by others. The absence of a duty here is a fortiori from every distinction that *Kesner* drew between product liability and the liability of premises and employer defendants. The sort of "supervisory control" that drove the duty analysis in *Kesner* [*id.* at *13-14], is entirely absent here.

Also unlike *Kesner* is any basis for confining liability to a "circumscribed category of potential plaintiffs" [*Kesner*, *supra*, 2016 WL 7010174, at *1], short of the everyone who uses generic drugs [see *id.* at *9-10 (limiting scope of duty)]. Plaintiffs allege *in utero* exposure, and thus were not even prescription recipients. According to the FDA, "over 90 percent of prescriptions in the US are now generics."[8] Thus, to accept Plaintiffs' theory would be to impose liability for 90 percent-plus of all prescription drugs upon the remaining less than 10 percent that neither made, nor profited from, the generic drugs at issue.

The present misapplication of the tort of "negligence" to drug warnings should be viewed accordingly. In *Kesner*, *supra*, courts in other jurisdictions "ha[d] reached the same conclusion we

[8] Califf, *Remarks of the FDA Commissioner: The Food & Drug Law Institute's 59th Annual Conference* (2016) 71 Food & Drug L.J. 201, 204.

do . . . ." 2016 WL 7010174, at *14. Although innovator liability is also a matter of first impression in this Court, many courts across the country have addressed this precise question, in this precise context, and they overwhelmingly reject liability of branded drug manufacturers for injuries caused by generic competitors. A "mountain of authority"[9] – literally dozens of appellate courts considering the same issue[10] – rejects innovator liability, with the

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[9] *Guarino v. Wyeth, LLC* (11th Cir. 2013) 719 F.3d 1245, 1253 (*Guarino*).

[10] ***State Courts:*** *Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, 369-381; *PLIVA, Inc. v. Dement* (Ga.Ct.App. 2015) 780 S.E.2d 735, 743, *cert. granted* (Ga. Sept. 6, 2016); *Guvenoz v. Target Corp.* (Ill.App.Ct. 2015) 30 N.E.3d 404, 409 fn. 1, 416; *Franzman v. Wyeth, Inc.* (Mo.Ct.App. 2014) 451 S.W.3d 676, 689-692 (applying Kentucky law); *Stanley v. Wyeth, Inc.* (La.Ct.App. 2008) 991 So.2d 31, 33-35; *Sharp v. Leichus* (Fla.Dist.Ct.App. 2007) 952 So.2d 555, 555 (per curiam); *Flynn v. American Home Products Corp.* (Minn.Ct.App. 2001) 627 N.W.2d 342, 350.

Federal Courts: *In re Darvocet, Darvon, & Propoxyphene Products Liability Litigation* (6th Cir. 2014) 756 F.3d 917, 938-939, 941-954 (applying Arkansas, Connecticut, Florida, Georgia, Illinois, Indiana, Kentucky, Louisiana, Maryland, Michigan, Mississippi, Nebraska, New York, North Carolina, Ohio, Oklahoma, Pennsylvania, South Carolina, Tennessee, Texas, Washington, and West Virginia law); *Eckhardt v. Qualitest Pharmaceuticals, Inc.* (5th Cir. 2014) 751 F.3d 674, 681 (applying Texas law); *Lashley v. Pfizer, Inc.* (5th Cir. 2014) 750 F.3d 470, 476-478 (applying Mississippi and Texas law); *Johnson v. Teva Pharmaceuticals USA, Inc.* (5th Cir. 2014) 758 F.3d 605, 614-616 (applying Louisiana law); *Strayhorn v. Wyeth Pharmaceuticals, Inc.* (6th Cir. 2013) 737 F.3d 378, 403-405 (applying Tennessee law); *Schrock v. Wyeth, Inc.* (10th Cir. 2013) 727 F.3d 1273, 1281-1284 (applying Oklahoma law); *Fullington v. Pfizer, Inc.* (8th Cir. 2013) 720 F.3d 739, 744 (applying Arkansas law); *Guarino, supra,* 719 F.3d at pp. 1251-1253 (applying Florida law); *Bell v. Pfizer, Inc.* (8th Cir. 2013) 716 F.3d 1087, 1092-1093 (applying Arkansas law); *Demahy v. Schwarz Pharma, Inc.* (5th Cir. 2012) 702 F.3d 177, 183-184 (applying Louisiana law); *Smith*

(footnote continued on following page)

only outlier being immediately overruled by legislation.[11] Trial court authority rejects innovator liability in several more states.[12]

(footnote continued from previous page)
v. Wyeth, Inc. (6th Cir. 2011) 657 F.3d. 420, 423-424 (applying Kentucky law); *Mensing v. Wyeth, Inc.* (8th Cir. 2009) 588 F.3d 603, 612-614 *rev'd on other grounds* (2011) 564 U.S. 604, *reaffirmed in pertinent part* (8th Cir. 2011) 658 F.3d 867 (applying Minnesota law); *Moretti v. Wyeth, Inc.* (9th Cir. 2009) 579 F. App'x 563, 564-565 (applying Nevada law); *Foster v. American Home Products Corp.* (4th Cir. 1994) 29 F.3d 165, 168-171 (applying Maryland law).

[11] *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649, 670-677. Within weeks, *Weeks* was a dead letter. See Ala. Code § 6-5-530(a) (a defendant's marketing of "the particular product the use of which is alleged to have caused the injury" declared an element of any personal injury claim).

[12] ***Arizona***: *In re Darvocet, Darvon & Propoxyphene Products Liability Litigation* (E.D.Ky. Sept. 5, 2012, MDL No. 2226) 2012 WL 3842045, at *7-8 (*In re Darvocet*), *aff'd on other grounds* (6th Cir. 2014) 756 F.3d 917; ***Colorado***: *Sheeks v. American Home Products Corp.* (D.Colo. Oct. 15, 2004, No. 02CV337) 2004 WL 4056060, at *1-2; ***Kansas***: *Anselmo v. Sanofi-Aventis, Inc. USA* (D.Kan. Oct. 13, 2014, No. 10-CV-77) 2014 WL 8849464, at *2-3; ***Massachusetts***: *Rafferty v. Merck & Co.* (Mass.Super.Ct. May 23, 2016, No. 2013-04459) 2016 WL 3064255, at *4-5 (discussing prior precedent); ***Missouri***: *In re Darvocet, Darvon & Propoxyphene Products Liability Litigation* (E.D.Ky. Aug. 21, 2012, MDL No. 2226) 2012 WL 3610237, at *2 & fn. 7, *aff'd on other grounds* (6th Cir. 2014) 756 F.3d 917; ***New Hampshire***: *In re Darvocet*, 2012 WL 3842045, at *7; ***New Jersey***: *Condouris v. Wyeth* (N.J.Super.Ct. Law Div. June 26, 2012) 2012 WL 2401776 (discussing prior precedent); ***Oregon***: *Phelps v. Wyeth, Inc.* (D.Or. 2012) 857 F.Supp.2d 1114, 1120-1121; ***Utah***: *Beutella v. A.H. Robins Co.* (D. Utah Dec. 10, 2001, No. 980502372) 2001 WL 35669202, at *2-3; ***Virginia***: *Colas v. Abbvie, Inc.* (N.D.Ill. June 13, 2014, No. 14 C 1452) 2014 WL 2699756, at *2 (applying Virginia law). See generally Sills, *Liability of Name Brand Drug Manufacturer for Injury or Death Resulting from Use of Prescription Drug's Generic Equivalent* (2010 & Cum. Supp. 2016) 56 A.L.R.6th 161 (collecting cases).

As Novartis points out, OBOM at 32-33, many of these courts considered and disapproved *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89 (*Conte*) by name. All in all, judicial or statutory authority in 36 states rejects innovator liability in the precise context of generic/branded drugs. "[H]armony with other courts" [*Kesner*, *supra*, 2016 WL 7010174, at *16], can only be maintained by rejecting the expansion of liability that Plaintiffs advocate.

The black letter of the Restatement Third of Torts is also incompatible with innovator liability. The Restatement considers all types of product-related misrepresentation (negligent or otherwise) a subset of product liability. For product-related physical harm, the Restatement recognizes the liability of "[o]ne engaged in the business of selling or otherwise distributing products" for a misrepresentation made "in connection with the sale of a product." Rest.3d Torts, § 9.[13] Like the common law, this section of the *Restatement* does not admit of liability for alleged misrepresentations made at any time, or in any place, by non-manufacturers, and thus rejects the proposition that liability for allegedly erroneous product-related information extends to those not in the chain of sale of the defendant's product.

The sort of "foundational" analysis conducted in *Kesner*, *O'Neil,* and *Merrill* is precisely what the Courts of Appeal

[13] Accord, *id.* at com. a (§ 9 "appl[ies] to commercial product sellers").

decisions here and in *Conte* lack. Just as putting lipstick on a pig does not alter the animal's porcine nature, calling a run-of-the-mill inadequate warning claim[14] an action for "negligence" does not make it any less a product liability allegation.

Nor does the particular context in which the issue arises warrant a departure from the policy-based tenet that "[i]n the context of products liability actions, the plaintiff must prove that the defective products supplied by the defendant were a substantial factor in bringing about his or her injury." *Rutherford v. Owens-Illinois, Inc.* (1997) 16 Cal.4th 953, 968. Only where, due to latency of injury and the inherent nature of the product, it was impossible to identify the manufacturer through no fault of the plaintiff has this requirement been relaxed in any product liability case brought under any theory. See *Sindell*, *supra*, 26 Cal.3d at p. 611.[15] Even in a *Sindell* situation, however, the Court has limited a defendant's liability to "responsibility for the injuries caused by its own products." *Id.* at p. 612. Innovator liability here, and in *Conte*

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[14] The claimed negligence is Novartis's failure "to revise the drug label . . . to include warnings" that Plaintiffs claim were required. Opn. at 13. Allegations that drug labeling understates or omits risks are routinely brought as product liability actions. E.g., *Carlin*, *supra*, 13 Cal.4th at pp. 1109-1110; *Brown*, *supra*, 44 Cal.3d at p. 1055; *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 58.

[15] FDA regulations require identification of the manufacturer on all generic products, 21 C.F.R. § 314.94(a)(8)(iv), thus *Sindell* product identification issues are not implicated here.

before it, wildly transgresses the traditional boundaries of product-related liability.

Federal law obligates generic manufacturers to adopt as their own the labeling originally created by branded/innovator manufacturers. Preemptive federal law does not, however, justify shifting the liability of generic drug manufacturers to their innovator competitors. Quite the contrary. Under established law, a defendant's adoption of someone else's allegedly inadequate labeling is "passing off," another basis for liability against the actual product manufacturer. See *Cravens, Dargan & Co. v. Pacific Indem. Co.* (1972) 29 Cal.App.3d 594, 599 ("[o]ne who puts out as his own product a chattel manufactured by another is subject to the same liability as though he were its manufacturer") (quoting Rest.2d Torts, § 400, p. 1086); Rest.3d Torts, § 14. Once again, the common law follows the fundamental proposition that liability follows profit.

Existing common law thus readily accommodates claims involving generic drug labeling. Plaintiffs claiming injury from generic drugs should not be better off – with an ***additional*** cause of action against non-manufacturing branded/innovator companies – than an identical plaintiff who took a branded drug. Cf. *Ramirez v. Plough, Inc.* (1993) 6 Cal.4th 539, 555-556; *Motus v. Pfizer Inc. (Roerig Div.)* (9th Cir. 2004) 358 F.3d 659, 661 (both affirming summary judgment in branded drug cases where, as here, the physician did not read the defendant's allegedly defective warning).

Plaintiffs here, who cannot establish a causal relationship to the warnings for the product that allegedly caused their injuries, should lose – as would any other plaintiff in any other product liability action whose prima facie warning case was similarly lacking essential causation evidence.

Under these facts, in the usual prescription drug product liability case, Plaintiffs would have been out of court. However, federal law mandates that generic manufacturers use verbatim the labeling initially prepared by the inventor of the drug – here, Novartis. Thus, Plaintiffs received a second bite at the apple against Novartis, even though they indisputably were never exposed to that drug, and Novartis no longer even manufactured it.

B. The Potential Liability Of Non-Manufacturer Defendants Under Theories Such As Innovator Liability Is Nearly Limitless.

"'[F]oreseeability alone is not sufficient to create an independent tort duty.'" *Kesner*, *supra*, 2016 WL 7010174, at *6 (quoting *Erlich v. Menezes* (1999) 21 Cal.4th 543, 552). Rather than 20/20 hindsight, legal foreseeability is a "sliding-scale balancing formula." *Delgado v. Trax Bar & Grill* (2005) 36 Cal.4th 224, 237, 243 & fn. 24. The "mere presence" of foreseeability does not confer liability. Rather, "social policy must at some point intervene to delimit liability even for foreseeable injury . . . ." *Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456, 476 (citation and internal quotation marks omitted).

In holding branded/innovator manufacturers liable in negligence for injuries caused by generic manufacturers' competing products, the Court of Appeal gave only passing attention to this Court's longstanding test for negligence duty set out in *Rowland v. Christian* (1968) 69 Cal.2d 108 (*Rowland*)– merely making reference to the discussion of those factors in *Conte*. See Opn. at 17. However, *Conte*'s duty analysis under *Rowland* was equally scanty, inflating one of the *Rowland* factors, "foreseeability of harm," almost beyond recognition, while altogether refusing to address others. *Rowland*, *supra*, 69 Cal.2d at p. 113.[16]

Plaintiffs seek to impose negligence liability for alleged inadequate product warnings – a theory typical of product liability litigation. See *Merrill*, 26 Cal.4th at 478 ("a plaintiff may seek recovery in a 'products liability case' either 'on the theory of strict liability in tort or on the theory of negligence'") (citation omitted). Thus, the most "[]apposite" precedent for *Rowland* analysis is that involving product liability theories sounding in negligence. *Kesner*, *supra*, 2016 WL 7010174, at *14. *O'Neil*, *supra*, 53 Cal.4th 535, the most important and most recent such decision, is discussed extensively in Novartis' papers [OBOM at 18-20; RBOM at 14-17],

[16] Aside from foreseeability, *Conte* refused to "assess" most other *Rowland* factors on grounds that the record was insufficient. *Conte*, *supra*, 168 Cal.App.4th at pp. 106 (moral culpability, preventing future harm), 107 (consequences to the community). *Conte* also spent less than a paragraph on the *Rowland* closeness of connection factor. *Id.* at p. 106.

and PLAC will not repeat that argument.[17] The same is true of the overriding policy considerations that attach to prescription drugs, given their unique life-saving attributes and their dependence upon extensive scientific research and continual innovation.[18] These concerns are also addressed at length in Novartis' papers. OBOM at 21-22; RBOM at 29-33.

Because it bears on relevant public policies, PLAC does point out that, under the FDA's regime, off-label use is a physician's prerogative, not a drug manufacturer's. E.g., *Perez v. Nidek Co.* (9th Cir. 2013) 711 F.3d 1109, 1115. Manufacturers cannot add warnings about risks of off-label use to their labels unless and until such warnings are "required" by the FDA. See 21 C.F.R. § 201.80(e) (governing drugs approved before 2001).[19]

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[17] The Court of Appeal's attempt to distinguish *O'Neil*'s extensive reasoning is unpersuasive. While *O'Neil* did not mention *Conte* [Opn. at 22], this Court has long recognized that its decisions can impliedly, as well as expressly, overrule prior precedent. E.g., *People v. Sarun Chun* (2009) 45 Cal.4th 1172, 1198-1199; *Cummiskey v. Superior Court* (1992) 3 Cal.4th 1018, 1028; *Stratmore v. State Bar* (1975) 14 Cal.3d 887, 890.

[18] See *Brown*, *supra*, 44 Cal.3d at pp. 1058-1064; accord, *Moore v. Regents of University of California* (1990) 51 Cal.3d 120, 146; *Finn v. G. D. Searle & Co.* (1984) 35 Cal.3d 691, 700-701.

[19] A prior FDA requirement is likewise necessary for off-label risk warnings in post-2001 approved drugs. 21 C.F.R. § 201.57(c)(6)(i).

Nor does the law encourage patients to look beyond their doctors and makers of the drugs they actually take for drug-related information. "[I]n the case of prescription drugs, the duty to warn runs *to the physician*, not to the patient." *Carlin, supra,* 13 Cal.4th at p. 1116. Thus, even pharmacists who perform the generic substitution at the core of the Court of Appeal's foreseeability analysis are not subject to liability merely for failure to warn. Otherwise, pharmacists "might restrict availability by refusing to dispense drugs which pose even a potentially remote risk of harm . . . ." *Murphy v. E. R. Squibb & Sons, Inc.* (1985) 40 Cal.3d 672, 680-681.

> [I]n order to assure that a pharmacy receives the maximum protection in the event of suit for defects in a drug, the pharmacist may select the more expensive product made by an established manufacturer when he has a choice of several brands of the same drug.

Id. at p. 681.

The *Rowland* duty analysis is concerned both with "'"the closeness of the connection between the defendant's conduct and the injury suffered"'" and with ability to "prevent[] future harm" by "ensur[ing] that those 'best situated' to prevent such injuries are incentivized to do so" *Kesner, supra,* 2016 WL 7010174, at *5, *7, *9 (citations omitted). It would be anomalous in the extreme to impose liability on an ***ex-manufacturer*** of a ***different product*** a duty to warn users of generic drugs while at the

same time exempting from such a duty the entire actual chain of distribution of the generic drug actually prescribed to Plaintiffs.

More broadly, any time that product liability diverges from product manufacturing, significant misallocation of responsibility can occur. Negligent disclosure can be alleged against any product. Competing product manufacturers would thus risk liability whenever uniform, shared product standards are imposed upon them – as with motor vehicles,[20] airplanes, [21] and chemicals[22] – or when voluntarily shared industry standards result in identical product warnings. The American Society for Testing and Materials ("ASTM") and the American National Standards Institute ("ANSI") promulgate literally thousands of voluntary product safety standards that industry has adopted.[23]

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[20] E.g., 49 C.F.R. § 571.208 (seatbelt and airbag-related warnings in passenger cars); 49 C.F.R. § 393.51 (pressure warnings for hydraulic brakes in commercial vehicles); 49 C.F.R. § 571.138 (low tire pressure warnings in commercial vehicles).

[21] The Federal Aviation Administration mandates uniform warnings for many aspects of aircraft operation. E.g., 14 C.F.R. § 29.1303 (airspeed and other flight warnings); 14 C.F.R. § 29.1413 (seatbelt warnings).

[22] OSHA hazard communication regulations mandate uniform safety data sheets for many types of potentially toxic substances. See 29 C.F.R. § 1910.1200.

[23] Searching the ASTM and ANSI websites can provide the Court with an understanding of the scope and extent of voluntary, uniform product safety standards in the United States and around the world. See ASTM website, <https://www.astm.org/> (as of Nov. 27, 2016); ANSI website, <http://webstore.ansi.org/default.aspx> (as

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For example, a single family may own different makes of cars, and in recent years automobile manufacturers have occasionally gone bankrupt or out of business altogether. May a plaintiff claim reliance on one company's inadequate airbag, tire inflation, or infant car seat installation warnings with respect to a different car? The Court of Appeal's negligence theory could create liability for non-manufacturers for injuries suffered in connection with cars that they did not make. Surviving companies that manufacture many kinds of products would be subject to unpredictable liability for products made by competitors that, for one reason or another, are later considered judgment proof. The Iowa Supreme Court articulated precisely these concerns in rejecting innovator liability:

> [W]e decline [plaintiff's] invitation to step onto the slippery slope of imposing a form of innovator liability on manufacturers for harm caused by a competitor's product. Where would such liability stop? If a car seat manufacturer recognized as the industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor's seat that copied the design? Why not, under [plaintiff's] theory, if it is foreseeable others will copy the design?

Huck v. Wyeth, Inc. (Iowa 2014) 850 N.W.2d 353, 380.

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of Nov. 27, 2016). In any instance of uniform product warnings, a court following the pure foreseeability standard applied here could find someone's reliance on a competing manufacturer's identical warnings sufficiently predictable to impose liability.

Non-manufacturer theories of liability for product-related injuries could also inhibit innovation in high-technology industries. The high-tech sector has notoriously been plagued by piracy and reverse engineering of electronic hardware and software by unscrupulous competitors.[24] It is certainly "foreseeable" – in the way the Courts of Appeal here and in *Conte* have misconstrued this concept – that many people will utilize counterfeit copies of devices and applications that falsely attribute their origin to major manufacturers. Obviously, such manufacturers can neither profit from the theft of their intellectual property nor can they control the quality of pirated items. Just as "foreseeably," however, some people will be injured by such products, either economically through viruses and other lurking malware, or physically when products of questionable origin malfunction.

This situation can only become more acute as additive manufacturing (colloquially termed "3D printing") allows individual consumers to manufacture actual products, even sophisticated medical devices,[25] on privately-owned printers using computer

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[24] "Online infringements . . . have been rampant for decades and shows no signs of abating." Kunkel, *Indifference & Secondary Liability for Copyright Infringement* (2016) 33 Santa Clara High Tech. L.J. 1, 1. Widespread copying of electronic information led to the enactment of the Digital Millennium Copyright Act in 1998. See Pub.L. No. 105-304, 112 Stat. 2860 (1998) (codified in scattered sections of 17 U.S.C.).

[25] In 2016, a college student 3D printed his own orthodontic braces. See Kleeman, *3D Printing Your Own Braces Works, Is a Terrible Idea* (March 15, 2016) Gizmodo, <http://gizmodo.com/3d-

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assisted design ("CAD") files. Existing products, including whatever trademarks they bear, can readily be reverse engineered using 3D scanning devices.[26]

> Companies may find their products competing not only with their traditional competitors' products, but also with copies of their own products, with customized versions of their own products, with generic substitutes . . . and with customized versions of generic substitutes. . . . Such products could be made by professional counterfeiters, 3D print shops, industrial customers, or consumers.[27]

In this environment, non-manufacturer liability for products distributed and sold by others entities could rapidly pose an existential threat to legitimate high-technology businesses. Already digital piracy costs legitimate high-tech enterprises billions of dollars annually. Innovator liability, under the theory being advanced here, would mean that in addition to having their designs stolen, legitimate companies would face the prospect of paying for "foreseeable"

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printing-your-own-braces-works-is-a-terrible-idea-1765059128> (as of Nov. 27, 2016).

[26] "[A] 3D scanner can instantly create a CAD design by using lasers and cameras to scan the contours of an object. . . . Once created, a CAD file can be widely distributed like any other computer file . . . ." Nicole A. Syzdek, *Five Stages of Patent Grief to Achieve 3D Printing Acceptance* (2015) 49 U.S.F. L.Rev. 335, 339 (fns. omitted).

[27] Hornick, *3D Printing Will Rock the World* (CreateSpace 2015) p. 159.

product-related injuries caused by counterfeited imitations of questionable quality. The demand for innovator liability in such cases would be driven, not by preemption, nor by bankruptcy, but by plaintiffs' sheer inability to litigate successfully against fly-by-night Internet-based entities located overseas.

For good reason, this Court in *Thing, supra,* 48 Cal.3d at p. 668, refused to allow courts to "foresee forever," and in *O'Neil* clipped the wings of the almost limitless "foreseeability" concept specifically as to product-related injuries. Product safety does not improve where "a manufacturer cannot be expected to exert pressure on other manufacturers to make their products safe." *O'Neil*, *supra*, 53 Cal.4th 335 at p. 363. Logical risk-spreading would not be advanced, since non-manufacturers "will not be able to share the costs of ensuring product safety with these other manufacturers." *Id.* Thus, as in *O'Neil*, "impos[ing] on manufacturers the responsibility and costs of becoming experts in other manufacturers' products. . . . would impose an excessive and unrealistic burden." *Id.* (citation omitted).

The novel negligence cause of action permitted by the Court of Appeal is fundamentally at odds with prior California precedent, runs roughshod over the policies that underlie the creation of product liability, and strips away time-tested limitations upon what is, at bottom, an action against a product manufacturer over warnings about a product-related risk. Unmooring liability for product-related injuries from a half-century of settled jurisprudence

could give rise to many unanticipated and unwanted consequences. This is precisely the sort of decision that should be made, if at all, by the Legislature, not the courts:

> Courts should be hesitant to impose new tort duties when to do so would involve complex policy decisions, especially when such decisions are more appropriately the subject of legislative deliberation and resolution.

Mirkin v. Wasserman (1993) 5 Cal.4th 1082, 1104-1105 (citations and internal quotation marks omitted).

C. Existing Due Diligence Requirements For Corporate Transactions Deter Concealment of Product Risks.

Plaintiffs cannot validly argue that innovator liability serves to prevent predecessor companies from concealing potential product liability during the sale of corporate assets. This argument – unsupported by facts – is as unjustified as it is unprecedented.

Current legal due diligence requirements already deter the possibility of concealment of product defects or adverse product events in connection with the sale of rights to such products. "[D]ue diligence is at a premium whenever product liability possibilities are suspected." Bartlett, *Equity Finance* (Aspen Pubs. 2d ed. 2013) § 21.16 – Product Liability. "[A] comprehensive due diligence review of a manufacturing company must include an assessment of the company's potential product liability exposure." Bass & Redick, *Products Liability: Design & Manufacturing Defects* (2d ed. 2016)

§ 1:29. Buyers of corporate assets "must perform extensive due diligence and must investigate past environmental, labor and products liability actions of the seller . . . ." Solow & Israel, *Buying Assets in Bankruptcy: A Guide to Purchasers* (2000) 10 J. Bankr. L. & Prac. 87, 101.[28] Thus, product manufacturers routinely "conduct internal investigations in response to allegations raised in product liability . . . and in the performance of due diligence in connection with mergers and acquisitions." Gitterman, *Ethical Issues & Practical Challenges Raised by Internal Investigations in the Life Sciences Industry* (2013) 80 Def. Couns. J. 372, 374-375 (fn. omitted).

> Corporate managers and officers are required to exercise due diligence in the management of corporate affairs. In the context of a merger or acquisition, due diligence refers to the analysis and investigation of the target company managers of the prospective acquirer are expected to carry out. In other words, due diligence is the research and analysis the acquirer must conduct to obtain all relevant information necessary to make an informed and reasoned decision about the desirability of the acquisition.

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[28] "Due diligence" investigation of product liability exposure includes: (a) liability potential; (b) contractual protection from liability; (c) product liability insurance; (d) pending and threatened litigation; (e) resolved claims; (f) studies of product liability risk; (g) product recalls; (h) successor corporation liability. See 1 *Corporate Counsel's Guide to Acquisitions & Divestitures* (Thompson Reuters 2016) § 3:7 (comprehensive checklist for acquisition or divestiture).

Brown, *Grandfathering Can Seriously Damage Your Wealth: Due Diligence in Mergers & Acquisitions of Medical Device Companies* (2000) 36 Gonz. L.Rev. 315, 338 (fns. omitted). Product liability exposure is precisely the sort of "contingent liability" subject to due diligence in corporate acquisitions. *Id.* at pp. 343-344.

As in other areas, those acquiring product lines may seek recovery from their sellers should product liability risks be inaccurately disclosed. Should a corporate seller fail to disclose known or suspected product liability risks in connection with a transaction, the buyer, under either contractual provisions or long-standing common-law indemnity principles, may seek recovery of its losses from the seller. See *Kazerouni v. De Satnick* (1991) 228 Cal.App.3d 871, 873 & fn. 3 (purchaser of business in reliance on seller's warranty may recover for its breach).

> The value of an indemnity – a promise to pay for the correction of any future problems or settlement of claims – from the seller relates directly to the availability of the assets backing the promise . . . . Problems which have been identified in due diligence, but have not yet been asserted as claims or demands, are problems which may ripen into claims . . . .

Shecter, *Selected Risk Issues in Merger & Acquisition Transactions* (1997) 51 U. Miami L.Rev. 719, 757. Thus, the threat of litigation already deters tortious behavior in the context of corporate transactions, making it unnecessary to create novel negligence duties

owed to remotely situated individuals such as purchasers of products manufactured long after the transaction at issue.[29]

Furthermore, liability for inaccurate representations and warranties made by sellers to buyers in the context of corporate acquisitions is insurable. "[R]epresentations and warranties insurance [is] increasingly used in private mergers and acquisitions." Cunningham, *Too Big to Fail: Moral Hazard in Auditing & the Need to Restructure the Industry Before It Unravels* (2006) 106 Colum. L.Rev. 1698, 1744 (fn. omitted). Such insurance "is used in acquisition agreements to allocate risks from breaches of representations or warranties," similar to title insurance in the real estate market. Cunningham, *Choosing Gatekeepers: The Financial Statement Insurance Alternative to Auditor Liability* (2004) 52 UCLA L.Rev. 413, 447 fn. 134. The "insurer's underwriting consists of reviewing the due diligence process, though not repeating it." *Id.*[30]

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[29] Since 2000, litigation over product liability-related disclosures in corporate transactions includes: *Genesis Merchant Partners, L.P. v. Nery's USA, Inc.* (S.D.Cal. June 30, 2016, No. 11cv1589 JM(WVG)) 2016 WL 3548497, at *2 fn. 3; *Schweizer v. Sikorsky Aircraft Corp.* (W.D.N.Y. Feb. 8, 2011, No. 10-CV-6547) 2011 WL 542355, at *2; *Weed Wizard Acquisition Corp. v. A.A.B.B., Inc.* (N.D.Ga. 2002) 201 F.Supp.2d 1252, 1259.

[30] See Tetler, *Buying and Selling a Privately Owned Business*, § 7.11(e) (Mass. CLE 2d ed. 2012 & Supp. 2016) (such insurance is written "on an occurrence basis" if carried by the seller, "on a claims-made basis," if carried by the buyer, and may include

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By contrast, innovator liability as urged by Plaintiffs is inherently uninsurable, as it involves other manufacturers' products. *O'Neil*, *supra*, 53 Cal.4th at p. 365; cf. *Kesner*, *supra*, 2016 WL 7010174, at *8 (risk insurable at the time). A corporate "seller's current insurance policies will neither apply to buyer post-acquisition, nor cover the specific risks of concern to buyer." Ibrahim, *The Unique Benefits of Treating Personal Goodwill As Property in Corporate Acquisitions* (2005) 30 Del. J. Corp. L. 1, 41 (fn. omitted). Innovator liability, as it arises from events involving unaffiliated corporations, is extraneous to corporate transactions and thus totally unpredictable.

> Predictability is vital in the corporate field. Unforeseeable alterations in successor liability principles complicate transfers and necessarily increase transaction costs. Major economic decisions, critical to society, are best made in a climate of relative certainty and reasonable predictability. The imposition of successor liability on a purchasing company long after the transfer of assets defeats the legitimate expectations the parties held during negotiation and sale.

Monarch Bay II v. Professional Service Industries, Inc. (1999) 75 Cal.App.4th 1213, 1218 (*Monarch Bay II)* (citation and internal quotation marks omitted). Innovator liability thus cannot be justified

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"special polic[ies] relating only to products manufactured by the seller prior to the closing").

as a measure that would maintain the integrity of corporate transactions.[31]

III. Conclusion

For the reasons stated above, and for the reasons stated in Novartis' Opening Brief on the Merits and Reply Brief on the Merits, this Court should accordingly reverse the judgment of the Court of Appeal to the extent that it reversed the judgment of the Superior Court in Novartis' favor.

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[31] Analogously, the strict liability concept of "product line liability" – successor liability for defective products made by a corporate successor – has never been extended beyond the "narrow circumstances" of strict liability. E.g., *Beatrice Co. v. State Bd. of Equalization* (1993) 6 Cal.4th 767, 779 (refusing to extend product line exception to contractual obligations); *Franklin v. USX Corp.* (2001) 87 Cal.App.4th 615, 628-629 (same, premises liability); *Monarch Bay II*, *supra*, 75 Cal.App.4th at pp. 1217-1218 (same; professional negligence); *Maloney v. American Pharmaceutical Co.* (1988) 207 Cal.App.3d 282, 289-290 (same; negligent manufacture of a drug).

DATED: December 7, 2016

Respectfully submitted,

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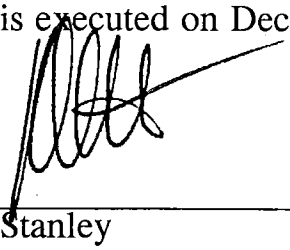
CERTIFICATE OF WORD COUNT
PURSUANT TO RULE 8.520(c)

The foregoing Proposed Amicus Curiae Brief contains 6,535 words (including footnotes, but excluding tables and this certificate). In preparing this certificate, I have relied on the word count generated by Microsoft Office Word 2010.

I declare under penalty of perjury that the forgoing is true and correct and that this declaration is executed on December 7, 2016, at Los Angeles, California.



David E. Stanley

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APPLICATION OF PRODUCT LIABILITY ADVISORY COUNCIL, INC. FOR PERMISSION TO FILE AMICUS CURIAE BRIEF AND PROPOSED AMICUS CURIAE BRIEF SUPPORTING DEFENDANT AND RESPONDENT NOVARTIS PHARMACEUTICALS CORP.

☒ by placing the document(s) listed above in a sealed envelope with postage thereon fully prepaid, in the United States mail at Los Angeles, California addressed as set forth below. I am readily familiar with the firm's practice of collection and processing of correspondence for mailing. Under that practice, it would be deposited with the U.S. Postal Service on that same day with postage thereon fully prepaid in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if the postal cancellation date or postage meter date is more than one day after the date of deposit for mailing in this Declaration.

I declare under penalty of perjury under the laws of the State of California that the above is true and correct. Executed on December 7, 2016, at Los Angeles, California.

Veronica Barreto

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