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

David E. Stanley, SBN 144025
James M. Beck
REED SMITH LLP
355 S. Grand Avenue,
Suite 2900
Los Angeles, CA 90071
Telephone: 213.457.8085
Facsimile: 213.457.8080
Email: dstanley@reedsmith.com

Hugh F. Young, Jr.
PRODUCT LIABILITY
ADVISORY COUNCIL, INC.
1850 Centennial Park Drive
Suite 510
Reston, VA 20191-1517

Attorneys for Amicus Curiae
Product Liability Advisory Council, Inc.

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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,

REED SMITH LLP

By _____
David E. Stanley

Attorneys for *Amicus Curiae*
Product Liability Advisory Council

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)