S233898

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

T.H., A MINOR, ETC., ET AL.,

Plaintiffs and Appellants,

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant and Respondent.

Fourth District Court of Appeal, Division One
Case No. D067839

San Diego County Superior Court,
Case No. 37-2013-00070440-CU-MM-CTL,
Judge Joan M. Lewis

APPLICATION FOR LEAVE TO FILE *AMICI CURIAE* BRIEF AND *AMICI CURIAE* BRIEF OF INTERNATIONAL ASSOCIATION OF DEFENSE COUNSEL AND FEDERATION OF DEFENSE & CORPORATE COUNSEL IN SUPPORT OF DEFENDANT AND RESPONDENT

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APPLICATION FOR LEAVE TO FILE *AMICI CURIAE* BRIEF

TO THE HONORABLE CHIEF JUSTICE:

Under California Rule of Court 8.520(f), the International Association of Defense Counsel (IADC) and Federation of Defense & Corporate Counsel (FDCC) request permission to file the attached *Amici Curiae* Brief in support of Defendant and Respondent Novartis Pharmaceuticals Corporation.

Interest of *Amici Curiae*; How the *Amici Curiae* Brief Will Assist the Court

The IADC is an association of corporate and insurance attorneys from the United States and around the globe whose practice is concentrated on the defense of civil lawsuits. The IADC is dedicated to the just and efficient administration of civil justice and continual improvement of the civil justice system. The IADC supports a justice system in which plaintiffs are fairly compensated for genuine injuries, responsible defendants are held liable for appropriate damages, and non-responsible defendants are exonerated without unreasonable cost.

The IADC maintains an abiding interest in the fair and efficient administration of product liability actions. The IADC's Product Liability Committee consists of more than 900 members, publishes regular newsletters and journal articles, and presents education seminars both internally and to the legal community at large. The IADC has also participated as *amici curiae* in several cases involving product liability issues, including *Kim v. Toyota Motor Corporation,* California Supreme Court Case No. S232754; *Ramos v. Brenntag Specialties, Inc., et al.*, California Supreme

Court Case No. S218176; and *Tincher v. Omega Flex, Inc.*, Pennsylvania Supreme Court Case No. 17 MAP 2013.

The FDCC, formed in 1936, has an international membership of over 1400 attorneys. The FDCC is composed of attorneys in private practice, general counsel, and insurance claims executives. Membership is available solely by nomination, and is limited to those attorneys who have been judged by their peers to have achieved professional distinction and demonstrated leadership in their areas of expertise. The FDCC is committed to promoting knowledge, professionalism, and high ethical standards among its members.

In this case, the Court has agreed to determine whether a brand name manufacturer of a pharmaceutical drug that divested all ownership interest in the drug may be held liable for injuries caused years later by another manufacturer's generic version of that drug. The answer, under this Court's precedent and in light of sound policy, should be categorically "no."

In *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 363-66 this Court held that a manufacturer has no duty to prevent injuries from another manufacturer's product. As explained in the accompanying brief, each of the factors that drove this Court's

decision in *O'Neil* apply with equal force to the pharmaceutical industry. Adopting any theory of "innovator" or "former manufacturer" liability would run afoul of the principles espoused in *O'Neil* by making a drug manufacturer liable for injuries allegedly caused by drugs it neither manufactured nor sold.

The arguments the IADC and FDCC present are complementary to, but not duplicative of, the briefing submitted by Novartis. In particular, while the parties focus on the nuances of the pharmaceutical industry, we view the *O'Neil* analysis through a broader policy lens and explain the far-reaching impact that a rule of "innovator" or "former manufacturer" liability could have on a wide range of industries, including the high-tech world.

No Party or Counsel for a Party Authored or Contributed to This Brief

The IADC and FDCC provide the following disclosures required by rule 8.520(f)(4) of the California Rules of Court: (1) no party or counsel for a party in this appeal authored or contributed to the funding of this brief, and (2) no one other than *amici curiae* or its counsel in this case made a monetary contribution intended to fund the preparation or submission of this brief.

Conclusion

For the foregoing reasons, the IADC and FDCC request that the Court permit the filing of the attached *amici curiae* brief in support of Novartis.

DATED: December 7, 2016

Respectfully submitted,

HAYNES AND BOONE, LLP
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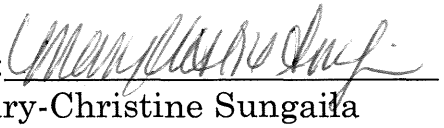
By: 
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Judge Joan M. Lewis

AMICI CURIAE BRIEF OF INTERNATIONAL ASSOCIATION OF DEFENSE COUNSEL AND FEDERATION OF DEFENSE & CORPORATE COUNSEL IN SUPPORT OF DEFENDANT AND RESPONDENT

INTRODUCTION

"The social value of innovation is virtually limitless."

--Torts and Innovation[1]

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[1] (Gideon Parchomovsky and Alex Stein, *Torts and Innovation* (2008) 7 MICH. L. REV. 285, 288; see also Maryann Feldman and Richard Florida, *The Geographic Sources of Innovation: Technological Infrastructure and Product Innovation in the United States* (1994) 84 Annals of the Ass'n of Am. Geographers 210, 210.)

In this appeal, Plaintiffs ask this Court to radically expand tort liability to reach former manufacturers and innovators of prescription drugs. Their request runs contrary to this Court's holding in *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335 that a manufacturer has no duty to prevent injuries from another manufacturer's product. If innovators are subject to perpetual liability, fewer beneficial new drugs and other types of technologies will make it to market—quashing innovation.

Plaintiffs contend that Novartis's bright-line rule against innovator and former manufacturer liability "is only good for one segment of the community: Big Pharma." (ABOM at 68.) Not so. The unprecedented expansion of tort liability sought by Plaintiffs will harm consumers by creating a duty so broad that it could stifle innovation in a range of industries across California, including discouraging companies in Silicon Valley from sharing new technologies with each other. This Court should not adopt a rule of product liability that has already been rejected by 35 states, particularly given its potential adverse, widespread impact on California's economy. (OBOM at 32-33.)

BACKGROUND

Plaintiffs Teagan and Carwell Hamilton allege that their autism was caused by their mother's 2007 use of generic terbutaline drugs to prevent pre-term labor. (1AA1.) They claimed failure to warn. Although the 2007 drug product labels included warnings against use of terbutaline to prevent pre-term labor, they did not mention harm to the fetus. (1AA46-49.)

Plaintiffs sued a number of manufacturers, including Novartis, which formerly owned the name-brand terbutaline drug, Brethine. (1AA3-5.) Novartis sold the Brethine product line in 2001, six years before Plaintiffs were exposed to the generic terbutaline drug that allegedly caused their autism. (1AA68-71.) Nonetheless, Plaintiffs allege that Novartis's failure to include an adequate warning on its 2001 product label contributed to later failures to warn. (1AA78-81, 98.)

The trial court sustained Novartis's demurrer on the ground that Novartis owed Plaintiffs no duty as a matter of law for claims that arose from prescribing terbutaline in 2007, after Novartis had sold its Brethine line. (1AA101.) The Court of Appeal reversed, holding that Novartis had a duty to consumers of a subsequent manufacturer's drug. This Court granted review

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

LEGAL DISCUSSION

A. There is no common law duty to protect against injuries caused by another manufacturer's product.

In *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 363-66, this Court categorically held that a defendant has no duty to prevent injuries from another manufacturer's product. Plaintiffs offer no compelling reason to depart from this well-settled law.

In *O'Neil*, the defendants manufactured valves and pumps used in Navy warships. (*Id.* at p. 342.) The plaintiffs sued for wrongful death allegedly caused by asbestos exposure released from insulation and packing that was manufactured by third parties and later added to the pumps and valves. (*Ibid.*) They argued that the defendants were negligent in failing to warn of the foreseeable risks of using such packing with their products.

This Court began its analysis with the threshold element of every negligence claim—the existence of a duty. (*Id.* at p. 363.) After carefully walking through each of the factors set forth in

Rowland v. Christian (1968) 69 Cal.2d 108, 113, this Court summarized its holding in a bold and italicized heading stating: "***No Duty of Care to Prevent Injuries from Another Manufacturer's Product.***" (*O'Neil, supra,* 53 Cal.4th at p. 363.) This Court reasoned that the "expansion of the duty of care . . . would impose an obligation to compensate those whose products caused the plaintiff no harm," (*id.* at pp. 363-65), and that "[t]o do so would exceed the boundaries established over decades of product liability law," (*ibid.*); see also *Kesner v. Pneumo Abex, LLC* (2016) No. S219534, 2016 WL 7010174, at *6 ["Foreseeability alone is not sufficient to create an independent tort duty."].)

Each of the factors considered in *O'Neil* applies with equal—and stronger—force to this case.

1. There is only a remote connection between a former manufacturer and a current consumer.

First, *O'Neil* noted that the connection between the parties was "extremely remote" because the defendant "did not manufacture, sell, or supply" the product that injured the plaintiff. (*O'Neil, supra,* 53 Cal.4th at p. 365.) Likewise here,

Novartis did not manufacture, sell, or supply the drugs that allegedly injured Plaintiffs. (OBOM at 11-12; AOB at 12, 32.)

Plaintiffs try to distinguish *O'Neil* by urging that there is a closer connection between manufacturers and remote consumers in the pharmaceutical industry because the FDA requires generic drugs to bear the same labels as their brand-name counterparts. (ABOM at 37.) But *former* brand-name manufacturers, such as Novartis, are barred by FDA regulations from communicating any warnings about their former drugs to current consumers. (21 U.S.C. § 352(n); 21 C.F.R. § 100.1(d)(1); OBOM at 15.)

If liability were to attach here, where Novartis was prohibited from issuing warnings about another manufacturer's drug, it would open the door to an explosion of tort liability between manufacturers and remote consumers. Products liability law has drawn the line at imposing liability based on such a remote connection. "Social policy must at some point intervene to delimit liability even for foreseeable injury." (*O'Neil, supra,* 53 Cal.4th at p. 365-66.) Deviating from that policy now would radically expand products liability in California.

2. There is little moral blame for failing to warn about another manufacturer's product.

Second, the *O'Neil* opinion concluded that "little moral blame can attach to a failure to warn about dangerous aspects of other manufacturers' products." (*O'Neil, supra,* 53 Cal.4th at p. 365.) Again, that rationale is strengthened where, as here, a former manufacturer is prohibited from warning consumers about dangerous aspects of a current manufacturer's drug.

Plaintiffs contend that unless former manufacturers are held liable they will be able to engage in morally blameworthy conduct by selling off dangerous product lines to avoid liability. (ABOM at 62.) But as Novartis explained in its merits briefing (RBOM at 23-24), there are many safeguards against such abuse. A drug company considering the purchase of a new product line will investigate the drug to ensure that it is purchasing a safe and profitable product—not a liability. (RBOM at 23.) And if the seller misrepresents the safety of its product, it can be held liable for breach of contract or fraud. (RBOM at 24.) The federal government also independently monitors drug safety through its Adverse Event Reporting System, which enables consumers and health care professionals to report suspected adverse drug effects

to the FDA.[2] Thus, there is no need to radically expand tort law just to police the sale of allegedly dangerous product lines.

3. Imposing liability on former manufacturers is unlikely to prevent future harm to consumers.

Third, *O'Neil* held that imposing a duty of care would be unlikely to prevent future harm because there is "no reason to think a product manufacturer will be able to exert any control over the safety of replacement parts or companion products made by other companies." (*O'Neil, supra,* 53 Cal.4th at p. 365.) Once again, that rationale is strengthened here, where Novartis cannot control current drug labeling practices.

Plaintiffs contend that imposing tort liability on former manufacturers will prevent future harm to consumers by eliminating any incentive for manufacturers "to delay the adoption of necessary warnings and then profit from their misconduct by selling" their drug lines. (ABOM at 63-64.) There is no reason to think that imposing liability on former manufacturers will increase consumer safety. To the contrary, as Novartis observed, imposing liability on former manufacturers could have the perverse effect of encouraging current

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[2] (See http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Surveillance/AdverseDrugEffects/ (last visited December 6, 2016).)

manufacturers to avoid strengthening their warning labels thereby ensuring that former manufacturers with deep pockets stay on the hook for liability. (RBOM at 22-24.)

Accordingly, adopting "innovator" or "former manufacturer" liability will not deter morally blameworthy conduct.

4. Innovator and former manufacturer liability would impose significant burdens on defendants.

Fourth, *O'Neil* noted that "recognizing a duty of care would clearly impose a significant burden on defendants and all other companies that could potentially be held liable for injuries caused by products they neither made nor sold." (*O'Neil, supra,* 53 Cal.4th at p. 365.) Here too, recognizing a duty of care would impose a "significant burden" on Novartis who neither manufactured nor sold the drugs that injured Plaintiffs. (*Ibid.*)

Plaintiffs claim that as long as drug companies draft perfect product warnings they will not face any additional burdens from the expansion of liability to remote consumers. (ABOM at 41, 67.) That argument is wildly overbroad. It would support an argument for unlimited liability on the theory that a company that has done no wrong has no reason to fear tort liability. Moreover, it is at best a naïve view. Even unmeritorious

claims can consume enormous time and resources until they are disposed on summary judgment or rejected at trial.

Plaintiffs also argue that a manufacturer who sells its product line can avoid the uncertainty of perpetual liability by requiring the buyer to indemnify it for any liability arising after the date of sale. (ABOM at 67.) To begin, Plaintiffs' reasoning is circular. It is only necessary to obtain indemnity if a defendant has an underlying liability and, under the current state of California law in *O'Neil,* a former manufacturer has no duty to prevent injuries from another manufacturer's product. (See *O'Neil, supra,* 53 Cal.4th at p. 363.) Regardless, an indemnity provision is only as strong as the company that provides it. If a buyer goes out of business, it provides no protection to the former manufacturer. In short, indemnity is not a viable solution to the type of perpetual liability championed by Plaintiffs.

5. Bringing new drugs to market is more beneficial to consumers than increased tort liability.

Finally, *O'Neil* noted that consumers could "suffer harm from the broad expansion of liability plaintiffs seek." (*O'Neil, supra,* 53 Cal.4th at p. 365.) Here too, the expansion of tort liability could harm consumers by stifling innovation.

There can be little doubt that imposing innovator and former manufacturer liability would increase the costs of developing new drugs and other technologies. "[T]he heightened risk of liability puts a drag on innovation and diverts its path." (Gideon Parchomovsky and Alex Stein, *Torts and Innovation* (2008) 7 MICH. L. REV. 285, 288.)

Moreover, the greater the investment in research and development needed to produce a certain innovation, the more likely it is that increased tort liability will stop a new drug or technology from ever reaching the market. (*Ibid.*) The cost of bringing new drugs to market has more than doubled in the last 10 years, now reaching close to $2.5 billion. (See Scientific American, "Cost to Develop New Pharmaceutical Drug Now Exceeds $2.5 Billion).[3] Accordingly, innovation in the pharmaceutical industry is particularly susceptible to deterrence from increasing tort liability.

Yet, the development of new drugs has enormous benefits for consumers. New medicines decrease mortality and health spending. (See Frank R. Lichtenberg, *Are the Benefits of Newer*

[3] (Available at https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/ (last visited December 6, 2016).)

Drugs Worth Their Costs? (2001) 20 HEALTH AFFAIRS 241.) To give one example, new immunotherapy drugs are now extending the lives of cancer patients with previously untreatable conditions by two to three years. (See, e.g., NBC News, *Promising Drugs Stoke Talk of Cancer "Cures"* (June 2016).)[4]

In short, each factor that drove this Court in *O'Neil* to reject any duty to prevent harm from injuries caused by another manufacturer's product applies with equal force in this case.

B. Innovator liability could destroy the culture of collaboration that created Silicon Valley.

Innovator liability could be particularly devastating in California, which has long been considered a center of high-tech innovation. This Court should not adopt such a rule without considering the full impact it could have on all industries.

There is no question that legal rules impact innovation and with it the development of high-tech havens. (See Ronald Gilson, *The Legal Infrastructure of High Technology Industrial Districts* (1999) 74 NYU L. REV. 575, 575; Parchomovsky, *supra*, at p. 288.) For example, Silicon Valley's success has been attributed in part to California's refusal to enforce standard non-compete

[4] (Available at http://www.nbcnews.com/health/cancer/promising-drugs-stoke-talk-cancer-cures-n585256 (last visited December 6, 2016).)

agreements. (See Gilson, *supra*, at pp. 589-91.) As a result, Silicon Valley has developed a unique culture where engineers move frequently and fluidly between companies and into start-ups. (*Ibid.*) That environment creates the opportunity for a remarkable amount of collaboration and "knowledge spillover," which has led to extraordinary innovation. (*Ibid.*)

Adopting innovator liability could suppress that culture by increasing a company's liability if it shares a new technology, and even expose a high-tech company to liability if a competitor imitates its new technology or even counterfeits its devices. The rationale would be the same as that embraced by Plaintiffs: if the high-tech company had warned of the dangers of its own device, it might have prevented injury to the consumer of an imitation device. If liability is imposed in these circumstances, then Silicon Valley employers will have an incentive to clamp down on the current culture of collaboration–stifling innovation.

Conversely, even if a company is able to unlock a competitor's innovative new technology, such as for self-driving cars for example, a company would have little incentive to improve upon its competitor's technology. If a family were injured in one of the company's self-driving cars, a jury could allocate

some fault to its competitor for creating the technology that contributed to the accident. (ABOM at 69.) Thus, adopting its competitor's technology wholesale, rather than improving on the technology to make it safer, would decrease the company's cost of doing business. The cost to society, however, would be great. The pace of innovation would slow, as would the development of newer and safer technologies. (See generally, James M. Anderson, et al., *Autonomous Vehicle Technology* (2016) The Rand Corporation at pp. 118-127 [discussing the need to develop tort rules that facilitate the adoption and improvement of socially beneficially technologies such as self-driving cars].)[5]

Even more troubling, imposing innovator and former manufacturer duties could stop a beneficial new technology from ever being developed. The principal problem with both duties is that they impose liability on a company that no longer has any control over a product. For example, a former manufacturer would have no say over the company culture or management practices of a current manufacturer, including such fundamental decisions as whether to continue to produce and market a

[5] (Available at http://www.rand.org/content/dam/rand/pubs/research_reports/RR400/RR443-2/RAND_RR443-2.pdf (last visited December 6, 2016).)

particular product in light of new research or information about its dangerous propensities. Yet, under the expansion of tort duty championed by Plaintiffs, the former manufacturer would remain on the hook for injuries to remote consumers. Such a legal rule would create enormous uncertainty for companies developing new technologies because they would be unable to control future liability. The result would be decreased innovation.

In short, holding innovators and former manufacturers liable for injuries caused by products they neither sold nor manufactured will not deter future harm to consumers. It will deter innovation of new and safer technologies.

CONCLUSION

For the foregoing reasons, and those expressed by Novartis in its merits briefing, this Court should reverse the decision of the Court of Appeal and remand this cause to the trial court with directions to enter a judgment for Novartis.

Dated: December 7, 2016

Respectfully submitted,

HAYNES AND BOONE, LLP

By: _____
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CERTIFICATE OF WORD COUNT

The undersigned certifies that, pursuant to the word count feature of the word processing program used to prepare this brief, it contains 2,640 words, exclusive of the matters that may be omitted under rule 8.520(c)(3).

DATED: December 7, 2016

Respectfully submitted,

HAYNES AND BOONE, LLP
Mary-Christine Sungaila
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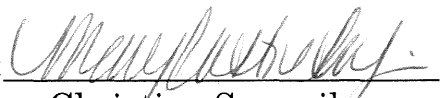
By: 
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PROOF OF SERVICE
(CCP § 1013(a) and 2015.5)

I, the undersigned, am employed in the County of Orange, State of California. I am over the age of 18 and not a party to the within action. I am employed with the law offices of Haynes and Boone, LLP and my business address is 600 Anton Blvd., Suite 700, Costa Mesa, California 92626.

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☒ **[BY MAIL]** I am readily familiar with the firm's practice of collection and processing 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 at Costa Mesa, California in the ordinary course of business. I am aware that on motion of the party served, service is presumed invalid if postage cancellation date or postage meter date is more than one day after date of deposit for mailing this affidavit.

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

Executed on December 7, 2016, at Costa Mesa, California.

Breean Cordova

Breean Cordova