No. 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.

Review of a Decision of the Court of Appeal
Fourth Appellate District, Division One, Case No. D067839

OPENING BRIEF ON THE MERITS

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STATEMENT OF 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?

INTRODUCTION

In allowing Plaintiffs to pursue claims against Novartis Pharmaceuticals Corporation for injuries allegedly caused by pharmaceutical drugs Novartis did not manufacture, the Court of Appeal ran roughshod over the fundamental legal principles and policy concerns that guided this Court's decision in *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335 and a line of cases before it. *O'Neil* holds "that a product manufacturer *may not be held liable in strict liability or negligence for harm caused by another manufacturer's product.*" (*Id.* at p. 342, italics added.)

O'Neil's holding is particularly compelling in cases involving prescription drugs. Prescription drugs are subject to a comprehensive federal regulatory regime that (1) focuses legal responsibility for safety monitoring and labeling on current drug manufacturers, (2) bars former drug manufacturers from any role in the drug's marketing and labeling, and (3) provides incentives for the entry of generic drugs in competition with branded drugs to secure the availability of lower costs for mature drug products.[1] This Court in turn has cautioned against expansive theories of drug manufacturer liability, and in leading decisions such as *Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588, it has squarely rejected claims that would hold a drug manufacturer liable for injuries known to be caused

[1] (See, e.g., FDA, *What Are Generic Drugs*,<http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/UnderstandingGenericDrugs/ucm144456.htm> [last accessed Aug. 4, 2016].)

by another drug manufacturer's product. (See *id.* at p. 605.) The Court of Appeal's decision stretched California law far beyond the limits of liability embraced by *O'Neil* and *Sindell.*

Novartis was at least twice removed from the prescription drugs alleged to have caused Plaintiffs' injuries — first, by Novartis's undisputed and complete *divestiture* of its branded terbulatine drug Brethine to aaiPharma *six years* before Plaintiffs' exposure to any terbutaline drug; and, second, by the fact that Novartis *never* manufactured either of the generic drugs alleged to have caused Plaintiffs' injuries. Two extraordinary expansions of traditional tort law are thus before this Court:

First, the Court of Appeal held that a *former* manufacturer of a prescription drug owes a duty of care to consumers allegedly injured by the *subsequent* manufacturer's prescription drug. The Court of Appeal cited no authority for this "former manufacturer" duty. In fact, this Court and other California courts repeatedly have refused to hoist liability on a company based on its status as a former manufacturer. (*O'Neil*, *supra*, 53 Cal.4th 335 [refusing to impose duty on former manufacturer of valves and pipes containing packing and gaskets for alleged injuries caused by replacement packing and gaskets]; *Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513 [refusing to impose duty on former manufacturer of pipe insulation]; *Gansberger v. Rockwell Intern. Corp.* (9th Cir. 1990) 911 F.2d 738, 1990 WL 115595 [applying California law, same for airplane manufacturer].) Courts outside of California also have rejected this "former manufacturer" duty, including specifically in prescription drug litigation. (E.g., *Lyman v. Pfizer, Inc.* (D.Vt. July 20, 2012, No. 2:09-cv-262) 2012 WL 2970627, *16-17.)

Second, the Court of Appeal held that the (in this case, former) manufacturer of a *brand name* prescription drug owes a duty of care to consumers allegedly injured by another manufacturer's *generic* "bio-equivalent" of that drug, *i.e.*, that the branded drug manufacturer owes a duty of care to consumers of a drug it never manufactured and which instead is manufactured by a competitor. The Court of Appeal relied on *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89 for this proposition, but *Conte* rests upon legal arguments soundly rejected by this Court in *O'Neil*, and *Conte*'s novel adoption of a "drug innovator" duty has been overwhelmingly rejected by courts around the country.

STATEMENT OF FACTS

I. THE COMPLAINT.

On October 8, 2013, minor Plaintiffs Teagan and Cardwell Hamilton filed this lawsuit and alleged that their autism was caused by their mother's 2007 use of generic drugs that were manufactured by Lehigh Valley Technologies, Inc. and Global Pharmaceuticals and that contained the active ingredient terbutaline. (1AA:1.) Terbutaline drugs are prescription bronchodilators approved by the Food and Drug Administration (FDA) and indicated for treatment of asthma, but they were prescribed to Plaintiffs' mother off-label as a tocolytic (to prevent pre-term labor). (1AA:22, 42-43.)[2]

Plaintiffs claimed a failure to warn. They alleged that the 2007 Lehigh Valley and Global drug product labels included warnings against tocolytic use but did not mention potential harm to the fetus. (1AA:46-49.)

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[2] Physicians may prescribe drugs for other than labeled or indicated uses, *i.e.*, "off label," if appropriate to do so in their medical judgment. (*Buckman Co. v. Plaintiffs' Legal Committee* (2001) 531 U.S. 341, 350.)

Plaintiffs asserted that the drug company defendants improperly promoted terbutaline drugs for use as a tocolytic and that they knew or should have known of the alleged risk of these drugs to cause autism in children exposed in utero. (1AA:40-42.) Plaintiffs claimed that this risk was identified in a series of studies conducted between the late 1970s and 2006. (1AA:22-42.)

Plaintiffs sued the physician who prescribed the drugs, the hospital where Plaintiffs were born, and Lehigh Valley and Global as the manufacturers of the generic drugs used by their mother.[3] Plaintiffs also sued a number of manufacturers or former manufacturers of branded terbutaline drugs, including Novartis, which at one time manufactured Brethine, and aaiPharma, the company that purchased all ownership rights in Brethine from Novartis in 2001, six years before Plaintiffs' mother's use of any terbutaline drugs. (1AA:3-5.)

II. THIS LITIGATION.

Novartis demurred, contending it owed no duty to Plaintiffs because Plaintiffs' mother did not use and could not have used a Novartis product. (1AA:59.) Novartis had sold all rights and interests in its terbutaline product Brethine to aaiPharma in 2001, and thus Novartis had left the market six years before Plaintiffs' mother's alleged terbutaline use. (1AA:68-71.) Plaintiffs stipulated that Novartis had divested its ownership interest in Brethine in 2001 (1AA:98-100), and Plaintiffs acknowledged that the obligation to monitor and update Brethine's label passed with that sale from Novartis to aaiPharma. (AOB:12, 32.) Plaintiffs also

[3] Plaintiffs' claims against the prescribing physician, the hospital, and one of the makers of the generic terbutaline are still pending in the trial court.

acknowledged that Novartis did not manufacture the generic drugs used by their mother. (AOB:32.) But Plaintiffs argued that Novartis owed them a duty because it was foreseeable that the warning on Novartis's Brethine label prior to the divestiture in 2001 would cause Plaintiffs' mother's doctor to prescribe Lehigh Valley's and Global's generic terbutaline drugs to her in 2007. (1AA:78-81, 98.) Plaintiffs did not allege that Novartis engaged in any wrongful conduct after December 2001. (AOB:26.)

The trial court sustained Novartis's demurrer (1AA:101), ruling in accord with California law that Plaintiffs could not prevail "because Novartis owed Plaintiffs no duty as a matter of law for claims that arise from the pr[e]scribing of terbutaline medication in 2007." (*Ibid.*)

The Court of Appeal reversed. The Court of Appeal found that former manufacturer Novartis could have foreseen a chain of events whereby its conduct prior to the Brethine divestiture in 2001 could have caused a failure to warn by the subsequent manufacturer. The Court of Appeal concluded that such foreseeability created a duty of care on Novartis that ran to consumers of the subsequent manufacturer's product. (Slip Opn. 23.) The Court of Appeal then held that (former) brand manufacturer Novartis also could be liable to future users of generic terbutaline drugs, *i.e.*, "bio-equivalent" drugs manufactured by competitors that were not and had never been manufactured by Novartis.

III. THE REGULATORY SCHEME FOR PRESCRIPTION DRUGS.

Congress established a comprehensive federal regulatory regime to support the development of beneficial new drugs while at the same time ensuring the availability of updated safety information to the public and lower cost alternatives for mature drug products. This regulatory regime

strictly limits labeling and safety monitoring authority and responsibilities to the current manufacturers of prescription drugs.

Under the Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et seq., the FDCA), "a drug manufacturer is prohibited from marketing a new drug unless the FDA has approved the drug as both safe and effective for its intended use." (*Id.* § 355(a); *Kanter v. Warner-Lambert Co.* (2002) 99 Cal.App.4th 780, 784-785.)[4] A manufacturer seeking approval of a new drug must submit a detailed New Drug Application (NDA), which must include "substantial evidence" that the drug is safe and effective based on "adequate and well-controlled investigations." (21 U.S.C. § 355(d).) The NDA must also include "specimens" of the labeling proposed for the drug. (*Id.* § 355(b)(1)(F); 21 C.F.R. § 314.50(c)(2)(1); 21 C.F.R § 201 et seq.) FDA may refuse to approve a NDA, among other reasons, if the agency determines that the labeling is false or misleading in any particular, if the application contains an untrue statement of a material fact, or if the proposed labeling does not comply with the requirements established in the regulations. (21 U.S.C. § 355(d)(7); 21 C.F.R. § 314.125(b)(6), (7), (8).)

The cost to innovator pharmaceutical companies of developing and securing FDA approval for *a single* new branded drug treatment has been estimated to exceed $2.5 billion. (Tufts Center for the Study of Drug Development, *Cost of Developing a New Drug* (Nov. 18, 2014), <http://csdd.tufts.edu/files/uploads/Tufts_CSDD_briefing_on_RD_cost_study_-_Nov_18,_2014.pdf>.) To provide the necessary incentive for the

[4] For the convenience of the Court, Novartis cites to the FDA regulations for prescription drugs currently in effect to provide the FDA regulatory framework. The substantive obligations of branded and generic drug manufacturers at the time of Novartis's divestiture of the Brethine NDA and Plaintiffs' mother's use of terbutaline sulfate are governed by the FDA regulations in effect in 2001 and 2007, respectively.

development of new drugs, innovator companies that secure NDA approval are granted a period of market exclusivity for the drug, during which time competitor companies are excluded from the market. (21 U.S.C. § 355(c).)[5]

Following the approval of a NDA, its holder assumes continuing responsibilities under federal law to monitor adverse drug events and new scientific studies and to update the drug labels with any necessary warnings. (21 C.F.R. §§ 201.57(c)(6), 314.80(b).) Because these responsibilities attach to the NDA, if the holder sells the NDA to another company, all safety monitoring and labeling authority and responsibilities for the drug are transferred to the new NDA holder. (*Id.* § 314.72(a)(2).) At the time of sale, the "new owner shall advise FDA about any change in the approved application under § 314.70, except the new owner may advise FDA in the next annual report about a change in the drug product's label or labeling to change the product's brand or the name of its manufacturer, packer, or distributor." (21 C.F.R. § 314.72(b); see also *id.* § 201.1(a) [a drug is misbranded if the label does not "conspicuously" bear the name of the current manufacturer].)

Pursuant to these assumed responsibilities, the new NDA holder is required to revise the drug label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." (21 C.F.R. § 201.80(e).) If the new NDA holder fails to meet these responsibilities, it is subject to a host of FDA enforcement alternatives. (21 U.S.C. §§ 331(a)(b)(ii), (jj), 332, 333(b), 334, 335a, 335b.)

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[5] *Actavis Elizabeth LLC v. U.S. Food and Drug Admin.* (D.C. Cir. 2010) 625 F.3d 760, 764 [explains the Congressional purpose — to "provid[e] incentives for innovation by granting five-year exclusivity" to FDA-approved new drugs and barring sale of a competing drug].

Upon its sale of the NDA, the former NDA holder is precluded from further involvement in the drug's labeling. The former NDA holder must "submit a letter or other document [to the FDA] that states that all rights to the application have been transferred to the new owner" (21 C.F.R. § 314.72(a)(1)) and must notify the FDA that it has discontinued the manufacture and marketing of the drug. (21 U.S.C. § 360(j)(2)(B).) The former NDA holder may not thereafter propose any changes to the drug label. (21 C.F.R. §§ 314.70, 314.71 [only the applicant may submit a supplement to an application].) Moreover, the former NDA holder is prohibited under federal law from communicating any warnings about its former drug or making any statements contrary to the FDA-approved labeling maintained by the new NDA holder. (21 U.S.C. § 352(n) [prohibiting as misbranding any communications regarding side effects for prescription drugs that are contrary to FDA-required labeling]; 21 C.F.R. § 100.1(d)(1) [communications must mirror language on FDA-approved label].)[6]

At the end of the NDA market exclusivity period, FDA permits generic manufacturers to enter the market to sell competing generic drugs that are "bio-equivalent" to the branded drug. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, 98 Stat. 1585, commonly known as the Hatch-Waxman Amendments, with the stated goal to "make available more low cost generic drugs by establishing a generic

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[6] Rather than sell the NDA, an innovator pharmaceutical company may formally withdraw the NDA at the end of the drug exclusivity period. In that event, the drug is moved to the "Discontinued Drug Product List" section of the FDA's Orange Book, and there is no NDA holder with ongoing responsibility to monitor the drug safety and labeling. (See 21 C.F.R. § 314.150(c); FDA, *Orange Book Preface* (June 10, 2016), <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079068.htm > [last accessed on Aug. 4, 2016].)

drug approval procedure." (H.R.Rep. No. 98-857, pt. 1, p. 14 (1984).) The Hatch-Waxman Act "allows manufacturers to develop generic drugs inexpensively, without duplicating the clinical trials already performed on the equivalent brand-name drug," and their costs are further lowered because the FDCA mandates that they use the "same . . . label[ing] approved [by the FDA] for the brand-name drug." (*PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 612-613.)

"These legislative efforts to expand production and consumption of generic drugs have proved wildly successful." (*PLIVA, Inc.*, *supra*, 546 U.S. at p. 629, Sotomayor, J., dissenting.) Today, generic drugs "dominate the market." (*Ibid.*) Upon the entry of generic drugs, the NDA holder of the branded drug rapidly loses market share to the lower-cost generic manufacturers. (H. Grabowski, G. Long & R. Mortimer, *Recent trends in brand-name and generic drug competition*, J. Med. Econ. 2013, 1-8, 6-7, <http://fds.duke.edu/db/attachment/2575> [brand manufacturers retain only 11% of the drug market after the first year of generic entry].)

Generic drug manufacturers must use the same labeling as that used by the NDA holder for the branded drug, and generic manufacturers are required to separately monitor the safety of their drugs. Under federal law, generic manufacturers must "develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA." (21 C.F.R. §§ 314.80(b), § 314.98 [making § 314.80 applicable to generic manufacturers].) Generic manufacturers also must submit to the FDA an annual report summarizing "significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product," including a "description of actions the [manufacturer] has taken or intends to take as a result of this new information." (21 C.F.R. §§ 314.81(b)(2)(i), 314.98(c).) In

implementing the Hatch-Waxman Amendments, the FDA instructed that if a generic drug manufacturer "believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and [branded] drugs should be revised." (57 Fed. Reg. 17950, 17961 (Apr. 28, 1992).)

LEGAL ARGUMENT

Plaintiffs' claims would eviscerate legal boundaries established over decades of California jurisprudence that ensure that a manufacturer may not be held liable for injuries allegedly caused by another manufacturer's product. The Court of Appeal here carved two "exceptions" into bedrock legal principle, such that a branded drug company would be held endlessly liable: (1) as a "former manufacturer," for injuries allegedly caused by the branded drug as manufactured by a different company years after the former manufacturer's divestiture of ownership in the drug, and (2) as an "innovator" (or former innovator), for injuries allegedly caused by generic drugs that the branded drug company never manufactured. These exceptions should not stand.

I. UNDER CALIFORNIA LAW, A MANUFACTURER IS NOT LIABLE FOR INJURIES CAUSED BY ANOTHER MANUFACTURER'S PRODUCT.

Plaintiffs' claims against Novartis are precluded by a single, unalterable and undisputed fact — Novartis did not manufacture either of the drugs that allegedly caused Plaintiffs' injuries. As this Court has made clear both generally and specifically for prescription drugs, there can be no liability in this circumstance.

A. *O'Neil* rejected a request to impose liability on one manufacturer for harm caused by another manufacturer's product.

Just four years ago, this Court held "that a product manufacturer may not be held liable in strict liability or negligence for harm caused by another manufacturer's product." (*O'Neil*, *supra*, 53 Cal.4th at p. 342.) *O'Neil* allows only two exceptions to this rule — in cases where the manufacturer had (i) produced a separate product alleged to have "contributed substantially to the harm" or (ii) created "a harmful combined use of the products." (*Ibid.*) Neither exception applies here and so Novartis "may not be held liable in strict liability or negligence for harm caused by [Lehigh Valley's and Global's] product[s]." (See *ibid.*)

In *O'Neil*, the plaintiff claimed the manufacturers of valves and pumps with asbestos-containing packing and gaskets should be liable for his asbestos-related disease, notwithstanding that he was allegedly injured by replacement packing and gaskets manufactured by different manufacturers. (*O'Neil*, *supra*, 53 Cal.4th at pp. 349-350.) The plaintiff contended it was foreseeable that the defendants' failure to warn about the risks from their own packing and gaskets would cause his injury because the replacement packing and gaskets were "no different" from those originally supplied by the defendants. (*Id.* at p. 347.) And the plaintiff argued that if the defendants "had warned the hypothetical original user, or protected that person by avoiding defective design, subsequent users, too, would have been protected." (*Ibid.*)

Rejecting plaintiff's arguments that would have imposed liability on one manufacturer for harm caused by another manufacturer's products, this Court held that "in strict liability as in negligence, foreseeability alone is not sufficient to create an independent tort duty." (*O'Neil*, *supra*,

53 Cal.4th at p. 362, internal citations and quotation marks omitted.) Rather, the fact that "the defendant manufactured, sold, or supplied the injury-causing product is a separate and threshold requirement that must be independently established." (*Ibid.*) This Court explained that the "same policy considerations that militate against imposing strict liability in this situation apply with equal force in the context of negligence." (*Id.* at p. 366.)

The *O'Neil* Court tested the existence of a legal duty of care against the factors set forth in *Rowland v. Christian* (1968) 69 Cal.2d 108. It concluded that none of the *Rowland* factors supported imposition of a negligence duty on one manufacturer to prevent harm caused by another manufacturer's product. (*O'Neil*, *supra*, 53 Cal.4th at p. 365.) An identical analysis and outcome is obtained here:

- *First*, even if a manufacturer can reasonably foresee the risk of latent disease arising from others' products, "strong policy considerations counsel against imposing a duty of care . . . ." (*Id.* at pp. 364-365.)

- *Second*, the connection between a defendant's conduct and a plaintiff's injury is "extremely remote" where the defendant did not manufacture, sell, or supply any product allegedly causing the injury. (*Id.* at p. 365.)

- *Third*, "little moral blame can attach to a failure to warn about dangerous aspects of *other* manufacturers' products." (*Ibid.*)

- *Fourth*, the imposition of a duty on an uninvolved manufacturer would not prevent future harm because the defendant would not "be able to exert any control over the safety" of another company's

products and would have "scant ability to influence their customers' choices about other products." (*Ibid.*)

- *Fifth*, the burdens imposed on such defendants and the consequences to the community weigh against imposing a duty:

> 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. Because the recognition of such a duty could lead to an overabundance of potentially conflicting product warnings, consumers could also suffer harm from the broad expansion of liability plaintiffs seek.

(*Ibid.*)

O'Neil also cautioned more generally that recognition of the proposed duty would have grave policy implications because — as here — it would impose liability on manufacturers who have no control over and earn no profit from the alleged injurious product. (See *O'Neil*, *supra*, 53 Cal.4th at p. 363.) California cannot wish to wreak such havoc upon existing notions of tort law, or to place such indiscriminate and immeasurable liability upon former manufacturers.

This Court concluded with words equally as dispositive today: "In short, expansion of the duty of care as urged here would impose an obligation to compensate on those whose product caused no harm. To do so would exceed the boundaries established over decades of product liability law. Social policy must at some point intervene to delimit liability even for foreseeable injury . . . ." (*O'Neil*, *supra*, 53 Cal.4th at pp. 365-366.)

B. A prescription drug manufacturer may not be held liable for harm caused by another manufacturer's drugs.

In departing from *O'Neil*, the Court of Appeal suggested California law might allow for broader theories of non-manufacturer liability against drug manufacturers than against manufacturers generally. (Slip Opn. 23.) Not so. This Court explicitly has cautioned against expansive theories of liability in prescription drug personal injury litigation because of the unique and critical value these drugs provide. Moreover, this Court has rejected legal theories that would hold a drug manufacturer liable, in negligence or otherwise, for harm caused by another manufacturer's drug.

In *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063, this Court noted that unlike most products "used to make work easier or to provide pleasure," prescription drugs "may be necessary to alleviate pain and suffering or to sustain life." (*Ibid.*) Public policy thus "favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering." (*Ibid.*)

The Court observed that "the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use." (*Brown, supra*, 44 Cal.3d at p. 1063.) At the same time, the Court warned that if drug manufacturers were subjected to expanded theories of liability "they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments." (*Ibid.*; see also *Moore v. Regents of University of California* (1990) 51 Cal.3d 120, 146.) The Court cautioned that "the additional

expense of insuring against such liability — assuming insurance would be available — and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most." (*Brown*, *supra*, 44 Cal.3d at p. 1063.)[7]

Consistent with these concerns, this Court regularly rejects theories of liability — such as the "exceptions" adopted by the Court of Appeal here — that would impose a duty on prescription drug manufacturers to consumers allegedly injured by another manufacturer's drug. In *Sindell v. Abbott Laboratories*, *supra*, 26 Cal.3d 588, a plaintiff sued several drug companies that manufactured the drug diethylstilbesterol (DES), alleging that her mother's use of DES during pregnancy had caused the plaintiff to develop cancerous vaginal and cervical growths. (*Id.* at pp. 594-595.) Although the plaintiff could not identify *which* defendant manufactured the DES her mother had used, she claimed all DES manufacturers could be jointly liable because all defendants (1) "collaborated in marketing, promoting and testing the drug, relied upon each other's tests, and adhered to an industry-wide safety standard," (2) produced DES "from a common

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[7] Many California intermediate courts have taken these policy considerations to heart in limiting theories of liability against prescription drug and medical device manufacturers. (E.g., *Garrett v. Howmedica Osteonics Corp.* (2013) 214 Cal.App.4th 173, 182-85 ["public interest in the development, availability and affordability of implanted medical devices justifies an exemption from design defect strict products liability"]; *In re Coordinated Latex Glove Litigation* (2002) 99 Cal.App.4th 594, 611 [*Brown* instructs that in "cases involving [medical] products that create significant scientific concerns with respect to research and innovation, more protection for a manufacturer is justified"]; *Hufft v. Horowitz* (1992) 4 Cal.App.4th 8, 18-19 [extending *Brown* to medical implants because imposing strict products liability would discourage manufacturers from researching and marketing new medical devices for fear of adverse judgments, high cost of insurance, and uncertainty of available insurance].)

and mutually agreed upon formula as a fungible drug interchangeable with other brands of the same product," and (3) "knew or should have known that it was customary for doctors to prescribe the drug by its generic rather than its brand name and that pharmacists filled prescriptions from whatever brand of the drug happened to be in stock." (*Id.* at p. 595.)

Although this Court adopted a "market share" liability theory whereby each manufacturer theoretically could be proportionately responsible "for the injuries caused *by its own products*," it drew a clear line in the sand against any theory — like the ones endorsed by the Court of Appeal here — that would hold a manufacturer liable for injuries caused by another manufacturer's drug. (*Sindell*, *supra*, 26 Cal.3d at p. 612, italics added.) In rejecting the plaintiff's grander claim, *Sindell* explains:

> What the complaint appears to charge is defendants' parallel or imitative conduct in that they relied on each others' testing and promotion methods. But such conduct describes a common practice in the industry: a producer avails himself of the experience and methods of others making the same or similar products. Application of the concept of concert of action to this situation would expand the doctrine far beyond its intended scope and would render virtually any manufacturer liable for defective products of an entire industry, even if it could be demonstrated that the product which caused the injury was not made by the defendant.

(*Id.* at p. 605.)

Sindell further held that the federal regulatory scheme governing prescription drugs weighs against imposing liability for harm caused by another manufacturer's drug: "since the government plays such a pervasive

role in formulating the criteria for the testing and marketing of drugs, it would be unfair to impose upon a manufacturer liability for injuries resulting from the use of a drug which it did not supply simply because it followed the standards of the industry." (*Sindell*, *supra*, 26 Cal.3d at p. 610.)

In subsequent rulings, this Court unsurprisingly and repeatedly has emphasized the requirement that liability for a drug manufacturer be limited to that arising from injuries caused by its own drugs. *Brown* explained that a "DES manufacturer found liable [under *Sindell*] would not be held responsible for injuries caused by another producer of the drug." (*Brown*, *supra*, 44 Cal.3d at p. 1074.) And *Jolly v. Eli Lilly & Co.* (1988) 44 Cal.3d 1103, 1115, rejected a plaintiff's theory under which "all drug companies would be liable even if plaintiff knew the actual manufacturer of the drug" because "that clearly is not the law."

II. PLAINTIFFS' "FORMER MANUFACTURER" AND "INNOVATOR" THEORIES OF LIABILITY ARE INCONSISTENT WITH THE RULES ANNOUNCED BY THIS COURT IN *O'NEIL* AND *SINDELL*.

Plaintiffs' theories here sweep far beyond the Court's bar against manufacturer liability for injuries caused by another manufacturer's product. Plaintiffs first argued, and the Court of Appeal accepted, that Novartis could be liable as a "former manufacturer" of the terbutaline drug Brethine, though Novartis had fully divested Brethine to another manufacturer and *exited the terbutaline market six years before Plaintiffs' alleged exposure*. And — because Plaintiffs allege their injuries were caused, not by Brethine, but by *generic drugs never manufactured by Novartis* — Plaintiffs also argued, and the Court of Appeal also accepted, that (former) brand manufacturer Novartis could be liable in "innovator

liability" for injuries caused by generic terbutaline drugs manufactured by competitor drug companies.

This Court should reject both extreme expansions of California tort law.

A. Novartis should not be held liable as a former manufacturer.

The Court of Appeal wrongly held that Novartis could be liable for injuries allegedly caused by terbutaline drugs manufactured in 2007 because Novartis had manufactured Brethine for a period of time before 2001 (the stipulated date of the divestiture). The Court of Appeal did not point to any legal authority imposing such a "former manufacturer" duty of care, and every court that has considered such an argument in prescription drug and medical device litigation correctly has concluded that no such duty exists.[8] Nor should this Court create a duty that is impossible to fulfill: the proposed duty directly conflicts with the federal regulatory scheme that precludes former NDA holders like Novartis from playing any role in the safety monitoring or labeling of their previously manufactured drugs. (See, e.g., 21 U.S.C. § 352(n); 21 C.F.R. § 100.1(d)(1).)

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[8] See *In re Darvocet, Darvon and Propoxyphene Products Liability Litigation* (E.D.Ky. Mar. 7, 2012, Master File No. 2:11-md-2226) 2012 WL 767595, *6-7 [Eli Lilly could not be liable for a plaintiff's use of prescription propoxyphene manufactured after Lilly had sold its NDA to Neosan]; *Lyman v. Pfizer, Inc.* (D.Vt. July 20, 2012, No. 2:09-cv-262) 2012 WL 2970627, *16-17 [Wyeth could not be liable for a plaintiff's use of prescription metoclopramide manufactured after Wyeth sold its NDA to Schwarz Pharma]; *Barbour v. Dow Corning Corp.* (Conn.Super.Ct. Apr. 19, 2002, No. X06CV930301054S) 2002 WL 983346, *3 [3M could not be liable for plaintiffs' use of breast implants manufactured after it sold its product line to McGhan Medical, notwithstanding evidence that the sale was motivated by mounting legal claims against the product].

California's courts have not had occasion to consider the "former manufacturer" duty in prescription drug litigation, but they repeatedly have rejected efforts to impose a duty of care on former product manufacturers in other litigations. In the seminal product liability case *O'Neil*, *supra*, 53 Cal.4th 335, for example, the "former manufacturer" defendants had supplied valves and pumps on the aircraft carrier on which the plaintiff worked and included gaskets and packing in those valves and pumps. (*Id.* at pp. 344-345.) The plaintiff alleged he was injured from subsequently-manufactured but identical replacement gaskets and packing used on the same valves and pumps. (*Ibid.*) Plaintiff further alleged that the former manufacturer defendants could have warned plaintiff's employer directly when they first installed the valves and pumps on the ship, that they had an ongoing business relationship with the plaintiff's employer through the continued use of their pumps and valves, and that there was no legal prohibition against them subsequently warning the employer about the risks of asbestos exposure from the replacement gaskets and packing. (*Id.* at pp. 344, 346, 347.) Still, this Court found no "former manufacturer" exception to the general rule that a manufacturer may not be held liable for injuries caused by another manufacturer's product. Particularly in light of *O'Neil*, there is no plausible basis to find that a new "former manufacturer" duty exists here.

Novartis, by contrast to the *O'Neil* defendants, had no relationship with Plaintiffs or their mother and had no opportunity to warn Plaintiffs' mother's physician in connection with his decision to prescribe terbutaline in 2007. Most starkly, Novartis was precluded in 2007 from warning the physician about any alleged risks from Brethine because the authority and obligation to issue warnings had transferred to aaiPharma in 2001 when Novartis sold the Brethine NDA. Moreover, Novartis knew at the time it

sold the Brethine NDA that subsequent terbutaline drug manufacturers would be subject to an extensive federal regulatory scheme requiring them to provide adequate warnings to their customers and imposing stringent penalties for any failures to do so.[9]

The Court of Appeal's proposed "former manufacturer" duty likewise directly conflicts with *Cadlo*, *supra*, 125 Cal.App.4th 513. The *Cadlo* plaintiffs claimed Owens-Illinois — the former manufacturer of the asbestos-containing insulation product Kaylo — should be held liable for injuries allegedly caused by Kaylo manufactured after Owens-Illinois sold its Kaylo division to Owens-Corning Fiberglas. (*Id.* at p. 516.) The plaintiffs' allegations against Owens-Illinois were based upon a far more direct relationship between Owens-Illinois and Owens-Corning Fiberglas than is alleged here between Novartis and aaiPharma (the purchaser of the NDA for Brethine): Owens-Illinois and Owens-Corning Fiberglas had co-marketed Kaylo for a number of years, Owens-Illinois maintained a partial ownership interest in Owens-Corning Fiberglas after it sold its Kaylo division, and the two companies historically shared a number of common directors and executive officers. (*Gillenwater v. Honeywell Intern., Inc.* (Ill.App.Ct. 2013) 996 N.E.2d 1179, 1194-1195; *Cadlo*, *supra*, 125 Cal.App.4th at p. 522.)

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[9] Plaintiffs' suggestion that federal law creates a "one-way ratchet" whereby a warning would remain on the drug label indefinitely is incorrect. (Slip Opn. 19, fn. 4.) Federal law requires the removal of a drug warning from a label if not warranted by the available evidence. (*Dobbs v. Wyeth Pharmaceuticals* (2011) 797 F. Supp. 2d 1264, 1276 [FDA required drug manufacturer to remove warning language because causal association had not been established].)

Notwithstanding the corporate relations, *Cadlo* rejected the plaintiffs' claim that former manufacturer Owens-Illinois owed a duty of care to Owens-Corning Fiberglas's customers:

> After [its sale of the product line in] 1958, Owens-Illinois made no representations about Kaylo, false or otherwise. Cadlo's first exposure to Kaylo was in 1965, and the Kaylo to which he was exposed was manufactured by [Owens-Corning Fiberglas]. Consequently, any misrepresentations about Kaylo's safety on which he might have relied would have been made by [Owens-Corning Fiberglas].

(*Cadlo*, *supra*, 125 Cal.App.4th at p. 520.) *Cadlo* dismissed the plaintiffs' claim that Owens-Illinois could be liable for indirect communications about Kaylo's safety, explaining that actionable communications would have to have been made specifically about Owens-Corning Fiberglas's Kaylo product. (*Id.* at p. 521.) The court concluded: "Owens-Illinois's historic role in the design, manufacture and marketing of Kaylo will not support plaintiffs' liability claims against Owens-Illinois in the absence of any allegation or evidence that Owens-Illinois had actual connection with the design, manufacture or distribution of the asbestos [in Kaylo] to which Anthony Cadlo was exposed." (*Id.* at p. 516.)

The Court of Appeal found *Cadlo* inapposite because Plaintiffs alleged they relied on Novartis's representations about Brethine before its sale of the NDA in 2001. (Slip Opn. 20, fn. 5.) But *Cadlo* explains that a former manufacturer can be liable only if it made misrepresentations specifically *about the subsequent manufacturer's product* to which plaintiff alleges exposure. (*Cadlo*, *supra*, 125 Cal.App.4th at pp. 520-521.) And *O'Neil* similarly expressly rejected the notion that a former manufacturer owes a duty of care based on the alleged impact a warning about its product

might have had on subsequent users of another manufacturer's product. (*O'Neil, supra*, 53 Cal.4th at p. 347.)

The United States Court of Appeals for the Ninth Circuit also rejected former manufacturer liability under California law in *Gansberger v. Rockwell International Corp.* (9th Cir. 1990) 911 F.2d 738, 1990 WL 115595, *3: "We conclude that Gansberger seeks a broad extension of tort law to reach a prior manufacturer. In the absence of clear direction from the California courts, we decline to approve this extension." There is also a solid wall of authority rejecting a former manufacturer duty of care in other jurisdictions, both in the pharmaceutical and non-pharmaceutical context.[10]

California law precludes the imposition of a duty of care on Novartis as the "former manufacturer" of a terbutaline drug.

B. Novartis should not be liable as a (former) manufacturer of the branded version of the generic drugs that allegedly caused Plaintiffs' injuries.

Remarkably, acceptance of Plaintiffs' "former manufacturer" theory alone was not and could not be sufficient to hold Novartis liable here because Novartis *never* manufactured the terbutaline drugs that allegedly caused Plaintiffs' injuries. The Court of Appeal relied on *Conte, supra*, 168 Cal.App.4th at pp. 100-102 to impose an *additional* duty of care on Novartis — an "innovator liability" duty that runs open-ended to consumers

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[10] For non-pharmaceutical cases, see *Emslie v. Borg-Warner Automotive, Inc.* (2d Cir. 2011) 655 F.3d 123, 126 [all-terrain vehicles]; *Emmons v. Bridgestone Americas Tire Operations, LLC* (E.D.Mo. Dec. 12, 2012, No. 1:10CV41 JAR) 2012 WL 6200411 [tire rims]; *Potwora v. Grip* (N.J. App. 1999) 725 A.2d 697, 701-04 [motorcycle helmets]; *Jones v. Borden Inc.* (E.D.La. Aug. 28, 1995, No. Civ. A. No. 93-2620) 1995 WL 517298 [spray paint cans]; *Fricke v. Owens-Corning Fiberglas Corp.* (La.Ct.App. 1993) 618 So.2d 473 [vinegar].

allegedly injured by generic terbutaline drugs manufactured by competitor drug companies. *Conte* is inconsistent with California law.

In announcing its theory of "innovator liability," *Conte* acknowledged there could be no strict product liability in California against a defendant that did not manufacture the product that allegedly caused harm. (*Conte*, *supra*, 168 Cal.App.4th at pp. 100-102.) But, *Conte* erroneously concluded that "the rule that a plaintiff in a *products liability* case must prove the defendant made or sold the allegedly defective product that causes injury *sheds no light* on" whether a manufacturer could be held liable in *negligence* for injury caused by another company's product. (*Id.* at p. 102, italics added.) Working backwards, *Conte* reasoned that "risk reasonably to be perceived defines the duty to be obeyed" and held that "in this case our duty analysis must look primarily to the foreseeability of physical harm." (*Id.* at pp. 103, 104, internal citation omitted.)

O'Neil, however, expressly rejects the distinction *Conte* drew between strict product liability and negligence. (*O'Neil*, *supra*, 53 Cal.4th at p. 356.) *O'Neil* holds that the policy considerations precluding the imposition of strict liability on a non-manufacturer "apply with equal force in the context of negligence." (*Id.* at p. 366.) This is consistent with *Sindell*'s rejection of negligence liability for injury caused by another manufacturer's drug in a product liability case. (*Sindell*, *supra*, 26 Cal.3d at p. 595.) *O'Neil* also rejects predicating a non-manufacturer negligence duty on foreseeability, explaining that "foreseeability alone is not sufficient to create an independent tort duty." (*O'Neil*, *supra*, 53 Cal.4th at p. 362, internal citation omitted.)

O'Neil further cautioned that in "some cases, when the consequences of a negligent act must be limited to avoid an intolerable burden on society,

policy considerations may dictate a cause of action should not be sanctioned no matter how foreseeable the risk." (*O'Neil*, *supra*, 53 Cal.4th at p. 364, internal citation and quotation marks omitted; see also *Bily v. Arthur Young & Co.* (1992) 3 Cal.4th 370, 397 [courts "have invoked the concept of duty to limit generally the otherwise potentially infinite liability which would follow from every negligent act," internal citation and quotation marks omitted].) *Conte's* construct would impose a new and infinite duty upon a prescription drug manufacturer in California for products it did not make, notwithstanding the havoc such an expanded tort theory could wreak upon the workings of the complex federal regulatory scheme and the consumers it protects. That is exactly the case that should not be sanctioned no matter how "foreseeable" the risk to a generic prescription drug user because "[s]ocial policy must at some point intervene to delimit liability even for foreseeable injury." (*O'Neil*, *supra*, 53 Cal.4th at pp. 365-366, internal citation and quotation marks omitted.)

In no small part due to its breathtaking run past traditional tort boundaries, *Conte*'s "innovator liability" theory has been squarely rejected by scores of other courts all over the country. In a recent opinion, the United States Court of Appeals for the Sixth Circuit reviewed the legal landscape and found "an overwhelming majority of courts, in at least fifty-five decisions from twenty-two states, have rejected 'the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug.'" (*In re Darvocet, Darvon, and Propoxyphene Products Liability Litigation* (6th Cir. 2014) 756 F.3d 917, 938-939.) Those fifty-five decisions included rulings by each of the six federal Courts of Appeals that had addressed the issue. (*Id.* at p. 939.)

The Sixth Circuit identified a number of policy considerations weighing against innovator liability. First, in an analysis echoing *O'Neil* and *Sindell*, the Sixth Circuit said "[p]ermitting negligence claims against one manufacturer for injuries caused by a competitor's products would reflect an 'unprecedented departure from traditional . . . tort law.'" (*In re Darvocet, supra*, 756 F.3d at pp. 943, 944-945, 947, internal citations omitted.) Second, the Sixth Circuit found it improper to punish brand manufacturers for any alleged foreseeability of harm arising from Congress's policy decisions to lower the barriers of entry for generic drugs through mandates of parallel labeling. (*Id.* at pp. 944, 945, 947.) Third, mirroring this Court's concerns in *Brown*, the Sixth Circuit warned "there are grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher priced brand name drugs and fewer innovative drugs." (*Id.* at pp. 944, 947-948.)

The Sixth Circuit's opinion actually understates the breadth of the national consensus on this issue. Innovator liability now has been rejected in thirty-five states in about one hundred decisions. (Drug and Device Law, *Innovator Liability at 100* (July 18, 2014), <http://druganddevicelaw .blogspot.com/2014/07/innovator-liability-at-100.html> [last accessed on Aug. 4, 2016].) Twenty-eight of those decisions expressly considered and rejected *Conte*'s analysis.[11] These courts have explained that "*Conte* is

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[11] *In re Darvocet, supra*, 756 F.3d at p. 941; *Johnson v. Teva Pharmaceuticals USA, Inc.* (5th Cir. 2014) 758 F.3d 605, 614-616. fn.3; *Moretti v. Wyeth, Inc.* (9th Cir. 2009) 579 F.Appx 563, 564; *Guarino v. Wyeth, LLC* (11th Cir. 2013) 719 F.3d 1245, 1251-1253; *Schrock v. Wyeth, Inc.* (10th Cir. 2013) 727 F.3d 1273, 1281-1286; *Strayhorn v. Wyeth Pharmaceuticals, Inc.* (6th Cir. 2013) 737 F.3d 378, 403-405; *Smith v. Wyeth, Inc.* (6th Cir. 2011) 657 F.3d. 420, 423-424; *Mensing v. Wyeth, Inc.* (8th Cir. 2009) 588 F.3d 603, 612-614, revd. in part on other grounds; *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, reaffd. in pertinent part and vacated in part on other grounds, *Mensing v. Wyeth, Inc.* (8th Cir. 2011)

anomalous." (*Burke v. Wyeth, Inc.* (S.D.Tex. Oct. 29, 2009, No. CIV. G-09-82) 2009 WL 3698480, *3; *Washington ex rel. Washington v. Medicis Pharmaceuticals Corp.* (S.D.Miss. Feb. 7, 2013, No. 3:12CV126-DPJ-FKB) 2013 WL 496063, *4 ["*Conte* broke from the majority rule and, since that departure, *Conte* has gained little traction"]; *Phelps v. Wyeth, Inc.* (D.Or. May 28, 2010, No. 09-6168-TC) 2010 WL 2553619, *2 ["I cannot find that a decision to hold a manufacturer liable for injury caused by its competitor's product is rooted in common sense"]; *Moretti v. Wyeth, Inc.*

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658 F.3d 867; *Tsavaris v. Pfizer, Inc.* (S.D.Fla. Jan. 7, 2016, No. 1:15-cv-21826-KMM) 2016 WL 80221, *10, app. pending (11th Cir. Feb. 8, 2016, No. 16-10541); *Gardley-Starks v. Pfizer, Inc.* (N.D.Miss. 2013) 917 F.Supp.2d 597, 601-604, fn. 4; *Washington ex rel. Washington v. Medicis Pharmaceuticals Corp.* (S.D.Miss. Feb. 7, 2013, No. 3:12cv126) 2013 WL 496063, *2-4; *Baymiller v. Ranbaxy Pharmaceuticals, Inc.* (D.Nev. 2012) 894 F.Supp.2d 1302, 1309-1311; *Phelps v. Wyeth, Inc.* (D.Or. 2012) 857 F.Supp.2d 1114, 1120-1121; *Metz v. Wyeth, LLC* (M.D.Fla. 2011) 830 F.Supp.2d 1291, 1293-1295, affd. (11th Cir. 2013) 525 F.Appx 893; *Levine v. Wyeth, Inc.* (M.D.Fla. 2010) 684 F.Supp.2d 1338, 1344-1346; *Howe v. Wyeth, Inc.* (M.D.Fla. Apr. 26, 2010, No. 8:09-CV-610-T-17AEP) 2010 WL 1708857, *3-4; *Craig v. Pfizer, Inc.* (W.D.La. May 26, 2010, No. 3:10-00227) 2010 WL 2649545, *2-4, adopted (W.D.La. June 29, 2010) 2010 WL 2649544; *Fisher v. Pelstring* (D.S.C. July 28, 2010, No. 4:09-cv-00252) 2010 WL 2998474, *2-4; *Finnicum v. Wyeth, Inc.* (E.D.Tex. 2010) 708 F.Supp.2d 616, 620-622; *Hardy v. Wyeth, Inc.* (E.D.Tex. Mar. 8, 2010, No. 909CV152) 2010 WL 1049588, *2-5, adopted (E.D.Tex. Mar. 29, 2010) 2010 WL 1222183; *Burke v. Wyeth, Inc.* (S.D.Tex. Oct. 29, 2009, No. G-09-82) 2009 WL 3698480, *2-3; *Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, 369-381; *Gross v. Pfizer, Inc.* (D.Md. Nov. 9, 2010, No. 10-CV-00110-AW) 2010 WL 4485774, *2-3; *Meade v. Parsley* (S.D.W.Va. Nov. 13, 2009, No. 2:09-cv-00388) 2009 WL 3806716, *2-3; *Anselmo v. Sanofi-Aventis Inc. USA* (D.Kan. Oct. 13, 2014, No. 10-CV-77) 2014 WL 8849464, *2; *Franzman v. Wyeth, Inc.* (Mo.Ct.App. 2014) 451 S.W.3d 676, 689-692; *Short v. Eli Lilly & Co.* (Ind.Super.Ct. Mar. 25, 2009, Nos. 49D12-0601-CT-2187, 4:13-cv-00539-VEH) 2009 WL 9867531, *4-7.

(D.Nev. Mar. 20, 2009, No. 2:08-CV-00396-JCM (GWF)) 2009 WL 749532, *4 ["Simply put, *Conte* stands alone"].)

This Court should reemphasize the boundaries established over decades of product liability law and reject innovator liability in California.

CONCLUSION

Because it rests on two separate, improper expansions of a manufacturer's duty of care, the Court of Appeal's opinion should be reversed and the cause remanded to the trial court with directions to enter judgment for Novartis.

Dated: August 8, 2016

Respectfully submitted,

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CERTIFICATE OF WORD COUNT

Pursuant to rule 8.204(c)(1) of the California Rules of Court and in reliance on the word count of the computer program used to prepare this Opening Brief, counsel certifies that this Opening Brief was produced using 13-point type and contains 7,466 words.

Dated: August 8, 2016

for

Eric G. Lasker

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Executed at San Diego, California, August 8, 2016.

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