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