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

REPLY BRIEF ON THE MERITS

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INTRODUCTION

The Court of Appeal dismantled "the boundaries established over decades of product liability law," *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 365, which limit a manufacturer's liability to injuries caused by its own products. Novartis Pharmaceuticals Corporation did not manufacture either of the generic drugs alleged to have caused Plaintiffs' injuries. But the Court of Appeal held this dispositive fact irrelevant and imposed a negligence duty on Novartis because: (1) six years prior to Plaintiffs' alleged injuries, Novartis had produced a branded version of the generic drugs at issue (the "former manufacturer duty") and (2) the generic drug manufacturers provided the same label warnings as the manufacturer that had purchased the branded drug product line from Novartis (the "innovator duty").

In asking this Court to uphold the Court of Appeal's extraordinary ruling, Plaintiffs misstate *O'Neil* and *Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588, both of which categorically reject the imposition of a negligence duty on manufacturers for failure to warn about injuries caused by other manufacturers' products. Plaintiffs also misconstrue the Restatement (Second) of Torts, which, as applied by this Court, requires a direct connection between a defendant and an alleged injury-producing product or actor for a duty to arise. Plaintiffs posture that the proposed rule is "longstanding" and "deeply rooted" in California's tort law. (ABOM:23, 26.) The opposite is true. (*O'Neil*, *supra*, 53 Cal.4th 335; *Sindell*, *supra*, 26 Cal.3d 588; see *Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513.)

The Court of Appeal did not and Plaintiffs do not cite any case in the history of California jurisprudence (or anywhere else) in which a negligence duty has been imposed arising from a defendant's status as a

former manufacturer. No such case exists. Plaintiffs' policy-based arguments in favor of a former manufacturer duty fare no better. Plaintiffs ignore the comprehensive federal regulatory regime for prescription drugs that imposes a duty to warn exclusively on current drug manufacturers and expressly prohibits former drug manufacturers from making any safety representations about their prior products. Plaintiffs likewise ignore routine due diligence practices and settled contract law that prevent their bogeyman scenario of a manufacturer earning a windfall profit by selling off a product line without disclosing product risks. The proposed duty would serve only to protect subsequent manufacturers who fail to update warning labels (so as to increase their own sales), by allowing them to point the finger back to a former manufacturer.

Plaintiffs likewise cannot dispute the overwhelming judicial rejection of the Court of Appeal's additional proposed duty on innovator manufacturers. (See generally *In re Darvocet, Darvon, and Propoxyphene Prods. Liab. Litig.* (6th Cir. 2014) 756 F.3d 917, 938-939.) Imposition of an innovator duty would disrupt a carefully constructed two-tiered prescription drug market created under federal law to spur innovation while constraining drug costs. This regulatory scheme relies upon the continued presence of the innovator or brand manufacturer – *i.e.*, the holder of the New Drug Application ("NDA") – after generic manufacturers enter the market, even as the brand manufacturer's market share rapidly diminishes. If the cost of this diminished market share is expansive liability for competitor generic drugs, brand manufacturers will sever their association with the drugs by withdrawing their NDAs, leaving the public without a key player in ongoing safety monitoring and labeling, and chilling research into new uses of existing drugs..

The Court of Appeal's flawed decision should be reversed.

LEGAL ARGUMENT

The "scope of defendants' duty, and the existence of duty is a pure question of law." (*O'Neil, supra*, 53 Cal.4th at pp. 363-364.) The Court of Appeal imposed two duties to warn consumers of another manufacturer's product, each of which is a necessary part of plaintiffs' negligence claim against Novartis. First, the Court of Appeal imposed a duty on former drug manufacturers that extends indefinitely to consumers of the drug subsequently manufactured by others. Second, the Court of Appeal imposed a duty on innovator drug companies that extends over the entire market to consumers of competing drug companies' copy-cat generic drugs. These rulings were in error.

This Court has stressed the vital importance of delineating duty so as to prevent unlimited escalations of tort liability. There "are clear judicial days on which a court can foresee forever and thus determine liability but none on which that foresight alone provides a socially and judicially acceptable limit on recovery of damages for [an] injury." (*Erlich v. Menezes* (1999) 21 Cal.4th 543, 552.) This judicial limit serves as a necessary check on the creativity of plaintiffs' counsel, who otherwise would be able to inundate the courts with all manner of cases alleging "foreseeable" consequences of corporate conduct.[1] The Court of Appeal's

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[1] Plaintiffs' allegations in this case amply demonstrate the lengths of plaintiffs' counsel's creativity. Plaintiffs offer no factual bases for their outlandish claims that Novartis concealed safety information to earn a windfall profit when it sold the Brethine NDA in 2001 or that Novartis had any reason to expect that the company that purchased the NDA (aaiPharma) would ignore subsequent scientific research allegedly demonstrating a safety risk. To the contrary, the same FDA Citizen's Petition cited by Plaintiffs (ABOM:16, fn. 7) concluded in 2011 – *some 10 years after Novartis sold its NDA* – that "[a]t the present time, it is not possible to draw conclusions regarding an association between terbutaline exposure in utero and autism." See FDA Response to Citizen's Petition (Feb. 17, 2011), at p.

broad imposition of two separate duties on Novartis to warn about drugs it did not manufacture blew past this limit and is contrary to California law.

I. CALIFORNIA LAW REJECTS THE IMPOSITION OF A NEGLIGENCE DUTY OWED TO CONSUMERS INJURED BY ANOTHER MANUFACTURER'S PRODUCT.

Plaintiffs' argument that Novartis owes them a duty to warn consumers of two other manufacturers' drug products is directly contrary to *O'Neil* and *Sindell* and disregards well-established California law. (*Garcia v. Joseph Vince Co.* (1978) 84 Cal.App.3d 868, 874 ["Regardless of the theory which liability is predicated upon, whether negligence, breach of warranty, strict liability in tort, or other grounds, it is obvious that to hold a producer, manufacturer, or seller liable for injury caused by a particular product, there must first be proof that the defendant produced, manufactured, sold, or was in some way responsible for the product . . . ."].)[2]

13, <http://www.fda.gov/downloads/drugs/drugsafety/ucm243797.pdf5> [last accessed Nov. 4, 2016]. Plaintiffs' allegations regarding off-label promotion likewise ignore the undisputed fact that the Brethine label in 2001 included a warning against the use of the drug as a tocolytic. (ABOM:16 & fn. 7.)

[2] In *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063, this Court pointed to the unique and critical value of prescription drugs and warned against expansive theories of tort liability in prescription drug litigation. Relying on *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, Plaintiffs contend this concern should not immunize "Big Pharma" from tort liability, pointing to the fact that pharmaceutical companies are subject to the same type of strict liability failure to warn claims as other product manufacturers. But the question here is whether this Court should impose unique and more expansive duties on pharmaceutical manufacturers, duties *that do not exist for any other industry*. It should not.

A. *O'Neil* holds that a product manufacturer may not be held liable in negligence for harm caused by another manufacturer's product.

O'Neil is clear and unequivocal. Save for two exceptions (neither of which applies here), *O'Neil* "hold[s] that a product manufacturer may not be held liable *in strict liability or negligence* for harm caused by another manufacturer's product." (*O'Neil*, 53 Cal.4th at p. 342 [emphasis added].)

Remarkably, Plaintiffs dismiss this holding as "a stray quote from the beginning of the decision." (ABOM:30, fn. 10.) Plaintiffs argue instead that *O'Neil's* holding "only applies to strict liability claims, not negligence claims," pointing to a sentence buried some 20 pages into the opinion at the end of this Court's strict liability analysis. (*Id.* at pp. 29-30 [quoting *O'Neil*, *supra*, 53 Cal.4th at p. 362].) Plaintiffs simply ignore this Court's explanation in its subsequent negligence analysis that "[t]he same policy considerations that militate against imposing strict liability in this situation [of harm caused by another manufacturer's product] apply with equal force in the context of negligence." (*O'Neil*, *supra*, 53 Cal.4th at p. 366.)

O'Neil repeatedly explains that its holding applies to both strict liability and negligence claims. *O'Neil* states that the fact that "the defendant manufactured, sold, or supplied the injury-causing product is a separate and threshold requirement that must be independently established. Moreover, 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 [emphasis added].) *O'Neil* cites favorably to the Washington Supreme Court's holding that "the duty to warn, *in negligence* or strict liability, extends only to those entities in the chain of distribution of a hazardous product" and "[t]he general rule [is] that there is no duty under

common law products liability *or negligence* principles to warn of the dangers . . . in other manufacturers' products." (*Id.* at p. 356 [emphasis added] [citing *Simonetta v. Viad Corp.* (Wash. 2008) 197 P.3d 127, 133-134, 138; *Braaten v. Saberhagen Holdings* (Wash. 2008) 198 P.3d 493, 495].) The heading for *O'Neil's* analysis of plaintiff's negligent failure-to-warn claim likewise is unambiguous – there is "no duty of care to prevent injuries from another manufacturer's product." (*O'Neil, supra*, 53 Cal.4th at p. 363.)

Plaintiffs' argument that strict liability and negligence are distinct causes of action misses the point. (ABOM:32.) *O'Neil* recognizes this distinction and properly analyzes each claim separately. But *O'Neil* holds that a plaintiff must – ***under both theories*** – satisfy the same threshold requirement that the defendant manufacturer manufactured the alleged injurious product. (*O'Neil, supra*, 53 Cal.4th at p. 362.)

O'Neil's rejection of a negligence duty under *Rowland v. Christian* (1968) 69 Cal.2d 108 is categorical and in no way limited to the facts before the Court.[3] For each of the *Rowland* factors, *O'Neil* explains that the balance weighs against imposing a negligence duty whenever a product manufacturer is sued for injury caused by another manufacturer's product.

[3] The only case-specific fact cited by *O'Neil* in its *Rowland* analysis is the passage of time between the defendant's sale of its product and the plaintiff's alleged exposure, which the Court considered in analyzing the "closeness of the connection" factor. (*O'Neil, supra*, 53 Cal.4th at p. 364.) Even there, the fact provided only secondary support to the Court's primary finding that a defendant who does not manufacture, sell, or supply the alleged injury-causing product is extremely remote from the alleged injury. (*Ibid.*) In this case, of course, Plaintiffs want the Court to create a duty to warn consumers of other manufacturer's products that extends indefinitely, even decades after a defendant left the market entirely. (ABOM:69.)

(*O'Neil*, *supra*, 53 Cal.4th at p. 365; OBOM:19-20.) *O'Neil* concludes its negligence analysis with a broad repudiation of such a duty:

> In short, expansion of the duty of care as urged here would impose an obligation to compensate on those whose products caused no harm. To do so would exceed the boundaries established over decades of product liability law. [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 omitted.)

Plaintiffs' attempt to distinguish *O'Neil* on its facts is misguided. Plaintiffs argue that "the key fact that makes [this case] different from *O'Neil*" is that "even though Plaintiffs were injured by another manufacturer's product, Novartis is being sued for breaching its own independent duty with regard to its own product." (ABOM:36.) Plaintiffs stress that they do not contend Novartis is liable for doing – or not doing – anything after it sold the Brethine NDA in December 2001. (ABOM:21.) But that is the same argument rejected in *O'Neil*. (See *O'Neil*, *supra*, 53 Cal.4th at p. 347 [reversing Court of Appeal's ruling that defendants could be liable because if they "had warned the hypothetical original user [of their own products], or protected that person by avoiding defective design, subsequent users, too, would have been protected"].) The *O'Neil* defendants likewise owed a duty to warn of risks posed by their own pre-replacement asbestos-containing products, and they have been held liable for negligent failure to warn in cases in which plaintiffs were exposed to their products. (*Paulus v. Crane Co.* (2014) 224 Cal.App.4th 1357, 1360 & fn. 2; *Faddish v. Warren Pumps, LLC* (E.D.Pa. Oct. 22, 2010, Civ. A. No. 09-70626) 2010 WL 4178337, *1, *2.) *O'Neil* holds, however, that this

negligence duty cannot be extended to injuries caused by another manufacturer's product.

B. *Sindell* rejects the proposed negligence duty in pharmaceutical cases.

The duty to warn about another manufacturer's product likewise was rejected specifically in the context of pharmaceutical products litigation in *Sindell v. Abbott Laboratories*, *supra*, 26 Cal.3d at p. 605. *Sindell* holds that a drug manufacturer may not be held liable "if it could be demonstrated that the product which caused the injury was not made by the defendant." (*Ibid.*) Plaintiffs dismiss this holding in a footnote, claiming that *Sindell* is inapposite because it "involve[d] strict-product liability claims, not negligent-misrepresentation claims." (ABOM:36, fn. 14.) Not so.

In *Sindell*, the plaintiff's first cause of action alleged "that defendants were jointly and individually *negligent* in that they manufactured, marketed and promoted [the drug at issue] . . . *without adequate* testing or *warning*." (*Sindell*, *supra*, 26 Cal.3d at p. 595 [emphasis added]; see also *id.* at p. 601.) The *Sindell* plaintiff relied on *Summers v. Tice* (1948) 33 Cal.2d 80 and *Orser v. George* (1967) 252 Cal.App.2d 660, both of which addressed negligence (see *Sindell*, *supra*, 26 Cal.3d at pp. 598-599, 606), and on the Restatement Second of Torts, section 433B, which is part of the Restatement's Chapter 16 discussion of the "Causal Relationship Necessary to Responsibility for Negligence." (*Id.* at p. 599.) Aside from a passing reference to plaintiff's other causes of action (*id.* at p. 595), the doctrine of strict liability played no role in *Sindell*'s holding.

In *Jolly v. Eli Lilly & Co.* (1988) 44 Cal.3d 1103, 1108, 1115, the Court confirmed that its ruling in *Sindell* was based on negligent failure to

warn. And the Court again held that such a negligence claim cannot lie against a drug company for an injury caused by another manufacturer's drug. (*Id.* at p. 1115 & fn. 15.)

C. The Restatement of Torts does not support the proposed negligence duty.

Nor does Restatement Second of Torts, sections 310 and 311, support the negligence duties proposed by the Court of Appeal. Sections 310 and 311 provide that a party may be liable for a misrepresentation to a third party if it is foreseeable that such misrepresentation may cause an injury to the plaintiff. But sections 310 and 311 only apply if the misrepresentation is specific to the product or chattel that is alleged to have caused harm. (*Id.*, § 310, coms. b-c, pp. 103-105; § 311, coms. c-e, pp. 107-109.)

Comment b to section 310 explains that a party may be liable for a misrepresentation "concerning the physical condition of a thing" giving rise to injury such as "the ice on a certain pond" or a "bottle of whiskey." Comment c to section 310 explains that a party may be liable when the party "actively conceal[s] a defect" in a particular chattel such as "a defective wheel or axle" of an automobile. Likewise, the illustrations to comments c, d, and e of section 311 discuss misrepresentations regarding the specific alleged injury-causing products, such as a "tombstone" and a "boiler." None of the comments to these Restatement sections suggest liability based on representations regarding a different product.

Aside from *Conte* – which has been uniformly rejected – the California cases cited by Plaintiffs to support their construction of the Restatement involve defendants who made misrepresentations about the injury-causing product or individual. The defendant in *Hanberry v. Hearst*

Corp. (1969) 276 Cal.App.2d 680, 683, placed its Good Housekeeping seal of approval on the product alleged to have caused the plaintiff's injury. On those facts, the Court held that "[s]ince the very purpose of [the defendant's] seal and certification is to induce consumers to purchase products so endorsed, it is foreseeable certain consumers will do so, relying upon respondent's representations concerning them, in some instances, even more than upon statements made by the retailer, manufacturer or distributor." (*Id.* at p. 684.) The defendant in *Garcia v. Superior Court* (1990) 50 Cal.3d 728, 733, made assurances to the plaintiff-decedent that she was safe from the individual who subsequently killed her. The defendants in *Randi W. v. Muroc Joint Unified School Dist.* (1997) 14 Cal.4th 1066, 1081, provided letters of recommendation for a school administrator – who subsequently molested several students – without disclosing their knowledge of that administrator's history of sexual misconduct.

In sharp contrast, our Plaintiffs concede that Novartis made no representation whatsoever regarding the generic terbutaline drugs that allegedly caused their 2007 injuries. (ABOM:21.) Sections 310 and 311 do not apply.

II. NEITHER CALIFORNIA LAW NOR CALIFORNIA POLICY SUPPORTS THE COURT OF APPEAL'S BREAK FROM ESTABLISHED PRECEDENT TO ADOPT A NOVEL "FORMER MANUFACTURER" THEORY OF LIABILITY.

A. The Court of Appeal imposed a duty on Novartis as a former manufacturer that is unprecedented in California and in the United States generally.

The Court of Appeal's imposition on Novartis of a duty to warn about a product sold by other manufacturers six years after Novartis left the

market is unprecedented and contrary to a solid wall of legal authority. Plaintiffs do not – because they cannot – point this Court to any other case imposing the Court of Appeal's proposed duty. Nor do they explain why the Court should depart from the holdings in *O'Neil*, *Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513, *Gansberger v. Rockwell Internat. Corp.* (9th Cir. Aug. 9, 1990, No. 89-15687) 911 F.2d 738 [1990 WL 115595], or any of the similar holdings across the country rejecting such a duty in both pharmaceutical and non-pharmaceutical cases. (OBOM:25, 29, fns. 8, 10.)

Plaintiffs offer three suggestions to counter or distinguish the collective wisdom of every court – including this Court – that has rejected their proposed former manufacturer duty.

First, Plaintiffs suggest (incorrectly) that *O'Neil* does not involve a former manufacturer. (ABOM:35, 70.) While *O'Neil* arose in a component parts setting, the plaintiff there also sought to hold defendants liable for their alleged failure to warn about their original asbestos-containing gaskets and packing, which warning plaintiff alleged would have protected him against injury from the subsequent manufacturer's identical replacement parts. (*O'Neil*, 53 Cal.4th at p. 347.) If this "former manufacturer" duty had been accepted, the Court would not need to have considered the additional component parts argument.

Second, Plaintiffs suggest that prior (and uniformly adverse) case law all turned on a determination that the former manufacturer could not have foreseen that a subsequent manufacturer would continue to provide (or fail to provide) the same product warnings. (ABOM:56, fn. 19.) Plaintiffs are wrong. Plaintiffs cite only to *Cadlo*, *supra*, 125 Cal.App.4th at pp. 517-518, but foreseeability was a certainty there – plaintiff specifically alleged

that the former manufacturer had "approved [the subsequent manufacturer's] failure to warn of the known hazards of [the product]," "agreed [with the subsequent manufacturer] to the fraudulent concealment of [the product's] hazardous qualities and agreed not to warn purchasers during the course of their distribution agreement" extending 5 years after the sale of the product line. Nonetheless, *Cadlo* held that the foreseeable consequences of the former manufacturer's pre-divestment warnings could not support a finding of liability based on post-divestment product injury. (*Id.* at p. 520 [noting that "[a]fter 1958, Owens-Illinois made no representations about Kaylo, false or otherwise"].)

Plaintiffs have it exactly backwards in their related argument that FDA regulations make it more foreseeable that a subsequent manufacturer would leave the former manufacturer's label unchanged. A drug company that purchases an NDA is subject to independent legal obligations under federal statute to update product warnings immediately upon obtaining the NDA and on an ongoing basis thereafter as soon as reasonable evidence of a health hazard emerges. (21 C.F.R. §§ 314.72, 201.80(e).)[4] A new NDA holder that fails to meet those responsibilities is subject to a host of FDA enforcement actions. (21 C.F.R. §§ 331(a)(b)(ii), 332, 333(b), 334, 335a, 335b.) Thus, again, in every pharmaceutical case in which this former manufacturer duty has been alleged, it has been rejected. (E.g., *Lyman v.*

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[4] Plaintiffs inexplicably cite 21 U.S.C. § 355 and 21 C.F.R. § 314.105(b) as requiring a new NDA holder to use the same warning label used by the prior NDA holder. (ABOM:53.) They do not. 21 U.S.C. § 355 sets forth broad obligations for NDA holders generally and in fact requires new NDA holders to monitor safety information and to keep labeling up to date. (*Id.* at § 355(o).) 21 C.F.R. § 314.105(b) likewise addresses NDA holders generally and provides that the FDA will not approve drug labeling if it does not contain appropriate safety warnings.

Pfizer, Inc. (D.Vt. July 20, 2012, No. 2:09-cv-262) 2012 WL 2970627, *16-17.)

Third, Plaintiffs suggest that none of the prior cases rejecting former manufacturer liability involved a negligent misrepresentation claim. (ABOM:71.) Plaintiffs again are incorrect. (See *Cadlo*, *supra*, 125 Cal.App.4th at pp. 519-521 [demurrer properly sustained on negligent misrepresentation claim]; *In re Darvocet, Darvon and Propoxyphene Products Liability Litigation* (E.D.Ky. Mar. 7, 2012, Master File No. 2:11-md-2226-DCR) 2012 WL 767595, *6-8 [former manufacturer not liable under product liability or misrepresentation theories]; *Lyman*, *supra*, 2012 WL 2970627, *16-18 [dismissing negligence and fraudulent misrepresentation claims]; *In re Minnesota Breast Implant Litig.* (D.Minn. 1998) 36 F.Supp.2d 863, 873 [same].)

B. The Court of Appeal's proposed duty would create a disincentive for subsequent manufacturers to update warnings.

The Court of Appeal's proposed former manufacturer duty rests on the proposition that a subsequent drug manufacturer maintains the warning language used by the former manufacturer. (ABOM:63-64.) As Plaintiffs admit, only an actual change in the warning by the subsequent manufacturer would break the proposed chain of causation back to the former manufacturer. (*Ibid.*)[5]

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[5] Plaintiffs' reliance on *Cline v. Watkins* (1977) 66 Cal.App.3d 174 is misplaced. (ABOM:5.) In *Cline*, the defendant attorney had a direct fiduciary relationship with the plaintiff, and the issue before the Court was whether his direct negligence in failing to identify community property in a divorce action was excused by a subsequent attorney's failure to correct the error. Here, Novartis had no direct relationship with Plaintiffs.

Plaintiffs never address the major adverse health consequences that would follow from such a rule. Under this rule, subsequent manufacturers would have an incentive to increase sales by keeping old warning language in place – even in the face of new safety concerns – because any future product liabilities would be shared with the former manufacturer. This case illustrates the point: Plaintiffs allege in more than 15 paragraphs in their Amended Complaint that the subsequent NDA holder for Brethine, aaiPharma, disregarded six years of post-divestiture safety studies so as to maximize its own profits. (ABOM:18, citing AA034-039.) Under a former manufacturer duty rule, aaiPharma is protected from the full consequences of this alleged misconduct because it can point to an alternate, deep-pocket defendant (Novartis) to reduce its liability.

Similarly, Plaintiffs' proposed rule would reward a subsequent manufacturer for failing to promptly investigate the safety of its product. Plaintiffs suggest that a new NDA holder is allowed to delay its analysis of drug labeling until after it purchases an NDA and that "there is simply no telling how long it would take even a diligent drug company [after an NDA purchase] to recognize a deficiency in the label and put a new label in action." (ABOM:64.) But federal law properly prohibits such gaps in safety monitoring and drug labeling. A subsequent drug manufacturer is solely responsible for the safety and labeling of its drug *from the moment it purchases the NDA*. (21 C.F.R. § 314.72(a)(2).) Thus, a drug manufacturer considering the purchase of a drug product line analyzes the drug's safety prior to obtaining the NDA, insuring a seamless safety regime for drug users. This same type of pre-acquisition due diligence is standard as well in all other manner of business and product line acquisitions. (Gutterman, Business Transactions Solutions (2016) Products liability exposure in acquisition, § 92:14 ["Products liability issues are important

considerations in the overall due diligence in advance of a proposed merger or acquisition . . ."].)

For the same reason, Plaintiffs are wrong when they say that a former manufacturer can earn a windfall profit by failing to update its warnings prior to selling its product line. (ABOM:17-18, 65-66.) Through the due diligence process, the purchaser will be aware of the product's safety risks, and the risk of any potential future product liability claims will be factored into the sales price.[6] If the former manufacturer conceals those risks from the purchaser before the sale, the legal remedy is a direct action by the purchaser for breach of contract and fraud. (E.g., *Genesis Merchant Partners, L.P. v. Nery's USA, Inc.* (S.D.Cal. June 30, 2016, No. 11CV1589 JM(WVG)) 2016 WL 3548497, *2, fn. 3 [purchaser entitled to damages or rescission of contract where seller "materially overstated" distribution company's sale price "in light of undisclosed liabilities"].)

Plaintiffs' review of the *Rowland* factors in support of a "former manufacturer" duty repeatedly ignores the fact that traditional tort law *and* FDA regulations appropriately impose the product-warning duty on the current drug manufacturer. (ABOM:61-70.) A former drug manufacturer should not reasonably foresee that the subsequent NDA holder will violate its tort law and FDA regulatory obligations to properly label its drug – nor would it be wise policy to legitimize such a possibility as a matter of law. (OBOM:14.) The current NDA holder has the most up-to-date safety information about the drug and the closest connection with consumers of its product. Plaintiffs' claim that a former drug manufacturer may be "more

[6] For example, in this very case, Plaintiffs allege that aaiPharma was aware of the alleged safety risks of Brethine when it purchased the NDA from Novartis. (AA047.)

culpable" than the subsequent manufacturer for post-divestiture drug injuries (ABOM:62) ignores this fact and rewards the new NDA holder for dilatory safety monitoring and warnings.

Plaintiffs' *Rowland* analysis also conflicts with the FDA's determination about how to best assure drug safety. FDA protects patient safety by placing the duty to warn exclusively on the current drug manufacturer. (See also *O'Neil*, *supra*, 53 Cal.4th at p. 365 [expressing determination under tort law that a contrary doctrine would result in "an overabundance of potentially conflicting product warnings"].) Indeed, FDA regulations ***do not allow*** a former manufacturer to issue its own warning about the drug or to correct any alleged deficiency in a prior pre-divestiture warning. (OBOM:15.) The Court of Appeal thus would impose potentially unending liability on a former drug manufacturer for alleged prior misconduct that the manufacturer is legally powerless to cure.

The Court of Appeal's proposed duty also would disrupt settled expectations in business transactions that account for the transfer of risk in pricing an NDA sale. And the duty would wreak havoc on an insurance market predicated on products-based liability coverage. (See *Armstrong World Industries, Inc. v. Aetna Casualty & Surety Co.* (1996) 45 Cal.App.4th 1, 63 ["coverage is triggered only if the claimant was exposed to the *policyholder's product* either before or during the policy period."] [emphasis added].)[7]

The proposed "former manufacturer" duty simply would not work.

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[7] See, also, Geistfeld, *Legal Ambiguity, Liability Insurance, and Tort Reform* (2011) 60 DePaul L.Rev. 539 ("[L]egal ambiguity [in tort law] fuels the insurance cycle, yielding particular hard markets with substantial increases in premiums and reductions in the availability of coverage.").

III. *CONTE'S* "DRUG INNOVATOR" DUTY HAS FAILED THE TEST OF TIME.

A. *Conte's* innovator liability theory is contrary to well-established tort law.

Plaintiffs do not dispute that the innovator duty endorsed by the Court of Appeal as proposed by *Conte v. Wyeth* (2008) 168 Cal.App.4th 89 has been overwhelmingly rejected in more than 100 cases across the country. (OBOM:32.) Nor do they deny that 28 of those decisions expressly considered and rejected *Conte's* analysis. (*Ibid.*)[8] This Court should do the same.

Plaintiffs seek to bolster *Conte* by citing to California's purportedly unique adoption of Restatement Second of Torts, sections 310 and 311. As set forth, *supra*, at 18-19, sections 310 and 311 do not apply. Indeed, numerous other states have adopted sections 310 and 311, and they each have rejected innovator liability.[9]

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[8] Plaintiffs cite only two cases agreeing with *Conte*, neither of which is still governing authority. (*Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649 [reversed by statute, Ala. Code, § 6-5-530]; *Dolin v. SmithKline Beecham Corp.* (N.D.Ill. 2014) 62 F.Supp.3d 705 [prediction about Illinois law rejected by *In re Darvocet*, *supra*, 756 F.3d at pp. 943-946].)

[9] See *Mandel v. United States* (8th Cir. 1983) 719 F.2d 963, 968 [Arkansas law; applying section 310]; *Fullington v. Pfizer, Inc.* (8th Cir. 2013) 720 F.3d 739, 744 [rejecting innovator liability under Arkansas law]); *Passmore v. Multi-Management Servs. Inc.* (Ind. 2004) 810 N.E.2d 1022 [applying section 310]; *In re Darvocet, supra*, 756 F.3d at p. 945 [rejecting innovator liability under Indiana law]; *Guidry v. United States Tobacco* (5th Cir. 1999) 188 F.3d 619, 627 [Louisiana law; applying sections 310 and 311]; *Johnson v. Teva Pharmaceuticals USA, Inc.* (5th Cir. 2014) 758 F.3d 605, 614-616 [rejecting innovator liability under Louisiana law].

Plaintiffs next argue that California law uniquely focuses on foreseeability as the basis for imposing a negligence duty. But *O'Neil* makes clear under California law as well that "foreseeability alone is not sufficient to create an independent tort duty." (*O'Neil*, *supra*, 53 Cal.4th at p. 364.) And foreseeability repeatedly is rejected as a basis for an innovator duty in other states.[10]

Plaintiffs' reliance on the distinction in California law between negligence and strict liability likewise is unavailing. Many other states recognize the same distinction, but their courts repeatedly reject an innovator duty for core policy reasons. (*Schrock v. Wyeth, Inc.* (10th Cir. 2013) 727 F.3d 1273, 1281-1284 [under Oklahoma law, "for a claim in negligence, whether or not a duty exists depends on the relationship between the parties" and "brand-name manufacturers do not have *any* relationship with [plaintiffs]" injured by a "competitor's product."].)[11]

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[10] See, e.g., *In re Darvocet*, *supra*, 756 F.3d at pp. 944, 945, 947, 951; *Smith v. Wyeth, Inc.* (6th Cir. 2011) 657 F.3d. 420, 423-424 [Kentucky law]; *Phelps v. Wyeth, Inc.* (D.Or. 2012) 857 F.Supp.2d 1114, 1120-1121 [Oregon law]; *Finnicum v. Wyeth, Inc.* (E.D.Tex. 2010) 708 F.Supp.2d 616, 620-622 [Texas law].

[11] See also *Guarino v. Wyeth, LLC* (11th Cir. 2013) 719 F.3d 1245, 1251-1253 [Florida law]; *Moretti v. Wyeth, Inc.* (9th Cir. 2014) 579 Fed. Appx. 563, 564 [Nevada law]; *Mensing v. Wyeth, Inc.* (8th Cir. 2009) 588 F.3d 603, 612-614 [Minnesota law]; *Foster v. American Home Products Corp.* (4th Cir. 1994) 29 F.3d 165, 168 [Maryland law]; *Moore v. Mylan, Inc.* (N.D.Ga. 2012) 840 F.Supp.2d 1337, 1344; *McNair v. Johnson & Johnson* (S.D.W.Va. June 26, 2015, No. 2:14-17463) 2015 WL 3935787, *6; *Fisher v. Pelstring* (D.S.C. July 28, 2010, No. 4:09-cv-00252-TLW) 2010 WL 2998474; *Goldych v. Eli Lilly & Co.* (N.D.N.Y. July 19, 2006, No. 5:04-CV-1477) 2006 WL 2038436, *3-8; *Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, 369-381; *Kelly v. Wyeth* (Mass. Super. Ct. May 6, 2005, No. CIV.A.MICV200303314B) 2005 WL 4056740, *2-5.

Plaintiffs' *Rowland* analysis fares no better. Plaintiffs rest their claim of foreseeability on the requirement that generic manufacturers use the same drug label as brand manufacturers, but this would impose a duty based not on "the foreseeable result of the brand manufacturer's conduct, but [on] the laws over which the brand manufacturers have no control." (*In re Darvocet, supra*, 756 F.3d at p. 944.) Further, Plaintiffs acknowledge that generic drug manufacturers have an independent duty to monitor drug safety and seek labeling changes if necessary. (ABOM:10.) Plaintiffs offer no explanation why brand drug manufacturers should foresee that generic drug manufacturers would disregard that duty or why it would be good policy to encourage generic manufacturers to do so.

Even more so than the "extremely remote" connection between the defendants and replacement part manufacturers in *O'Neil*, brand drug manufacturers have no meaningful connection to consumers of a competing manufacturer's generic drug. Nor do brand manufacturers bear a moral responsibility to protect users of their competitors' generic product. (*Huck, supra*, 850 N.W.2d at p. 376 [noting that "it would be 'especially unfair' to find brand manufacturers have a duty to those who take generic drugs 'when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising'"].)

Plaintiffs also ignore the significant financial burden that the proposed innovator duty would impose upon brand manufacturers in serving as the insurers of the (generally much larger) generic drug market. (See *Royal Neckware Co. v. Century City, Inc.* (1988) 205 Cal.App.3d 1146, 1153 [rejecting negligence duty under *Rowland* analysis based on financial burden it would place on defendants].)

Finally, Plaintiffs' assertion that an innovator liability duty would prevent future harm ignores "the grave health policy consequences associated with recognizing brand manufacturer liability in these situations including higher priced brand drugs and fewer innovator drugs." *In re Darvocet, supra*, 756 F.3d at p. 944. Moreover, brand manufacturers are required under federal law to properly label their branded drugs, and they are subject to liability to consumers of those drugs if they fail to do so. There is no basis for Plaintiffs' speculation that an added innovator duty is needed to enforce those existing legal obligations.

B. California should not adopt a new tort theory to counteract federal statutory and regulatory judgments in regulating prescription drugs.

With tort precedent and policy weighing heavily against innovator liability, Plaintiffs argue that this Court nonetheless should wield state common law to counteract what they allege are adverse consequences of Congressional and FDA policy judgments in regulating prescription drugs. (ABOM:7-12, 37-44.)

In particular, Plaintiffs argue that the Court should adopt innovator liability because the preemption holding in *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 612-613 leaves many consumers of generic drugs – although not (as they concede) these plaintiffs[12] – with no recourse against the manufacturer of the drug that injured them. (ABOM:48-49.) Plaintiffs are wrong, as illustrated by the at least 49 cases across the country rejecting

[12] Plaintiffs continue to pursue a claim below against the generic manufacturer of the drugs that allegedly caused their injury because of that manufacturer's purported improper off-label promotion. (ABOM:44, fn. 17.) Accordingly, Plaintiffs' separate reliance on their off-label promotion claims in support of innovator liability against Novartis (ABOM:46) is unavailing.

innovator liability after *Mensing* was decided. (See Beck & Herrmann, Drug and Device Law, Scorecard: Innovator Liability In Generic Drug Cases (Nov. 12, 2009), <https://www.druganddevicelawblog.com/2009/11/scorecard-non-manufacturer-name-brand.html> [last accessed on Oct. 21, 2016].) These courts explain that "using federal . . . laws designed to increase the availability of generic drugs as the basis of supplying the duty element for tort liability stretches foreseeability too far." (*In re Darvocet*, *supra*, 756 F.3d at p. 947.) Likewise, the United States Supreme Court in *Mensing* explained that "it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre." (*PLIVA*, *supra*, 564 U.S. at p. 625.) Rather, "[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire." (*Id.* at p. 626.)

Plaintiffs' conception of state common law as a sword to be used against purportedly unwise federal policy is seriously misguided. This Court has explained that state law must give way if it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." (*Dowhal v. SmithKline Beecham Consumer Healthcare* (2004) 32 Cal.4th 910, 929.) Plaintiffs' argument here, however, endorses a far more aggressive misuse of state law. Plaintiffs urge this Court to adopt an extraordinary, expansive, and novel state tort law duty for the express purpose of nullifying federal law policy judgments governing the regulation of prescription drugs. The Court's endorsement of such a nullification argument would have far-reaching implications that would extend well beyond the present case. Similar nullification arguments were used as a basis for resisting federal civil rights legislation in the 1960s, and nullification arguments more recently have been revived by states seeking to block the implementation of the Affordable Care Act. (Lusky, *Racial*

Discrimination and the Federal Law: A Problem of Nullification (Nov. 1963) 63 Colum. L.Rev. 1163; Card, *Can States "Just Say No" to Federal Healthcare Reform? The Constitutional and Political Implications of State Attempts to Nullify Federal Law* (Nov. 1, 2010) 2010 B.Y.U. L.Rev. 1795.) The argument should not be entertained here.

Moreover, "courts are not institutionally qualified to balance the complex, interrelated, and divergent policy considerations in determining labeling and liability obligations of brand and generic pharmaceuticals." (*Huck, supra*, 850 N.W.2d at p. 377.)

Through carefully crafted legislation, Congress has made policy choices that impact the economics of prescription drug sales to increase access to medication. [Plaintiff] cites nothing in the text of the Hatch–Waxman Amendments or congressional record suggesting Congress intended to render brand defendants liable to consumers of generic products. To impose such liability would alter the relationship between generic and brand manufacturers. Specifically, extending liability to brand manufacturers for harm caused by generic competitors would discourage investments necessary to develop new, beneficial drugs by increasing the downside risks.

(*Ibid.*) Plaintiffs urge the Court to reach a different balance, but even a brief review of the Hatch-Waxman Amendments' objectives makes clear the peril of such judicial second-guessing.

The Hatch-Waxman Amendments were intended to achieve two vitally important public health goals. ***First***, the Amendments provide a necessary incentive for the development of new drugs by granting innovator manufacturers a period of market exclusivity for the new drug,

during which time competitor companies are excluded from the market. (See 21 U.S.C. §§ 335(c), 335(j)(5)(F); see also *Actavis Elizabeth LLC v. United States FDA* (D.C. Cir. 2010) 625 F.3d 760, 764 [explaining Congressional purpose to provide "incentives for innovation by granting five year exclusivity" to FDA-approved new drugs and barring sale of a competing drug].) ***Second***, the Amendments reduce prescription drug prices by allowing generic drug manufacturers to enter the market after the exclusivity period and sell lower-cost drugs that are bioequivalent to, and use the same FDA-approved labeling as, the branded drug. (See *PLIVA*, *supra*, 564 U.S. at pp. 612-613.)

Plaintiffs contend that innovator liability would not interfere with these federal objectives, but they do not offer anything but attorney argument to support their contention. They cannot dispute that imposing liabilities on brand manufacturers for generic drug use after the expiration of the exclusivity period would shift the financial balance struck under federal law to the detriment of innovators. Nor do they consider the likelihood that imposing an innovator duty would cause brand manufacturers to formally withdraw their NDA rather than risk liability for injuries caused by competing generic drugs, thus imposing added costs on generic drug manufacturers that would be required to assume a more central role in product safety labeling.

The federal regulatory scheme depends in part upon the continued presence of brand name drug manufacturers in the market after the end of the exclusivity period, despite a significantly diminished market share that drops to 11% of the drug market within a year. (Grabowski, Long & Mortimer, *Recent trends in brand-name and generic drug competition* (Dec. 6, 2013) J. Med. Econ. 2013, 1-8, 6-7, <http://fds.duke.edu/db/attachment/2575>.) NDA holders provide the market with established

safety monitoring programs and an anchor for drug labeling, while allowing generic manufacturers to continue to run more streamlined operations offering lower priced drugs. However, if the cost of retaining a diminishing 11% of the drug market is an assumed liability for 100% of all brand and generic drug sales, brand manufacturers will have a strong incentive to formally withdraw their NDA, leaving the public with 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 Nov. 5, 2016].) The withdrawal of NDAs also will impede further innovations through which brand manufacturers with strong research and development programs can investigate established drug products for additional therapeutic purposes.[13]

Plaintiffs weakly argue that the Court need not worry about the potential adverse public health impacts of an innovator liability rule because lawsuits like this one "are fairly rare." (ABOM:47.) But the stubborn persistence of the innovator liability theory requiring the judicial attention of – and rejection by – more than 100 courts to date amply demonstrates the falsity of that assertion.

It is time for the Court to put this theory to rest.

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[13] See, e.g., U.S. Department of Health and Human Services, Food and Drug Administration Guidance for Clinical Investigators, Sponsors, and IRBs: Investigational New Drug Applications (INDs) — Determining Whether Human Research Studies Can Be Conducted Without an IND, Sept. 2013, at http://www.fda.gov/downloads/Drugs/.../Guidances/UCM229175.pdf.

CONCLUSION

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: November 7, 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 brief, counsel certifies that this Reply Brief was produced using 13-point type and contains 6,857 words.

Dated: November 7, 2016

Eric Lasker (JYP)

Eric G. Lasker

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

Executed at San Diego, California, November 7, 2016.

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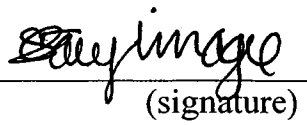
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