S233898

IN THE

SUPREME COURT OF CALIFORNIA

T.H., A MINOR, 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

Plaintiffs' Consolidated Answer to Amicus Curiae Briefs in Support of Respondent

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Novartis's amici argue, predictably, that allowing brand-name manufacturers to be held liable for injuries caused by generic drugs would up-end California tort law and wreak havoc on the drug industry. None of amici's arguments withstands scrutiny.

I. Brand-Name Liability Is Entirely Consistent with California Tort Law.

A. Novartis Can Be Held Liable Even Though It Did Not Manufacture the Drug That Injured Plaintiffs.

Amici's principle legal argument is that Novartis can't be held liable because it didn't make the actual drug that injured Plaintiffs, a fact that would be fatal to Plaintiffs' claims under the law of strict products liability.

This argument fails on multiple levels.

1. Plaintiffs Seek Recovery for Negligent Misrepresentation Under Section 311 of the Restatement of Torts.

First, this is not a product-liability case, and the wrongdoing at issue does not concern the actual product that injured Plaintiffs. Rather, Plaintiffs seek recovery for Novartis's negligent misrepresentation of the risks of its *own* product, a

claim under Section 311 of the Restatement (Second) of Torts. And it has long been recognized that a negligent-misrepresentation claim involving physical injuries caused by a product is distinct from a products-liability claim. (See *Hanberry v. Hearst Corp*. (1969) 276 Cal.App.2d 680, 688–689 [recognizing negligent-misrepresentation claim based on reliance on "commercial endorsement" of product, but rejecting claim based strict liability in tort, because defendant had not manufactured product].)[1]

This distinction is underscored by the Restatement (Third) of Torts, which recognizes misrepresentation claims as entirely separate from product-liability claims. Section 9 of the Restatement provides that "separate causes of action set forth in the Restatement (Second) of Torts, governing liability for fraudulent and negligent misrepresentation, are contained in §§ 310 and 311. Case law has followed these Sections." (*Id.*) It goes on to state that "[a]lthough these Sections do not explicitly apply

[1] (See also Brief of Consumer Attorneys of California and American Assn. for Justice, pp. 15–19 [explaining origins of tort of negligent misrepresentation claim].)

to commercial product sellers, *they admit of such application*." (*Ibid*., emphasis added.)

Along similar lines, Section 2 of the Restatement (Third) of Torts, which defines the three categories of strict products liability, provides:

> Plaintiffs may … join claims based on product defect … and claims based on theories of recovery that do not rest on a premise of product defect at time of sale. *Claims based on misrepresentation*, express warranty, and implied warranty of fitness for particular purpose, in particular, *are not within the scope of this Chapter and thus are unaffected by it*.

(Rest.3d Torts, Product Liability, § 2, com. O, emphasis added.)

Thus, the "black letter of the Restatement [Third of Torts]" is *not* "incompatible with innovator liability." (Brief of Product Liability Advisory Council ("PLAC"), p. 16). In reality, the misrepresentation claims are "unaffected" by, and coextensive with, the chapter governing product liability. (*Id.*)

2. Negligent Misrepresentation Claims Are Not Subject to an Instrumentality Requirement.

Second, unlike product-liability claims, a claim for negligent misrepresentation under Section 311 has no "instrumentality" or "product-identification" requirement. Section 311 provides:

> One who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results (a) to the other, or (b) to such third persons as the actor should expect to be put in peril by the action taken.

None of this Court's cases adopting Section 311 suggests that it should be limited to cases where the defendant manufactured or controlled the "instrumentality" that injured the plaintiff otherwise. (*See Randi W. v. Munroc Joint Unified School Dist.* (1997) 14 Cal.4th 1066, 1077 [holding that a school district's misrepresentations about a former employee in a letter of recommendation could render district liable under Section 311 for employee's molestation of student at his new school]; *Garcia v. Superior Court* (1990) 50 Cal.3d 728, 735–736 [holding that parole officer's misrepresentations to parolee's prior victim resulting in her death could be basis for liability under Section 311].)

The U.S. Chamber of Commerce (the "Chamber") attempts to distinguish *Garcia* and *Randi W.* on the ground that, in both cases, "the defendants had made representations about the future conduct of specific individuals, and those same individuals later injured others"—arguing that, unlike here, "[t]hose individuals …

provided the very 'instrumentality' required under the general principles of tort law to link the alleged wrongdoers' misrepresentations to the plaintiffs' harm." (Chamber Br., p. 5.)

But unlike *Garcia* and *Randi W.,* where the "instrumentalities" that harmed the plaintiffs were individuals over whom the defendants had no formal relationships and exerted no control, Plaintiffs seek to hold Novartis liable for misrepresenting the risks of a drug that was pharmalogically identical to the "instrumentality" that ultimately injured them. (See 21 U.S.C. § 355(j)(2)(A)). And because federal law requires generic manufacturers to use the same warnings as the brand-name equivalent (see *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 613), Novartis could easily foresee that its inadequate labeling would be relied on by doctors when prescribing Brethine to patients whose prescriptions might ultimately be filled with generic Brethine. Thus the link between Novartis' misrepresentations and Plaintiffs' injuries was actually *more* direct and foreseeable than in either *Randi W.* or *Garcia.*[2]

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[2] (See Allen Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers* (2011) 60 Duke L. J. 1123, 1174 ["If a brand-name drug manufacturer is negligent in designing its product or in

It would be no more justifiable to excuse Novartis for disseminating false information about Brethine simply because it didn't make the tablets that injured Plaintiffs, than it would be to conclude that Plaintiffs' mother's physician owed her no duty of care simply because he didn't make the tablets she ingested. In both cases, the defendant's duty toward the Plaintiffs arises independent of the manufacture or sale of the tablets, and the defendant's breach of the duty leads proximately to the Plaintiffs' injury, regardless of who manufactured the terbutaline she took.

3. Negligent-Misrepresentation Claims Are Not "Substantively Indistinguishable" from Product-Liability Claims.

Amici nonetheless insist that negligent-misrepresentation claims should be subject to an instrumentality requirement because they are "substantively indistinguishable" from product-liability claims. (See PLAC App., p. 3.) Not so.

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preparing labeling …, it is highly foreseeable that the risk created will extend to those taking the generic substitutes …. And given that brand-name manufacturers effectively dictate crucial aspects of the generic products' designs and the contents of their labeling, the brand-name manufacturers' insistence that they have no control over generic drugs is like a person saying that he has no control over his own shadow."].)

This argument fails, first, because even if Plaintiffs' negligent-misrepresentation claim were "substantively indistinguishable" from a product-liability claim (and it is not—see below), allowing that fact to categorically preclude claims for product-caused injuries from being brought under Section 311 would turn the law of product liability against the very constituency it was designed to help.

The doctrine of strict product liability, first adopted in *Greenman v. Yuba Power Prods*. (1963) 59 Cal. 2d 57, 63, was intended to *assist* consumers and advance overall social goals by eliminating the need to prove fault in cases involving defective products. (*Ibid.*; see generally David G. Owen, *The Evolution of Products Liability* Law (2007) 21 Rev. Litig. 955, 966–974.) But Novartis and its amici seek to use the doctrine of strict liability as a *sword* against injury victims, arguing that product-liability claims were intended to displace all other available remedies, even where the plaintiffs can prove the defendant was negligent and would otherwise be left without any remedy. That cannot be how the law was intended to apply.

That aside, amici's argument that there is no real difference between negligent-misrepresentation claims and strict-

liability claims—and, as a result, that the former should be subject to the same "instrumentality" requirement as the latter—is wrong on its own terms, as the Alabama Supreme Court held in *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649.)

There, as here, the brand-name manufacturer argued that because the plaintiff's negligent-misrepresentation claim alleged physical injuries caused by a product, "the plaintiff must prove that the defendant manufactured the product the plaintiff claims injured him." (*Id.* at p. 656.) In rejecting this argument, *Weeks* explained that negligent misrepresentation "is *not* a claim that the drug ingested by [plaintiff] was defective; instead, it is a claim that Wyeth fraudulently misrepresented or suppressed information about the manner in which (i.e., the duration) the drug was to be taken." (*Id.* at p. 658.) And, because the plaintiff's claim was based "on what Wyeth said or did not say about Reglan and their assertion that those statements or omissions caused [plaintiff's] injuries ...," there was no basis for concluding that the misrepresentation claim "[was] in substance a products-liability claim." (*Id.* at p. 658.)[3]

[3] (See also *Huck v. Wyeth, Inc.*, 850 N.W.2d 353, 385-389 (Iowa 2014) (conc. & dis. opn. of Hecht, Wiggins, and Appel, JJ.)

The flawed attempt to equate negligent-misrepresentation claims with strict-liability claims was one of the central errors in *Foster v. American Home Products, Inc.*, 29 F.3d 165 (4th Cir. 1994), the ruling underlying the "mountain" of authority cited by amici. (See *Prescription for Fairness*, *supra*, 60 Duke L. J. at p. 1164.)

Weeks criticized *Foster* on this point, concluding that, "[b]ecause a warning label is not a part of the manufacturing process, we do not agree that the fact that a brand-name manufacturer did not produce the version of the drug ingested by the plaintiff bars the plaintiff's tort action [based on] failure to warn." (*Weeks*, 159 So.3d at p. 670.)

Foster and its progeny all make the same basic error: they fail to understand that where, as here, a brand-name manufacturer is being sued for negligently misrepresenting the defects of its own product, the fact that it did not make the product that injured the plaintiff is irrelevant to the underlying cause of action. The question, rather, is whether the

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[disagreeing with majority's imposition of instrumentality requirement and collecting cases rejecting same in product-liability context.])

manufacturer's wrongdoing with respect to its *own product* is the proximate cause of the plaintiff's injuries.

The policies underlying strict products liability make clear why the defendant's liability in such cases is tied to its status as the supplier or manufacturer of the injury-causing product. As reaffirmed in *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, the core rationale behind strict product liability "is to insure that the costs of injuries resulting from defective products *are borne by the manufacturers that put such products on the market* rather than by the injured persons who are powerless to protect themselves." (*Id.*, emphasis added.)

It thus makes sense that strict-liability claims can only be brought against the manufacturer of the product that caused the injury—that is the only way to achieve the cost-spreading goal behind strict liability. In contrast, in the context of a negligent-misrepresentation claim, the need to establish fault by the defendant obviates the need to strictly limit liability to those who made or sold the offending product. (See, e.g., *Hanberry*, *supra*, 276 Cal.App.2d at p. 686.)

Put another way, the reason for the instrumentality requirement in the strict-liability context—to ensure that the cost

of injuries are borne by the offending product's *manufacturer*—is simply not present in the negligence context, where the overriding consideration is not one of social cost spreading but rather determination of *fault*.

4. Amici's "Instrumentality" Case Law Does Not Help Its Cause.

Amici's main instrumentality case is *Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588, 597, which they cite for the proposition that, as a "general rule, the imposition of liability depends upon a showing that the plaintiff that his or her injuries were caused *by the act of the defendant* ***or*** *by an instrumentality under the defendant's control*." (See U.S. Chamber of Commerce Br., p. 3, emphasis added.) As the bolded word in that sentence reveals, *Sindell* permits liability where the plaintiffs' injuries were caused by "[an] act of the defendant." (*Id.*) And in this case, Plaintiffs allege that their injuries *are* caused by "an act of the defendant"—specifically, Novartis's act of negligently misrepresenting the serious risks of its product to the developing fetal brain.

Where amici go wrong is by confusing negligent *design-defect* claims (which were alleged in *Sindell*) with negligent-

misrepresentation claims (which are alleged here). When it comes to the former, it makes sense to require that the defendant have made the injury-causing product, because the wrongdoing is *inseparable* from the "instrumentality." Again, the focus is on the *product*, not the defendant's conduct.

But in negligent-misrepresentation cases, the inquiry is whether the defendant misrepresented the facts and, if so, whether those *misrepresentations* presented a foreseeable risk of harm to a third party. The fact that, here, the "instrumentality" that injured Plaintiffs was another manufacturer's product does nothing to lessen the extent of Novartis's wrongdoing.

Amici's reliance on *Merrill v. Navegar* (2001) 26 Cal.4th 465, is equally misplaced. (See PLAC Br., p. 20.) *Merrill* held that a statute prohibiting "product-liability" claims against gun manufacturers barred the plaintiffs' negligence claim because the "allegations squarely fit within the risk/utility test for defective design that applies in a products liability action under both negligence and strict liability theories." (*Id.* at p. 481.) Properly understood, *Merrill* merely stands for the proposition that a statutory reference to "product liability" should be read broadly where doing so was necessary to effectuate the statute's manifest

purpose. (E.g., *id.* at p. 493 (conc. opn. of Kennard, J. ["The task of the judiciary is to interpret those statutes by ascertaining and effectuating the Legislature's intent. It is not for us to question the wisdom of the Legislature's considered judgments."].)

Kesner v. Superior Court (2016) 1 Cal. 5th 1132, does not further amici's cause either. Amici argue that *Kesner* supports their "instrumentality" theory because, there, the asbestos fibers that employees carried home from their workplace constituted "an instrumentality linking the defendant's alleged negligence with the plaintiffs' harm." (See Chamber Br., pp. 3–4, fn. 1.)

This argument improperly assumes that there must be some sort of physical "instrumentality" (such as asbestos fibers) linking a defendant's negligence and the plaintiffs' injuries. This Court has never held such a thing—neither *Garcia* nor *Randi W.* involved any kind of "physical instrumentality" linking the defendant and the plaintiff—and such a rule would make no sense in a negligent-misrepresentation case, where the very essence of the claim is informational in nature.

That aside, amici fail to recognize that, if anything, this is a far more persuasive case for recognition of a tort duty than *Kesner*. There, the predominant focus was the foreseeability of

the hazard (i.e., secondary exposure from asbestos fibers). (*Kesner*, *supra*, 1 Cal.5th at pp. 1145–1149.) But because, under the federal scheme, *all* warnings associated with a drug—brand-name or generic—are dictated by the brand-name manufacturer, the fact that consumers of generic drugs will rely on warnings issued by a brand-name manufacturer is at least as foreseeable as the secondary exposure this Court deemed foreseeable in *Kesner*.

And while the defendants' control over airborne asbestos fibers was a factor in *Kesner*, the control that brand-name manufacturers exert over *any* warnings associated with *any* form of their drug is *at least* as strong as the degree of control that landowners and employers have over stray asbestos fibers clinging to their employees' and visitors' clothing.

Stripped of these cases, all that amici are left with is *O'Neil v. Crane Co* (2012) 53 Cal.4th 553, which they argue established an instrumentality requirement for both strict-liability *and* negligence claims. Because *O'Neil* is addressed at length in Plaintiffs' Answer Brief (at pp. 28–36), Plaintiffs merely reemphasize one key point:

O'Neil helps *Plaintiffs*, not Novartis, because it reaffirmed the distinction between strict-liability and negligence claims. As to the former, *O'Neil* held that "a product manufacturer generally may not be held *strictly liable* for harm caused by another manufacturer's product." (*Id.* at p. 362, emphasis added.) But as to the latter, *O'Neil* applied the *Rowland* factors to determine whether to create an exception to the general duty of care under California law (*id.* at pp. 364–366), just as the Court of Appeal did in *Conte* and the decision below, and just as Plaintiffs ask the Court to do here.

If, as amici contend, *O'Neil* intended to categorically preclude negligence claims for product-caused injuries against defendants who did not make the injury-causing product, then why did *O'Neil* bother with a *Rowland*[4] analysis of the plaintiffs' negligence claim? Amici have no answer to that question, which is not surprising, for there is none.

5. Amici's Policy Arguments in Support of their "Instrumentality" Theory Lack Merit.

Amici insist that affirming the lower court's decision would result in an unprecedented "slippery slope" of tort liability by

[4] (See *Rowland v. Christian* (1968) 69 Cal.2d 108, 112.)

allowing plaintiffs to sue companies for injuries caused by products they didn't make—including generically identical products (e.g., chlorine bleach), high-tech products, and counterfeit goods. (E.g., PLAC Br. at p. 24.)

This argument overlooks a crucial distinction between ordinary consumer goods and pharmaceutical drugs that undermines amici's "slippery slope" argument: Makers of ordinary consumer goods have *sole discretion* regarding the content of their own warning labels. In contrast, brand-name prescription drug manufacturers dictate the content of *all* warnings associated with that drug, whether brand-name or generic. (See *Mensing*, *supra*, 564 U.S. at p. 613.)

This matters because, in any case involving allegedly inadequate product warnings, the law presumes the plaintiff would have escaped injury if an adequate warning appeared on the product the plaintiff actually used. (See, e.g., *Johnson v. American Standard, Inc.* (2008) 43 Cal.4th 56, 65.)

And because, in the context of ordinary consumer goods, the absence of an adequate warning on the product the plaintiff actually used was solely the fault of the manufacturer of that product, the causal nexus between the plaintiff's injuries and

warnings issued by *another* company is inherently—if not fatally—attenuated.

But because the absence of adequate warnings on any generic drug label is the direct result of choices made by the *brand-name* manufacturer of that drug, the causal chain between the brand-name manufacturer's negligence in crafting those warnings and the plaintiff's resulting injury is inherently direct.

This distinction makes all the difference from a causal perspective. (E.g., *State Department of State Hospitals v. Superior Court* (2015) 61 Cal.4th 339, 356 [holding that causal chain between negligent omission and injury severed where occurrence of injuries depended on independent, discretionary acts of third parties].) Thus, existing tort rules would prevent amici's doomsday "slippery slope" of tort liability without the need to impose new and artificial limits on the tort of negligent misrepresentation.

* * *

In short, amici's attempt to derail this case by importing an "instrumentality" requirement from the law of products liability fails on all fronts. This case addresses whether brand-name manufacturers should be held liable for violation their *own* duty

of care with regard to their *own* products—specifically, their duty to update their labels to warn of serious risks that only become known during the post-market period, a duty that already exists under federal law. So long as Novartis's misconduct played a causal role in Plaintiffs' injuries—which Plaintiffs seek to prove in this lawsuit—the fact that Novartis did not manufacture the tablets that injured Plaintiffs is, as the Alabama Supreme Court found, irrelevant. (*Weeks, supra*, 159 So.2d at p. 658.)

B. The *Rowland* Factors Counsel in Favor of Recognizing a Duty of Care in this Case.

The only serious question in this case is whether Plaintiffs' negligent-misrepresentation claim satisfies the test set forth in *Rowland, supra,* 69 Cal.2d at p. 112. Contrary to what amici imply, this Court relies on the *Rowland* factors "not to determine whether a *new duty* should be created, but whether an *exception* to Civil Code section 1714 … should be created." (*Ibid*., emphasis added, citation omitted.) And, crucially, this Court "will not carv[e] out an entire category of cases from th[e] general duty rule" of section 1714, subdivision (a), unless doing so "is justified by *clear considerations of policy*." (*Ibid*., quoting *Cabral v. Ralphs*

Grocery Co. (2011) 51 Cal. 4th 764, 772, emphasis added.) Amici have not made that showing here.

1. Amici's "Foreseeability" Arguments Lack Merit.

Foreseeability is not seriously disputed in this case. For all the reasons previously explained (see ABOM, pp. 37–38), it is not merely "foreseeable" to a brand-name manufacturer that its misinformation will mislead consumers of generic drugs as easily as consumers of brand-name drugs, it is a virtual *certainty*. (See also *Prescription for Fairness*, *supra*, 60 Duke L. J. at pp. 1165–1166.)

Tellingly, amici don't even attempt to deny foreseeability as a factual matter. Instead, they argue that "mere foreseeability" is not the proper legal test for imposition of a tort duty under California law. (See Brief of Civil Justice Association of California ("CJAC"), p. 11 [arguing that Plaintiffs "equat[e] *foreseeability* with *duty* under negligence law…despite this Court's sound authority to the contrary," emphasis in original, citations omitted.)

But Plaintiffs have never argued that foreseeability is the only factor relevant to the duty analysis under California law. To the contrary, Plaintiffs have argued that the test to determine

whether an exception to the general duty of care is warranted is the multi-factor test set forth in *Rowland*, *supra*, 69 Cal.2d at p. 113, which includes, *but is not limited to*, factors related to foreseeability. (ABOM, pp. 37–47.) And, indeed, Plaintiffs went on to explain why *all* of the *Rowland* factors are met in this case, including foreseeability. (*Ibid.*)

It is in fact *amici* who treat foreseeability inappropriately by arguing that "'foreseeability' is an elusive, open-ended touchstone" and therefore that "as a factor for ascertaining duty, 'foreseeability' offers little guidance." (E.g., Civil Justice Association of California (CJAC), p. 10.) But that sentiment directly contradicts this Court's unequivocal admonition that "foreseeability [i]s the predominant factor in duty analysis." (*Kesner*, *supra*, 1 Cal.5th at p. 1163; see also *id.* at p. 1132 [holding that foreseeability is "[t]he most important factor to consider in determining whether to create an exception to the general duty to exercise ordinary care…."].)[5]

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[5] Amici also rely heavily on *In re Darvocet* (6th Cir. 2014) 756 F.3d 917, 944, for the proposition that the lower court's approach somehow "stretches foreseeability too far." But in so ruling, the Sixth Circuit improperly conflated foreseeability with a *policy* conclusion that it is somehow not "fair" to hold brand-name manufacturers liable for injuries caused by generic drugs

2. Amici's Public Policy Arguments Do Not Justify a Categorical Exception to the Duty of Care.

The only remaining question under *Rowland* is whether there is any "clearly" compelling policy reason to create an exception to the duty of care. Amici have provided none.

a. Prevention of Future Harm.

Amici don't dispute the serious health risks posed by inadequately labeled generic drugs. Nor do they dispute that serious hazards often emerge long after a drug has been approved. That is not surprising, since there are myriad real-world examples of serious drug risks becoming known only after a drug has "gone generic." (See Brief of Public Citizen, pp. 2–3; *Prescription for Fairness*, *supra*, 60 Duke L.J. at p. 1191 [citing examples in support of the observation that "drug companies have also been responsible for some of the world's most notorious product catastrophes"].)

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based on federal drug laws "over which the brand manufacturers have no control." (*Id.*) Not only was that approach to foreseeability legally erroneous, but the Court's policy conclusion—which appears to have been based on a single law review article written by advocates for the drug industry (see *id.* at p. 945)—it is also indefensible, for all the reasons explained below.

Instead, amici argue that it is not necessary to impose tort liability on brand-name manufacturers to protect the public from inadequately labeled drugs. Amici advance several arguments in support of that premise, none of which persuade.

First, amici argue that the FDA's regulations already provide sufficient incentives to drug manufacturers to update their labels without tort liability. (E.g., Brief of Pharmaceutical Researchers and Manufacturers of America ("PHARMA"), p. 21.)

This argument ignores the U.S. Supreme Court's holding that "state tort suits" are critical to maintaining American citizens' access to safe drugs because they "uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly." (*Wyeth v. Levine* (2009) 555 U.S. 555, 579.) As the Court observed, tort suits "serve a distinct compensatory function that may motivate injured persons to come forward with information." (*Ibid.*) Thus, *Wyeth* concluded, "state law offers an additional, and important, layer of consumer protection that complements FDA regulation." (*Ibid.*)

Relatedly, amici's argument depends on the premise that the FDA can adequately police drug labels by monitoring postmarketing safety data and, where necessary, bringing

"misbranding" actions against drug manufacturers who fail to keep their labels up to date. But that premise is pure fiction.

The FDA's inability adequately to monitor postmarketing safety data has been a subject of intense concern for over a decade (see David A. Kessler & David C. Vladeck (2008) 96 Geo. L. J. 461, 485, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, ["*A Critical Examination*"]), and it is *still* a serious concern today. As recently as December 2015, for example, a U.S. Government Accounting Office report concluded that, for a variety of reasons, a "the FDA's ability to conduct systematic oversight of postmarket safety" is "restrict[ed]."[6]

Amici's argument that brand-name manufacturers could be induced to update their labels in order to avoid FDA "misbranding actions" is just as fanciful. As one former FDA Commissioner has explained, "the FDA has rarely, *if ever*, brought a misbranding action against the manufacturer of an

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[6] (See U.S. Government Accountability Office, *FDA Expedites Many Applications, But Data for Postapproval Oversight Need Improvement* (Dec. 2015), at p. 26 <http://www.gao.gov/assets/680/674183.pdf> [as of Feb. 15, 2017].)

approved drug being promoted only for approved uses." (*A Critical Examination*, *supra,* at p. 479, fn. 80, emphasis added.)[7]

Amici's argument that brand-name-manufacturer liability is not necessary because generic drug manufacturers have the means to effectuate a label change is just as flawed. In so arguing, amici drastically overstate the ability of generic-drug manufacturers to update their labels in a timely fashion. Unlike brand-name manufacturers, which can unilaterally add warnings under the FDA's "changes-being-effected" regulation (21 C.F.R. § 310.70(c)), the only thing a generic drug company can do is ask the FDA for permission to add or strengthen the warnings in its labeling. (See 21 C.F.R. § 314.70.) This may sound adequate in theory, but it is manifestly inadequate in practice.

That premise is implicit in the U.S. Supreme Court's holding that it would be "impossible" for generic drug manufacturers to meet state tort duties to update drug labeling without violating federal regulations that require generics to use

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[7] "Misbranding" actions are typically brought against companies selling *unapproved* drugs or approved drugs being markets for *unapproved uses.* (See *id.*) Research has uncovered no misbranding actions by the FDA against brand-name drug companies based on a company's failure to update its label to disclose a postmarket risk, and amici have cited none.

the same labels as brand-name manufacturers. (*Mensing*, *supra*, 564 U.S. 604.) If requesting a label change from the FDA were an efficient and effective method for generic-drug manufacturers to update drug labeling, then it would not have been "impossible" for them to simultaneously satisfy their obligations under both state and federal law. (*Id.*)

And whatever motive generic manufacturers might have had to police their labels and request label changes before the U.S. Supreme Court's preemption ruling in *Mensing* would have vaporized now that generic drug manufacturers cannot be sued for failing to warn of newly discovered risks. As the FDA itself recently observed in the preamble to a proposed rule that, if enacted, would give generic manufacturers the right to unilaterally change their labels to disclose newly discovered risks, the immunity from suit under *Mensing* has greatly "alter[ed] the incentives for generic drug manufacturers to comply with current requirements to conduct robust postmarketing surveillance, evaluation, and reporting, and to

ensure that the labeling for their drugs is accurate and up to date." (78 Fed. Reg. 67,985, 67,988–67,989.)[8]

But even generic manufacturers who do take their duties seriously and request a label change are likely to receive a slow response from the FDA. The ability to request a labeling change is, as a practical matter, no different than the ability of an ordinary citizen to file a "Citizen's Petition" seeking a revision to a drug's label. (See 21 C.F.R. §§ 10.25, 10.30, 10.33.) But because, as noted above, the FDA simply does not have the resources to monitor the many drugs on the market in a timely fashion, it lacks the ability to timely respond to requests for label changes. (See *Wyeth*, *supra*, 555 U.S. at pp. 578–579 ["The FDA has limited resources to monitor the 11,000 drugs on the market…"]; see generally Public Citizen Br. at pp. 2-6 [describing limitations on generic drug manufacturers' ability to update labels].)

Using this case as an example, it took the FDA *three years* to respond to a 2008 citizen's petition calling for stronger

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[8] That amendment has been repeatedly delayed as a result of drug industry lobbying and may never become law. (See ABOM, p. 10, fn. 2.)

warnings on the Brethine label regarding risks to fetal health.[9] There is no telling how many children suffered severe cognitive defects from Brethine exposure during that period.

The FDA's limited resources and resulting inability to quickly react to label deficiencies is why the federal scheme gives brand-name manufacturers both the obligation *and* the means to immediately implement additional warnings when the need arises. By vesting brand-name manufacturers with the *proactive* ability to unilaterally add warnings to drug labeling while giving generic manufacturers only the *passive* ability to request a label change, it is clear that Congress intended brand-name drug manufacturers to be the primary guardians of warning-label accuracy. (See, e.g., *Strayhorn v. Wyeth Pharmaceuticals, Inc.* (6th Cir. 2013) 737 F.3d 378, 410 (conc. & dis. opn. of Stranch, J.).) A rule that would significantly diminish the motivation of brand-name manufacturers to quickly implement label changes would thus undercut the primary mechanism for ensuring

[9] (See FDA Response to Citizen Petition on Terbutaline, Doc. No. FDA-P-0358 (Feb. 17, 2011) <http://www.fda.gov/downloads/Drugs/DrugSafety/UCM243797.pdf> [as of Feb. 15, 2017].)

adequate drug labeling, in direct contradiction of Congress's intent.

Amici's fallback argument is that imposition of tort liability for injuries caused by generic drugs would backfire, by causing brand-name manufacturers to withdraw their NDAs and leave the marketplace. This argument, too, fails on several levels.

First, as Public Citizen points out, "no evidence supports the speculation that a rule allowing brand-name manufacturers to be held liable for injuries caused by generic versions of their products would cause brand-name manufacturers to change their behavior." (Public Citizen Br., p. 11.)

And for good reason: For one, under the lower court's approach, NDA withdrawal would not relieve a manufacturer of liability for its *past* misconduct, if (as in this case) the label was inadequate at the time the manufacturer withdrew the NDA and the injured patient's reliance on the label was foreseeable. Indeed, the specter that brand-name manufacturers might seek to evade liability for mislabeled drugs by fleeing the market is yet another reason to impose liability on even *former* brand-name manufacturers, not a reason to grant brand-name manufacturers blanket immunity.

That aside, the fact that brand-name manufacturers *might* withdraw their NDAs when faced with tort liability for injuries caused by generic drugs is not a reason to categorically foreclose the imposition of such liability. Brand-name manufacturers' responsibility to update their labels while they still own the NDA "does patients little good if those manufacturers have no responsibility for failing to fulfill that responsibility." (Public Citizen Br., p. 11.) And without a rule imposing liability on brand-name manufacturers who negligently fail to update drug labels while they still control them, brand-name manufacturers will have little incentive to update the labels once their patent expires and generics enter the market.

In short, "Novartis's plea to be exempt from accountability for labeling for which it is solely responsible for exacerbates a dangerous safety gap." (*Id.* at p. 10.) Brand-name manufacturers play a key role in terms of ensuring the safety of drug labels, both for their own drugs and for their generic counterparts. Tort liability, in turn, helps ensure that they take this job seriously. Granting them the immunity they seek here would reward wrongdoing at the expense of public safety.

b. Burden on the Defendant.

In *Kesner*, this Court reaffirmed that "the relevant burden in the analysis of duty is not the cost to the defendants of compensating individuals for past negligence," but "the cost to the defendants of upholding, not violating, the duty of care." (*Kesner, supra*, 1 Cal.5th at p. 1152.)

With that in mind, the imposition of tort liability on brand-name manufacturers for injuries caused by generic drugs is "burdenless" insofar as it would require things—closely monitoring scientific data for hazards associated with their drugs and immediately adding warnings to address those hazards—that brand-name manufacturers *are already required to do* under federal law. (See 21 C.F.R. § 201.80(e).)

Absent a burden to bemoan, amici default to the complaint that it simply isn't "fair" to ask brand-name manufacturers to pay the tort liability of their generic competitors.

This argument fails on several levels.

First, amici's fairness argument incorrectly focuses *exclusively* on the brand-name and generic manufacturers, without any concern for the innocent victims who were harmed by a dangerously mislabeled drug.

But any "unfairness" of holding brand-name drug manufacturers liable to customers who purchased a generic product is dwarfed by the unfairness of denying compensation to the millions of future victims of mislabeled drugs for often serious injuries because of the chance fact that the customers' prescription was filed with a generic equivalent of the drug they were prescribed. This unfairness grows exponentially when one remembers that the victims often had no say in the determination to dispense them a generic version of the drug as opposed to the brand-name version. (See *Prescription for Fairness*, *supra,* 60 Duke L. J. at p. 1176.)

Second, amici's fairness argument rests at least in part on the premise that to hold brand-name manufacturers liable for injuries caused by generic drugs would effectively treat a brand-name manufacturer's own customers the same as its competitors' customers (i.e., consumers of generic drugs). But that is far from true.

Under this Court's decision in *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, consumers of a brand-name medication can hold the corresponding manufacturer *strictly liable* for failing to warn of risks that are "*scientifically knowable*" even if they

were not actually known to the drug manufacturer at the time it manufactured the drug. (*Id.* at p. 1111.)

In contrast, if affirmed, the decision below would only permit consumers of generic drugs to assert liability against brand-name manufacturers who *negligently* fail to provide accurate warning information regarding a hazard they *actually knew or reasonably should have known.*

As such, from a "fairness" perspective, the decision below reflects a principled compromise between, at one extreme, strict liability for failing to disclose merely "knowable" risks of a medication, and at the other extreme, foreclosing *any* compensation to victims merely because, likely unbeknowst to them, their prescription were filled with a generic rather than a brand-name version of the drug.

Third, it cannot be overemphasized that liability in this case will depend on proof that Novartis negligently disseminated inaccurate information regarding serious risks of its own drug product, and did so despite the knowledge that *every* consumer of that drug product—brand-name or generic—would depend on the accuracy of that information in choosing whether or not to use the drug. Indeed, the false premise in amici's fairness argument

is that brand-name manufacturers will be forced to pay for the liability of their generic competitors. But because brand-name manufacturers dictate the contents of drug labeling, in a case arising out of an inadequate label, the fault is *theirs*, not the generic manufacturers'.

As this Court recently observed, California law maintains a strong public policy "aimed at protecting consumers from the potential dangers posed by prescription medication, including warnings about serious side effects and prohibiting false and misleading labeling" (*Bristol–Meyers Squibb Co. v. Superior Court* (2016) 1 Cal.5th 783, 810.) Given that strong public policy, there is nothing inherently "unfair" about requiring a brand-name drug manufacturer "to shoulder its share of responsibility for injuries shown to have been caused, at least in part, by its dissemination of false information," which it reasonably should expect will be relied upon by consumers of that drug product, brand-name or generic. (*Conte*, *supra*, 168 Cal.App.4th at pp. 109–110.)

Finally, amici's fairness argument ignores the numerous benefits that brand-name manufacturers were granted when Congress decided to make it easier for generic drug

manufacturers to enter the marketplace. Under the Hatch–Waxman Act, brand-name drug manufacturers are entitled to an initial period of government-protected monopoly privileges in the form of patent protection. (See 35 U.S.C. § 154.) They are also entitled to an extension of those monopoly privileges when generic versions of their drugs receive FDA approval (See *id.* § 156 [patent-term extension]; 21 U.S.C. § 355 [pairing generic approval with patent-term extension].) In addition, they enjoy "the fiscal rewards of name-brand recognition and the commensurate ability to charge a higher price ..., even after [their] exclusive marketing position expires." (*Conte*, *supra*, 168 Cal.App.4th at p. 111.)

Ultimately, the allegedly "unfair" situation is the result of a federal drug scheme created by Congress—a scheme that grants considerable benefits to brand-name manufacturers, as well as certain burdens. Amici ask this court to second-guess that scheme—to declare it "unfair" and eliminate an entire category of tort liability—in order to rectify the allegedly unjust treatment of brand-name manufacturers. But as amici themselves repeatedly have argued to this Court, the perceived "unfairness" of federal drug law is not a sufficient basis to upset what Congress has

created. (E.g., Brief of Wash. Legal Foundation, p. 14; CJAC Br., p. 7.) Plaintiffs wholeheartedly agree.

c. Consequences to the Community.

In terms of "consequences to the community," amici insist that imposition of liability on brand-name manufacturers would devastate the brand-name drug industry by destroying innovation and stimulating "over-warning," ultimately harming public health. (See, e.g., Chamber Br., pp. 20–29; PHARMA Br., pp. 10–17.)[10]

Amici offer no actual evidence that affirming the decision below will lead to over-warning *or* stifle innovation. Instead, they offer only self-serving conjecture, conjecture that is belied by the fact that California law has imposed liability on negligent brand-name manufacturers for injuries caused by generic drugs since 2008 and yet no apparent increase in over-warning or decrease in drug innovation has occurred since that time.

Not coincidentally, amici's over-warning argument was already rejected by this Court in *Carlin*, *supra*, 13 Cal.4th at pp.

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[10] Amici also argue that, if affirmed, the lower court's ruling would result in skyrocketing brand-name drug prices. Because that argument is rebutted throughout AARP's amicus brief, Plaintiffs do not address it here.

1353–1354, which allowed strict-liability claims against brand-name drug manufacturers for failing to warn about risks that were "scientifically knowable," even if they were not actually known by the manufacturer at the time of the plaintiff's injury. Ultimately, *Carlin* concluded that "there is no evidence that any such [over-warning] problem has emerged …, despite the fact that strict liability has long been the rule in California." (*Id.* at p. 1354, fn. 6.)

That holding should control here. If, as *Carlin* held, the imposition of strict liability for failure to warn of "scientifically knowable" risks would not stimulate over-warning, then it is exceedingly difficult to see how the imposition of mere negligent-misrepresentation claims for risks a brand-name manufacturer knows or should know about will suddenly inspire over-warning.

But even in the exceedingly unlikely event that it would, as between the two alternatives—under-warning or over-warning—the latter is certainly the lesser of two evils. Indeed, the FDA retains the power to remove warnings it deems unnecessary. (*Wyeth*, *supra*, 555 U.S. at p. 571 ["[T]he FDA retains authority to reject labeling changes made pursuant to the CBE regulation in its review of the manufacturer's supplemental application."].)

Given the FDA's strained resources and resulting slow response time, from the perspective of public safety, it makes more sense to rely on the FDA to remove unnecessary warnings than to supply necessary ones that are dangerously absent.

Carlin also rejected the argument tort liability would deter innovation in the pharmaceutical industry. (See *Carlin*, *supra*, 13 Cal.4th at p. 1117.) In fact, this Court reached the opposite conclusion, holding that because "[d]rug manufacturers need only warn of risks that are *actually known or reasonable scientifically knowable* ... requiring manufacturers to internalize the costs of failing to determine such risks may instead *increase* the level of research into safe and effective drugs." (*Id.*)

Carlin's holding should apply with even greater force in the context of this case. If, as *Carlin* held, stifling innovation is not a concern in the context of a strict-liability failure-to-warn case, then surely those policy concerns should be accorded even *less* weight in a negligent-misrepresentation case.[11]

Notably, the most recent evidence on the actual impact of tort liability on the pharmaceutical industry refutes amici's

[11] Only one of Novartis's amici even attempts to deal with *Carlin* (see PHARMA Br., p. 14, fn. 5); most ignore it completely.

apocalyptic predictions. A 2013 study from the RAND Institute for Civil Justice attempted to evaluate the economic effects of product liability litigation on the pharmaceutical industry.[12] The report concluded that "there is scant empirical evidence to support the claims on either side of the debate, and the literature provides little reliable information about common or typical product liability." (See Garber, *Economic Effects*, note 12, at p. xiv.) Arguments about "over-warning," the study stated, "are controversial within the medical community, and there is no direct evidence about it." (*Ibid.*) "Policymakers," the study concluded, should "be wary of broad claims about economic effects of pharmaceutical liability, including generalizations based on anecdotes or examples." (*Id.* at p. xv.)[13]

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[12] (See Steven Garber, Rand Institute for Civil Justice, *Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals* (2013), at p. xv <http://www.rand.org/content/dam/rand/pubs/monographs/MG1200/MG1259/RAND_MG1259.pdf> [as of Feb. 15, 2017].)

[13] (See also *Huck, supra,* 850 N.W.2d at p. 399 (conc. & dis. opn. of Hecht, Wiggins, and Appel, JJ.) [citing RAND study and stating that "[t]he majority's claim that the pharmaceutical industry will be substantially harmed by a rule imposing a duty on the brands, who controlled the content of the warning PLIVA was legally required to use, is…speculative and overblown"].)

Amici have offered no reason for this Court to deviate from *Carlin* or ignore the findings of the RAND report. They rely on scare tactics and conjecture, while ignoring the benefits brand-name manufacturers gain from selling their products on the market, and that they continue to reap even after their drugs "go generic." This Court should not leave prescription drug consumers unprotected and uncompensated based on so thin a reed.

d. Availability of Insurance.

Amici also argue that brand-name manufacturer liability for injuries caused by generic drugs—liability they characterize as "innovator" or "pioneer" liability—would be "uninsurable."

This argument fails because it rests on a false premise—that Plaintiffs seek to punish "faultless" brand-name manufacturers whose sole "offense" is bringing the particular drug at issue to the market. (E.g., PLAC Br. at p. 32 ["By contrast, innovator liability as urged by Plaintiffs is uninsurable."].) But, again, Plaintiffs' claims rest instead on the assertion that Novartis negligently failed to update the Brethine label while it still owned the drug.

So long as the insured's liability is premised on its own negligent acts or omissions, the mere fact that the claimants may never have been one of the insured's patrons is irrelevant from a legal—and thus, insurance—perspective. (*Kesner*, *supra*, 1 Cal.5th at pp. 1163 ["[W]e have never held that such a relationship is a perquisite to finding that a defendant had a duty to prevent injuries to its own conduct or possessory control."].)

Here again, *Carlin* is instructive. If brand-name manufacturers are able to secure insurance for claims arising out of their *strict liability* failure to warn of *"scientifically knowable"* risks—and there is no indication they have been unable to do so—they should have little trouble securing insurance against claims arising out of their *negligent* failure to warn regarding risks about which they *knew or should have known*.

C. Amici's Out-of-State Authority is Distinguishable or Unpersuasive.

Like Novartis, amici argue that, by imposing liability on brand-name manufacturers for injuries caused by generic forms of their drugs, California is at odds with the vast majority of courts in other jurisdictions to consider the issue. (E.g., PLAC, pp. 14–15.) But as in *Kesner*, a closer examination reveals that

these out-of-state authorities "are readily distinguishable" because they arose in jurisdictions that do not have "general tort law principles commensurate with [California's]." (*Kesner*, *supra*, 1 Cal.5th at p. 1163.)

For example, because "foreseeability [i]s the predominant factor in duty analysis" in California (*ibid.*), *Kesner* rejected several out-of-state cases on the simple ground that they "downplayed the significance of foreseeability" in "the establishment of a duty." (*Id.* at p. 1162.) This fatal distinction is also true of several of amici's cases, including the Iowa Supreme Court's narrow 4-3 decision on which amici heavily rely.[14]

Similarly, because a pre-existing relationship between plaintiff and defendant is not a prerequisite to negligence liability in California (*Kesner*, *supra*, 1 Cal.5th at pp. 1163), in *Kesner* this Court rejected cases that "asserted as a foundational principle of tort liability that a plaintiff and a defendant must have a prior

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[14] (See *Huck*, *supra*, 850 N.W.2d at p. 376 ["In *Thompson*, we said that foreseeability should not enter into the duty calculus but should be considered only in determining whether the defendant was negligent."]; see also *Colaccio v. Apotex, Inc.* (E.D. Pa. 2006) 432 F.Supp.2d 514, 543 [applying Pennsylvania tort law under which, in contrast to other states, "foreseeability is [not] the principal determinant of duty," citing *Althaus v. Cohen* (2000) 562 Pa. 547)].)

relationship for a duty to exist from the latter to the former." (*Id.* at p. 1162.) Yet, several of amici's cited authorities rest on the premise that a plaintiff and a defendant must have a prior relationship for a duty to exist from the latter to the former.[15]

"Another significant difference" between California law and the states from which amici draw their cases "is the availability in California of a claim for negligence misrepresentation." (*Short*, *supra*, 2009 WL 9867531, p. 8.) Indeed, many of amici's decisions

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[15] (*Moretti v. Wyeth* (9th Cir. 2009) 579 F. App'x 563, 564 [holding that, under Nevada law, a negligence misrepresentation claim "'requires, at a minimum, some form of relationship between the parties'"]; accord *Baymiller v. Ranbaxy Pharmaceuticals, Inc.* (D. Nev. 2012) 894 F.Supp.2d 1302, 1311; *Moretti v. Wyeth, Inc.* (D. Nev. 2009, No. 2:08–cv–00396) 2009 WL 749532, p. 3; see also *Schrock v. Wyeth, Inc.* (10th Cir. 2013) 727 F.3d 1273, 1282–1283 [holding that, under Oklahoma law, "'[w]hether or not a duty exists depends on the relationship between the parties,'" and yet "the brand-name manufacturers had no relationship with the Schrocks"]; *Mensing v. Wyeth, Inc.* (8th Cir. 2009) 588 F.3d 603, 613 ["[U]nder Minnesota law negligent misrepresentation requires the plaintiff to 'prove some relationship that is sufficient to create a duty owed by the defendant to the plaintiff.'"]; *Foster v. American Home Products Corp.* (4th Cir. 1994) 29 F.3d 165, 171 ["The duty required for the tort of negligent misrepresentation arises when there is 'such a relation that one party has the right to rely for information upon the other, and the other giving the information owes a duty to give it with care.'"]; *Short v. Eli Lilly & Co.* (Ind. Sup. Ct. Mar 25, 2009, No. 49D12-0601-CT-2187) 2009 WL 9867531, p. 8 ["In contrast, under Indiana law a duty does not arise unless there is a relationship between the parties."].)

were issued by courts sitting in states that maintain blanket prohibitions on negligent-misrepresentation claims that are inconsistent with California law.[16]

But perhaps the most important distinction in amici's cited cases is that many were issued in states with "Product Liability Acts" that (1) expressly define any case involving a product-caused injury as a "products-liability case" regardless of the theory pleaded, and (2) expressly limit liability in a product-liability case to manufacturers of the product at issue. This

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[16] (See, e.g., *Huck*, 850 N.W.2d at p. 371 [holding that courts applying Iowa law "have refused to allow a suit for negligent misrepresentation where the defendant was a retailer in the business of selling and servicing merchandise"]; *Moretti*, *supra*, 2009 WL 749532, at p. 3 ["Indeed, Nevada has expressly rejected the tort [of negligent misrepresentation] in cases such as this, where Plaintiff seeks recovery for personal injuries."]; *Baymiller, supra*, 894 F.Supp.2d at p. 1311 [same]; *Short*, *supra*, 2009 WL 9867531, p. 8 ["Indiana does not recognize the tort of negligent misrepresentation except in the limited context of emoloyee/employeer relationships. Furthermore, Indiana law does not recognize any cause of action for misrepresentation that is baesd on representations made to third parties."]; *Flynn v. American Home Products Corp.* (Minn. Ct. App. 2001) 627 N.W.2d 342, 351 ["[T]he Minnesota Supreme Court has recognized negligent misrepresentation involving damages only for pecuniary loss, and has expressly declined to recognize the tort of negligence misrepresentation involving the risk of physical harm."]; *Mensing*, *supra*, 588 F.3d at p. 613 ["As for Mensing's negligent misrepresentation claim, 'the Minnesota Supreme Court has recognized negligent misrepresentation involving damages only for pecuniary loss[.]'"].)

significant distinction from California's product liability law applies to at least **19** of the 40 or so state and federal decisions amici collectively cite.[17]

In recounting the contrary decisions from other jurisdictions, amici place special emphasis on the fact that "every federal court of appeal to consider the issue has held that brand-name manufacturers are not liable to plaintiffs who are injured by a generic's drug." (*Strayhorn v. Wyeth Pharmaceuticals, Inc.* (6th Cir. 2013) 737 F.3d 378, 406.)

That statistic sounds impressive until one realizes that all of those federal appellate decisions were the direct result of state tort law that is fundamentally at odds with California's. As noted

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[17] (*Sheeks v. American Home Products Corp.* (Dist. Ct. Colo. Oct. 15, 2004, No. 02CV337) 2004 WL 4056060, p. 1; *Short v. Eli Lilly & Co.* (Ind. Sup. Ct. Mar. 25, 2009, No. 49D12-0601-CT-2187) 2009 WL 9867531, p. 8; *Anselmo v. Sanofi–Aventis Inc.* (Kan. Dist. Ct. Oct. 13, 2014, No. 10-CV-77) 2014 WL 8849464, pp. 1–2; *Stanley v. Wyeth* (La. Ct. App. 2008) 991 So.2d 31, 33–34; *Franzman v. Wyeth* (Mo. Ct. App. 2014) 451 S.W.3d 676, 689; *Gardley-Starks v. Pfizer, Inc.* (N.D. Miss. 2013) 917 F.Supp.2d 597, 602; *Washington v. Medicis Pharmaceuticals Corp.* (S.D. Miss. Feb. 7, 2013, No. 3:12cv126) 2013 WL 496063, p. 2; *Phelps v. Wyeth* (D. Or. 2012) 857 F.Supp.2d 1114, 1121; *Burke v. Wyeth, Inc.* (S.D. Tex. Oct. 29, 2009, No. G-09-82) 2009 WL 3698480, p. 3; *Finnicum v. Wyeth, Inc.* (E.D. Tex. 2010) 708 F.Supp.2d 616, 619; *Hardy v. Wyeth, Inc.* (E.D. Tex. Mar. 8, 2010, No. 9:09CV152) 2010 WL 1049588, p. 4.)

above, four were based on state laws that conditioned duty analysis on a relationship between the defendant and plaintiff (see *Moretti*, *supra*, 579 F. App'x at p. 564; *Mensing*, *supra*, 588 F.3d at p. 613; *Schrock, supra*, 727 F.3d at pp. 1282–1283; *Foster*, *supra*, 29 F.3d at p. 171), or categorically prohibited negligent-misrepresentation claims for personal injury. (*Mensing*, *supra*, 588 F.3d at p. 613.) The balance of the federal appellate decisions arose out states that, unlike California, had a codified "Product Liability Act."[18]

Of course, decisions in states with "Product Liability Acts" are irrelevant here because, as even some of the courts that departed from *Conte* have noted, "California does not have a statute … that governs all claims brought for physical harm allegedly caused by a product and that specifically limits liability

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[18] (*Johnson v. Teva Pharmaceuticals USA, Inc.* (5th Cir. 2014) 758 F.3d 605, 615; *Eckhardt v. Qualitest Pharmaceuticals, Inc.* (5th Cir. 2014) 751 F.3d 674, 678; *Lashley v. Pfizer, Inc.* (5th Cir. 2014) 750 F.3d 470, 476–478; *Demay v. Scharz Pharma, Inc.* (5th Cir. 2012) 702 F.3d 177, 182–183; *Strayhorn*, *supra*, 737 F.3d at pp. 401–403; *Smith v. Wyeth, Inc.* (6th Cir. 2011) 657 F.3d 420, 423; *Fullington v. Pfizer, Inc.* (8th Cir. 2013) 720 F.3d 739, 744; *Bell v. Pfizer, Inc.* (8th Cir. 2013) 716 F.3d 1087, 1092–1093; see also *In re Darvocet, supra*, 756 F.3d at pp. 941–953 [Arkansas, Connecticut, Louisiana, North Carolina, Ohio, and Washington Product Liability Acts].)

to manufacturers or sellers of the alleged injury-causing product." (*Short*, *supra*, 2009 WL 9867531, p. 8; see also *Anselmo*, *supra*, 2014 WL 8849464, p. 2 ["California product liability law differs from the significant majority of the states, including Kansas, in that it does not 'collapse' all theories of recovery into a single product liability claim."].)[19]

The balance of amici's decisions appear to rest at least in part on the false premise that generic drug manufacturers have the ability to unilaterally update an inadequate warning label. This includes the Fourth Circuit in *Foster* itself, district courts sitting in the Fourth Circuit,[20] and a line of Florida cases that all

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[19] Indeed, the fact that so many states rely on statutes to expressly "collapse" any claims for product-caused injuries into "product liability claims," and then expressly limit such claims to the manufacturer of seller of that product, is at least a tacit admission of Plaintiffs' earlier point that, left unfettered, the tort principles reflected in the Restatement of Torts would *permit* negligent-misrepresentation claims against a company other than the manufacturer of the product at issue so long as the causal nexus between that company's misrepresentations and the plaintiff's resulting injuries is foreseeable. (See, e.g., *Stanley, supra*, 991 So.2d at pp. 33–34 [characterizing state "Product Liability Acts" as "preempting" negligent-misrepresentation claims].)

[20] (See, e.g., *Fisher v. Pelstring* (D.S.C. July 28, 2010, No. 4:09-cv-00252-TLW) 2010 WL 2998474, p. 6 ["[T]his Court is bound by the Fourth Circuit's holding in *Foster*."]; see also *Meade v. Parsley* (S.D. W.Va. Nov. 13, 2009, No. 2:09-cv-00388) 2009 WL

directly or indirectly relied on *Sharp v. Leichus* (Fla. Cir. Ct. Feb. 17, 2006, No. 2004-CA-0643) 2006 WL 515532), an unpublished opinion resting, in turn, on the false premise that, "under Florida law, all pharmaceutical manufacturers, including generic manufacturers, are obligated to ensure the accuracy of their *own* warning information." (*Id.* at p. 7.)[21]

In short, virtually all of the foreign cases on which amici rely are either the product of a flawed understanding of federal drug law or, more commonly, the product of state tort law that is fundamentally different from California's insofar as those states (1) do not place the same emphasis on foreseeability in assessing duty as do California courts, (2) condition a duty on the existence of a relationship between plaintiff and defendant, (3) maintain blanket prohibitions on the tort of negligent misrepresentation that are alien to California, and/or (4) have codified a "Product Liability Act" which expressly limits any claims for a product-

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3806716, p. 3; *Gross v. Pfizer, Inc.* (D. Md. Nov. 9, 2010, No. 10-CV-00110-AW) 2010 WL 4485774, p. 2.)

[21] (*Metz v. Wyeth, Inc.* (M.D. Fla. 2011) 830 F. Supp. 3d 1291, 1293; *Levine v. Wyeth, Inc.* (M.D. Fla. 2010) 684 F.Supp.2d 1338, 1343; *Howe v. Wyeth, Inc.* (M.D. Fla. Apr. 26, 2010, No. 8:09-CV-610-T-17AEP) 2010 WL 170885, p. 3; see also *Guarino v. Wyeth, LLC* (11th Cir. 2013) 719 F.3d 1245, 1251; *Tsavaris v. Pfizer, Inc.* (S.D. Fla. 2016) 154 F.Supp.3d 1327, 1339–1340.)

caused injury to the manufacturer of that product. Because none of those is true of California tort law, those decisions "are readily distinguishable" (*Kesner*, *supra*, 1 Cal.4th at p. 303), as are any decisions that rely on the now discredited premise that generic-drug manufacturers can unilaterally change their own labels.

In contrast, courts that have applied tort principles commensurate with California's (*Kesner*, *supra*, 1 Cal.4th at p. 303)—and possess a proper understanding of the interplay of federal drug law—have reached the same conclusion as the California Court of Appeal. (See *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649, 677; *Dolin v. SmithKline Beecham Corp.* (N.D. Ill. 2014) 62 F.Supp.3d 705, 713; *Chatman v. Pfizer, Inc.* (S.D. Miss. 2013) 960 F.Supp.2d 641, 654; *Kellogg v. Wyeth, Inc.* (D. Vt. 2010) 762 F.Supp.2d 694, 704; *Clark v. Pfizer, Inc.* (Pa. Ct. Co. Pl. 2008, No. 1819) 2008 WL 7668730, p. 29.)[22]

[22] This is not to mention that even among the contrary authorities—including, most notably, the Sixth Circuit and the Iowa Supreme Court—the decision to depart from the rule expressed in *Conte* was not met with uniform approval. (See, e.g., *Strayhorn*, *supra*, 737 F.3d at p. 409–410 (dis. opn. of Stranch, J.); *Huck*, *supra*, (conc. & dis. opn. of Hecht, Wiggins, and Appel, JJ.)

Thus, far from the outlier that amici's massive string cites suggest, the California Court of Appeal's decisions in *Conte* and below actually reflect the majority view—if not the *unanimous* view—among courts that applied tort principles akin to California's.[23]

II. "Former" Manufacturer Liability is Consistent with California Tort Law.

The only remaining question is whether the fact that Novartis off-loaded its mislabeled drug onto aaiPharma in 2001,

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[23] Amici also argue that imposition of liability on a brand-name manufacturer for injuries caused by a generic version of its product would undermine various aspects of *federal* law, including the Hatch–Waxman Act. (See generally Brief of Atlantic Legal Foundation ("ALF").) These arguments were not raised below and are not properly before the Court. (See *Professional Engineers in California Gov't v. Kempton* (2007) 40 Cal.4th 1016, 1047, fn. 12.).) They also lack merit. In particular, amici's argument that suits like this one would conflict with the purposes of Hatch–Waxman—which, to Plaintiffs' knowledge, has never been adopted by any court—ignores that the Hatch–Waxman Act is subject to the Food Drug and Cosmetic Act's savings clause, which provides that state law may only be invalidated upon a "direct and positive conflict" with the FDCA. (See *Wyeth, supra,* 555 U.S. at p. 567, citing 21 U.S.C. § 321.) This provision, coupled with the absence of an express preemption clause in the FDCA and Congress' "certain awareness of the prevalence of state tort litigation" surrounding all prescription drugs, supplies powerful "evidence that Congress did not regard state tort litigation as an obstacle to" the Hatch-Waxman Act. (*Wyeth*, *supra*, 555 U.S. at pp. 574–576; see also *Kellogg, supra,* 762 F.Supp.2d at pp. at 431–432 [rejecting preemption argument].)

and therefore no longer held the NDA for Brethine at the time Plaintiffs were brain damaged in utero, immunizes it from liability under California law. When the question is evaluated according to the *Rowland* factors, the answer is clearly no, notwithstanding amici's protestations to the contrary.

A. Foreseeability.

Amici don't seriously argue that Novartis's status as a "former manufacturer" rendered Plaintiffs' injuries unforeseeable to it. This is not surprising, because as previously explained (see ABOM at pp. 53), successor manufacturers who purchase the brand rights from a predecessor manufacturer inherit—and are bound to use—the label used by the outgoing manufacturer, with all the inadequacies it might entail. (See 21 U.S.C. § 355; 21 C.F.R. § 314.105(b).) Thus, when it sold aaiPharma the NDA for Brethine, Novartis knew aaiPharma was bound to use its label, warts and all.

Amici also do not deny that it was just as foreseeable to Novartis that aaiPharma would not update the label to disclose the risk of the drug to the developing fetal brain. This is true not only because it would be disingenuous for Novartis to deny the foreseeability that another would do exactly that which Novartis

itself just did, but particularly because adding such a warning would have thoroughly devastated Brethine's sales potential as a tocolytic, which was, by then, responsible for at least half of Brethine's annual sales. (AA042.) Thus, aaiPharma's own, identical failure to add a warning to Brethine's label regarding its serious risks to fetal health was highly foreseeable to Novartis.[24]

B. Closeness of Connection.

Nor do amici dispute the closeness of the connection between Novartis's wrongdoing and aaiPharma's own negligent failure to update the Brethine label—which, in turn, led to the Plaintiffs' injuries. And for good reason: In *Kesner*, this Court reaffirmed that, "[i]n determining whether one has a duty to prevent injury that is the result of third party conduct, the touchstone of the analysis is the foreseeability of that intervening conduct." (*Kesner*, *supra*, 1 Cal.5th at p. 1148.)

As just discussed, it was at least reasonably foreseeable to Novartis that aaiPharma would *not* update the Brethine label.

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[24] The *Rowland* factor—the degree of certainty that the Plaintiffs' suffered injury—does not depend on the defendant's status as a "concurrent" brand-name manufacturer or a "former" manufacturer of the drug at issue. In either case, the question is the degree of certainty that Plaintiffs suffered injury (here, serious cognitive birth defects from prenatal exposure to Brethine).

And because aaiPharma's foreseeable failure to update the label would not have "occurred" but for Novartis's negligent failure to add warnings to the Brethine label before it sold the NDA—warnings aaiPharma would have been *obligated* to use (see *Wyeth*, *supra*, 555 U.S. at p. 568; 21 C.F.R. § 314.70(c)(6)(iii)(A)–(C))—aaiPharma's subsequent failure to update the Brethine label "do[es] not diminish the closeness of the connection between [Novartis's] conduct and [P]laintiff's injury for purposes of determining the existence of a duty of care." (*Kesner*, *supra*, 1 Cal.5th at p. 1149, internal quotation marks omitted, quoting *Beacon Residential Community Assn. v. Skidmore, Owings & Merrill LLP* (2014) 59 Cal.4th 568, 583).)

C. Moral Blameworthiness of the Defendant.

Amici next argue that "former manufacturers" like Novartis are somehow blameless, as though their sale of a mislabeled drug to a successor company absolves them of their sins. (E.g, Brief of National Association of Manufacturers, p. 19.)

In reality, however, there is little difference between a "concurrent" brand-name manufacturer that has not yet updated a drug label with a necessary warning and a "former" brand-name manufacturer that negligently failed to do so. In either

case, the manufacturer breached its federal duty to timely update a drug label with the significant risk for serious physical injury to unsuspecting consumers.

Indeed, if there is any difference in moral blame between a "concurrent" and "former" brand-name manufacturer, the moral blame is perhaps *stronger* as to the former manufacturer. Why? Because the former manufacturer's very status as a "former" manufacturer means that more time has elapsed since its negligent failure to update the label, with a corresponding increase in the number of victims.

Using this case as an example, had Novartis updated the Brethine label with a warning prior to divesting the Brethine NDA in 2001, the drug would not have gone *10 years* without that warning, a warning that was only ever added by the FDA in 2011 in response to a citizen's petition. (See *supra* note 12.) The approximately **two million** additional children exposed to Brethine between 2002 and 2011 thus places more moral blame on Novartis's shoulders than if Novartis had at least stopped the bleeding by adding a necessary warning regarding fetal health before it sold Brethine in December 2001. (See AA042 [alleging

that, by 2001, Brethine was prescribed for tocolysis over 200,000 times per year].)

D. Burden on the Defendant.

Regarding burden, amici argue that it is impossible for "former" manufacturers to comply with the standard of care because once they relinquish the brand-rights to the drug, a former brand-name manufacturer no longer has any control over the label. (E.g., Brief Pacific Legal Foundation ("PLF"), p. 9.)

But in so arguing, amici fundamentally mischaracterize the nature of Plaintiffs' claims. Again, the gravamen of Plaintiffs' claim is that Novartis should be held liable for the future, foreseeable consequences of its negligent failure to update the Brethine label with a necessary warning *while it still owned the brand*. Plaintiffs do not suggest that Novartis is liable for anything it did or did not do after it sold the Brethine NDA in December 2001.

Thus, whether the defendant was a "concurrent" or "former" manufacturer at the time the Plaintiffs were exposed to the drug at issue, the relevant time period for "burden" analysis remains the same—the brand-name manufacturer's conduct while it still owned the drug. (See *Kesner*, *supra*, 1 Cal.5th at p.

1152 [holding that "burden" under *Rowland* "is forward-looking" and focuses on "the cost to the defendants of upholding, not violating the duty of ordinary care"].) And since federal law already imposes a duty on brand-name manufacturers to monitor data regarding potential adverse risks and update labels accordingly, Plaintiffs' proposed rule adds nothing that is not already on a brand-name manufacturer's plate by virtue of federal law.

E. Prevention of Future Harm.

Regarding the prevention of future harm, amici first attempt to argue that because Novartis did not own the Brethine NDA at the time Plaintiffs' mother was prescribed Brethine, and therefore "no longer ha[d] any ability to avert the harm," holding Novartis liable for Plaintiffs' injuries would not exert any deterrent effect. (E.g., PLF Br., p. 9.)

But again, that argument is simply another manifestation of amici's fundamental mischaracterization of Plaintiff's claims. The focus of Plaintiffs' operative complaint against Novartis is its conduct *when it still owned the Brethine brand*, ***not*** its acts or omissions thereafter. If Novartis's failure to update the Brethine labeling while Novartis still owned the drug was negligent, then

holding Novartis liable for that failure would certainly have a deterrent effect on Novartis and other similarly situated brand-name manufacturers, even if they are not haled into court until after they sold the misbranded "hot potato" drug to a successor.

Next, amici collectively spend dozens of pages rebutting an argument Plaintiffs never made. Specifically, amici argue that imposing liability on "former" manufacturers who sell a mislabeled drug to a successor manufacturer is not necessary to prevent successor manufacturers from being defrauded in the purchase of a drug's brand rights. To that end, amici emphasize that "[t]he due diligence routinely undertaken in such transactions, together with existing legal liability for misleading would-be buyers," would avoid successor manufacturers from being misled regarding the liabilities inherent in the drug they are buying. (E.g., PLAC Br., p. 3.)

But such arguments are wasted breath. Frankly, the potential that a seller of a drug's brand rights might dupe a buyer into thinking it is buying a risk-free drug had not really occurred to Plaintiffs and, in any event, was not even remotely a fixture of Plaintiffs' argument.

To be clear, Plaintiffs do not suggest that by failing to update the Brethine label with a warning regarding the drug's risk to fetal health that Novartis somehow duped aaiPharma. To the contrary, Plaintiffs have always believed that aaiPharma knew *exactly* what it was getting when it bought Brethine.

Rather, Plaintiffs are focused on *public safety,* and argue that when Novartis sold its dangerously mislabeled drug to aaiPharma, it increased the likelihood that Brethine would *remain* dangerously mislabeled indefinitely because it was reasonably foreseeable to Novartis that future manufacturers, including aaiPharma, would similarly fail to update the Brethine label.

This, of course, is precisely what happened in this case. Plaintiffs allege that, based on the scientific data that had already accumulated at the time, the Brethine label should have included a warning regarding the risks to fetal health prior to December **2001**. But through negligence of several brand-name manufacturers—including Novartis—the Brethine label was not updated until **2011** when the FDA, in response to a citizen's petition filed in 2008, mandated the label update that Novartis should have implemented 10 years earlier. (See*, supra*, note 12.)

As a result, an untold number of children were needlessly injured from prenatal Brethine exposure between at least 2002 and 2011.

And yet, because every subsequent Brethine manufacturer would have invariably been stuck with a warning regarding risks to fetal health had Novartis added one (see *Wyeth*, *supra*, 555 U.S. at p. 568; 21 C.F.R. § 314.70(c)(6)(iii)(A)–(C)), Novartis could have prevented that cavalcade of injury at its source by adding a such a warning to the Brethine label while it still owned the drug.

As this case thus demonstrates, a brand-name manufacturer who sells the rights to a mislabeled drug to a successor manufacturer on the assumption that the successor will "clean up the mess" is taking a serious gamble with consumers' well-being. This is because the assumption that the successor will "fix the problem" depends, in turn, on the assumption that the successor will be a law-abiding, efficient actor who will not only seek to identify deficiencies in the drug's labeling and correct them, but will do so with great haste.

But if either of these assumptions is wrong—if the successor manufacturer is inefficient or, even worse, is tempted to avoid adding the warning at issue based on the allure of profit

from the sales that such a warning would jeopardize—then a necessary warning would be at best delayed, if it ever appears at all.

This is not an unrealistic concern. Indeed, of countless examples that might be cited, it is perhaps no coincidence that perhaps the two most "famous" cases in this area of the law—*Conte* and *Foster*—both involved drugs that remained dangerously mislabeled for *decades* despite passing from brand-name manufacturer to brand-name manufacturer, all of whom were charged with the duty to monitor, review, and respond to data regarding potential health consequences of their drugs.

In *Conte*, for example, the plaintiff—who first began taking metoclopramide in 2000—introduced evidence that, as early as **1985**, drug manufacturers knew or should have known that long-term use of metoclopramide could result in serious neurological side effects. And yet, an adequate warning against such use did not appear until **2009** when the FDA stepped in and mandated it. (*See Prescription for Fairness*, *supra*, 60 Duke L.J. at pp. 1155–1156, fn. 189.)

Similarly, in *Foster*, there was evidence that as early as **1969,** manufacturers were already aware of reports that the

active ingredient in Phenergan, a popular cough syrup, had caused fatal respiratory distress in numerous children. (*Id*. at p. 1147.) And yet, no such warning against Phenergan's use with children appeared on its labeling information when generic Phenergan was given to—and killed—six-week-old Brady Foster in **1988**. (*Foster*, *supra*, 29 F.3d at 167.)

Indeed, the epilogue to *Foster* provides a significant cautionary tale about the public-health ramifications of a rule that insulates brand-name manufacturers for liability for injuries caused by generic drugs (as well as the dangers of relying on the FDA to police drug labels). Even after the Foster's now-infamous lawsuit against American Home Products (the then-brand name manufacturer of Phenergan), no one—including American Home—made *any* effort to update the label with a warning against use with children. Indeed, it was not until "a **decade** after the Fourth Circuit's decision" in *Foster* that the FDA finally "announced that a boxed warning would be added to the drug to bar it from being given to children less than two years of age." (*Prescription for Fairness*, *supra*, 60 Duke L.J., p. 1146–1147, emphasis added.) One can only imagine the immense fury that the parent of a child who died from Phenergan a month before

the FDA's announcement would have felt toward American Home.

In short, a rule limiting a brand-name manufacturer's liability for failing to update a drug to only those injuries that occur while the brand-name manufacturer still owns the NDA would do nothing to discourage brand-name manufacturers who know (or should know) that their product is dangerously mislabeled from gambling with public health by selling the brand-rights to a successor manufacturer who may—or, if history is any indication, may *not*—move swiftly to provide the necessary label update, if it provides one at all.

In fact, if anything, such a rule would only serve to *encourage* manufacturers to delay or omit warnings where they perceive a pecuniary advantage to doing so, such as where the warning would jeopardize one of the drug's predominant therapeutic purposes. And history not only teaches that this very thing in fact happens with an alarming frequency, but that the consequences to life and health can be absolutely devastating when it does.

F. Consequences to the Community

Amici brush aside the health risks of imposing a categorical ban on "former manufacturer" liability, arguing instead that affirming the lower court's ruling would give rise to a sort of twilight zone of "perpetual liability," in which brand-name drug manufacturers could be sued "in perpetuity" for injuries caused by their drugs. Amici argue this would stifle innovation and backfire on consumers in all sorts of terrible ways.

As a threshold matter, given the examples in the preceding discussion of cases where drug manufacturers' negligence in failing to provide necessary warnings caused serious injuries or death over a period of several decades, from a public-safety standpoint, one might wonder which way the specter of "perpetual liability" cuts in the duty analysis. (See *Kesner*, *supra*, 1 Cal.5th at p. 1152 ["[S]hielding tortfeasors from the full magnitude of their liability for past wrongs is not a proper consideration in determining the existence of a duty."].)

Nevertheless, there are stop-gap measures available to brand-name manufacturers that may serve to mitigate, if not eliminate, a former-manufacturer's liability for injuries arising after they sell the brand rights to a drug.

For example, a defendant's status as a "former" manufacturer necessarily assumes that there will be at least one—and, as time goes on, likely several other—brand-name manufacturers who also negligently failed to update the warning label at issue and who will therefore share in any fault for injuries caused thereby. (See ABOM, p. 59, fn. 20.)

In addition, to insulate themselves from future liability, rational brand-name manufacturers could—and likely *would*—respond to a ruling of this Court affirming the decision below by adding a term to the sale of any NDA under which the buyer agrees to bear the liabilities of the seller for any subsequent claims arising out of an alleged insufficient warning label after a specific date (if not the purchase date). (E.g., *Conte*, *supra*, 168 Cal.App.3d at p. 95, fn. 1.) The effect of such agreements would be to "funnel" liability for insufficient warning labels to the current brand-name manufacturer.

Of course, to secure such an agreement, a company looking to sell an NDA would be wise to exercise vigilance in monitoring and updating its drug labels while it owns those drugs so as to minimize the scope of liability a successor would face by purchasing the drug. Otherwise, a negligent brand-name

manufacturer would risk losing money on the sale of a drug's NDA as any rational successor would likely discount its purchase price in light of the liabilities it might acquire by purchasing the product line.

This outcome would thus satisfy those concerned about public safety *and* "perpetual liability": Brand-name manufacturers would have a significant financial incentive to ensure their labels are accurate and update to date, and yet would offer them an avenue to mitigate the remote possibility of being named in a lawsuit long after they divested the drug at issue.

Tellingly, amici do not deny the intrinsic utility of either method by which former manufacturers might avoid liability. Rather, their primary response is to argue that these alternatives would be of no help to a brand-name manufacturer who sells an NDA to a successor that later becomes insolvent. (E.g., IADC & FDCC, p. 10.) Admittedly, the facts of this case show that amici's concern is not implausible.

But a successor's insolvency is a two-way street and would have adverse consequences for the plaintiff as well, if for no other reason than it ensures the plaintiff will invariably lose a portion

of their noneconomic damages under Proposition 51. (Civ. Code, § 1431.2 [imposing several liability for noneconomic damages].) Of course, as a corollary, Proposition 51 also means that any brand-name manufacturer would still only pay its proportional share of fault regardless of the solvency of a successor manufacturer.

In any event, the mere fact that an *occasional* successor manufacturer may become insolvent should not justify a blanket rule of immunity for *all* former brand-name manufacturers. Indeed, this is particularly true when one remembers that this "worst-case scenario" of an insolvent successor would only result in liability to what is, at bottom, a negligent actor. (See *Kesner*, *supra*, 1 Cal.5th at p. 1152 ["To the extent defendants argue that the costs of paying compensation for injuries that a jury finds they have actually caused would be so great that we should find no duty to prevent those injuries, the answer is that shielding tortfeasors from the full magnitude of their liability for past wrongs is not a proper consideration in determining the existence of a duty."].)

Amici's other response is to argue that Plaintiffs' proposed stop-gaps for "perpetual liability" are of diminished value because "even unmeritorious claims can consume time and resources until

they are disposed on summary judgment or rejected at trial." (IADC & FDCC, p. 10.)

Amici's underlying premise is correct, but their ultimate conclusion is not. For one, there is no reason the indemnification agreements Plaintiffs envision need be limited to compensation for settlements or judgments. Indeed, as is common in such agreements, they could easily include provisions for attorneys' fees and costs. This is not to mention that California law contains mechanisms by which a defendant who ultimately prevails against a meritless claim can recover most if not all of its costs. (See Code Civ. Proc., §§ 998, 1032, 1033.5.)

More importantly, the fear that frivolous claims may follow the creation of a duty of care could be said about *any* duty of care that exists in California tort law. The mere specter that some plaintiffs may pursue meritless claims is no justification to close the courthouse doors to the many seriously injured plaintiffs with legitimate ones.[25]

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[25] Amici also err in asserting that former-manufacturer liability was expressly disclaimed in *Conte* in light of the potential for "perpetual liability." (E.g., CJAC, p. 9; PLF, p. 6.) In fact, *Conte* implicitly *assumed* that its rule applies with equal force to "former" manufacturers. This is because Wyeth, the title defendant, sold the NDA for Reglan (the brand-name drug at

G. Availability of Insurance.

Amici also argue that a "former" brand-name manufacturer like Novartis would be unable to obtain insurance, but the only things that distinguish such a case from one against a "concurrent" brand-name manufacturer are (1) the passage of time and (2) the subsequent negligent acts of one or more successor manufacturers. Neither characteristic should convert an insurable claim into an uninsurable one.

Nothing in California law suggests that the mere passage of time between a negligent act and its harmful manifestations

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issue) to a successor—Schwarz—in December 2001. (*Conte*, *supra*, 168 Cal.App.4th at p. 95, fn. 1.) And yet, although the plaintiff alleged her injuries were "a result of taking [generic Reglan] for almost four years between August 2000 and April 2004" (*id.*, at p. 95), Wyeth's divesture of the Reglan NDA relatively early in that period received only passing mention in a *footnote*. (*Id.* at p. 94, fn. 1.)

Amici also mischaracterize *Conte*'s statement that "it appears Wyeth no longer has primary responsibility for Reglan-related claims arising after March 31, 2002." (*Ibid.*) That sentence was *not* a reference to Wyeth's divesture of the Reglan NDA, but rather a reference to the fact that, as part of the agreement to purchase of the Reglan NDA from Wyeth, Schwartz agreed to bear responsibility for any Reglan-related claims arising after March 31, 2002. Thus, the fact that *Conte* responded to Wyeth's concerns regarding perpetual liability by citing to Schwarz's contractual obligation to assume liability for future Reglan-related claims and *not* Wyeth's divesture of the NDA implies that, in the *Conte* court's mind, Wyeth's divesture of the NDA did *not* immunize it for liability for its past misconduct.

inherently affects the insurability of the resulting claim. Indeed, California's statutes of limitation supply ample indicia that California law readily anticipates that there will often be even a significant temporal gap between a negligent act and the manifestation of injury—and, thus, a resulting insurance claim—particularly in the healthcare industry.

For example, under California law, a lawsuit for injuries caused to a person prior to or during their birth may be filed up to "six years after the date of birth." (Code Civ. Proc., § 340.4.) And even then, that six-year limitations period does not actually begin to run until the plaintiff (or, in the case of a minor, his or her guardian) discovers the injuries that form the basis of the lawsuit, which may take years. (See Rylaarsdam & Turner, Cal. Practice Guide: Civil Procedure Before Trial—Statutes of Limitation (The Rutter Group) ¶ 4:442, pp. 4-35 to 4-36.)

Similarly, the three-year limitations period for medical-malpractice actions (see Civ. Code, § 340.5), does not begin to run until the injury manifests. (*Drexler v. Petersen* (2016) 4 Cal.App.5th 1181, 1190.) In certain cases—such as a physician's negligent failure to appreciate the early signs of cancer—the lag

between negligent act and resulting malpractice-insurance claim can be lengthy.

Nor should the presence of other negligent actors—namely, successor manufacturers who similarly failed to update the label—alter the insurance calculus. It is bedrock California law that, so long as the subsequent negligence was reasonably foreseeable, an original tortfeasor remains liable for injuries wrought in part through its negligence, even where those injuries were only made possible—or were made *worse*—as a result of a third-party's subsequent negligence. (E.g., *Kesner*, *supra*, 1 Cal. at p. 1148.) Indeed, in California, auto insurers are stuck with the fact that it is foreseeable to their insureds *as a matter of law* that anyone they strike with their car could be the victim of medical malpractice during the ensuing medical treatment. (E.g., *Blecker v. Wolbart* (1985) 167 Cal.App.3d 1195, 1201.)

Ultimately, neither of the distinctions between a "concurrent" and "former" brand-name manufacturer—the passage of time or the involvement of other similarly, negligent actors—should disturb the availability of insurance for claims against brand-name manufacturers who negligently fail to

provide a necessary warning on their drug label while they still controlled the drug.

* * *

In short, none of the *Rowland* factors counsels in favor of creating a categorical immunity for "former" brand-name drug manufacturers. Amici's contention that "former" drug manufacturers should receive total immunity from tort liability under *all* circumstances simply because the imposition of liability in *some* circumstances might not be fair or reasonable, even if a defendant's past misconduct bore a causal nexus to the plaintiff's injuries, has no support in the law and should be firmly rejected.

CONCLUSION

For the foregoing reasons, Plaintiffs pray this Court will affirm the decision below and remand for further proceedings.

Dated: February 16, 17

By: /s/ Leslie A. Brueckner
Leslie A. Brueckner, Esq.

By: /s/ Benjamin I. Siminou
Benjamin I. Siminou, Esq.

CERTIFICATE OF COMPLIANCE

As required by California Rules of Court, rule 8.520(c)(1), I certify that, according to the word-count feature in Microsoft Word, this "**Plaintiffs' Consolidated Answer to Amicus Curiae Briefs filed in Support of Respondent**," contains words **13,921**, including footnotes, but excluding any content identified in rule 8.520(c)(3).

Dated: February 16, 17

By: /s/ Benjamin I. Siminou
Benjamin I. Siminou, Esq.

PROOF OF SERVICE

I, the undersigned, say: I am over 18 years of age, employed in the County of San Diego, California, and not a party to the subject cause. My business address is 2550 Fifth Ave., Ste. 1100, San Diego, California, 92103.

On February 16, 2017, I served the attached "**Plaintiffs' Consolidated Answer to Amicus Curiae Briefs filed in Support of Respondent**," of which a true and correct copy of the document filed in the cause is affixed by placing a copy thereof in a separate envelope for each addressee named hereafter, addressed to each such addressee respectively as follows:

See attached Service List

Each envelope was then sealed, and with the postage thereon fully prepaid, deposited in the United States mail by me at San Diego, California, on February 16, 2017.

I declare under penalty of perjury that the foregoing is true and correct, and this declaration was executed at San Diego, California, on February 16, 2017.

_____

Diane DeCarlo

PROOF OF SERVICE

I, the undersigned, say: I am over 18 years of age, employed in the County of San Diego, California, and not a party to the subject cause. My business address is 2550 Fifth Ave., Ste. 1100, San Diego, California, 92103.

On February 16, 2017, I served the attached "**Plaintiffs' Consolidated Answer to Amicus Curiae Briefs filed in Support of Respondent**," of which a true and correct copy of the document filed in the cause is affixed by placing a copy thereof in a separate envelope for each addressee named hereafter, addressed to each such addressee respectively as follows:

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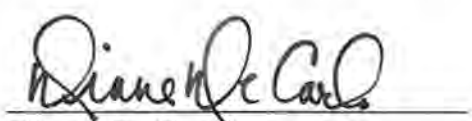

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H. (T.) v. Novartis Pharmaceuticals Corporation
Case Number S233898

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