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IN THE SUPREME COURT OF CALIFORNIA

T.H., a Minor, etc., et al., Plaintiffs and Appellants, v. NOVARTIS PHARMACEUTICALS CORPORATION, Defendant and Respondent.	S233898 Ct.App. 4/1 D067839 San Diego County Super. Ct. No. 37-2013-00070440-CU-MM-CTL

Under California law, a brand-name drug manufacturer has a duty to warn of known or reasonably knowable adverse effects arising from an individual's use of its drug. (See *Stevens v. Parke, Davis & Co.* (1973) 9 Cal.3d 51, 65.) In this case, we examine whether — and if so, under what circumstances — a brand-name drug manufacturer may be sued under a theory of "warning label" liability when the warning label for its drug was alleged to be deficient, but the plaintiffs were injured by exposure to a generic bioequivalent drug bearing the brand-name drug's warning label.

Plaintiffs' mother, J.H., was prescribed terbutaline, a generic form of the brand-name drug Brethine, to suppress premature labor during her pregnancy. Plaintiffs T.H. and C.H. were born full term, but were diagnosed with developmental delays at three years of age and autism by the time they turned five. Through their father as guardian ad litem, the minors allege that those responsible

SEE CONCURRING AND DISSENTING OPINION

for the terbutaline label knew or should have known — based on studies of the drug's effects in rats and in humans — that the drug posed a serious risk to fetal brain development. They further allege that the drug's label unreasonably failed to include a warning about this risk.

Federal law explicitly conveys to the brand-name manufacturer — and only that manufacturer — the responsibility to provide an adequate warning label for both generic terbutaline and its brand-name equivalent, Brethine. As explained in more detail below, only the brand-name drug manufacturer has unilateral authority to modify the drug's label by adding to or strengthening a warning. Generic drug manufacturers are required to follow the brand-name manufacturer's label to the letter. Accordingly, the manufacturer of Brethine controlled both the form and content of the terbutaline warning label.

Plaintiffs brought suit against defendant Novartis Pharmaceuticals Corporation (Novartis), which manufactured Brethine until December 2001, and aaiPharma Inc. (aaiPharma), which purchased the rights to and manufactured Brethine thereafter — using the same label Novartis had used — when plaintiffs' mother was prescribed the generic bioequivalent in 2007. Plaintiffs claim that Novartis knew or should have known that its warning label failed to alert pregnant women or their physicians to the risk Brethine posed to fetal brain development; that manufacturers of terbutaline were compelled by federal law to include Brethine's deficient label on their own products; that it was foreseeable Novartis's successor (aaiPharma) would not change or update Brethine's deficient label; and that in reliance on the deficient warning label, plaintiffs' mother was prescribed terbutaline, which adversely affected plaintiffs' developing brains in utero. What Novartis asserts in response is that its duty to provide a safe and adequate warning label for Brethine did not encompass those who were prescribed terbutaline in reliance on the Brethine label. Novartis further contends that any such duty should

not extend to those who were exposed to terbutaline after Novartis ceased manufacturing Brethine and sold its rights in the drug to aaiPharma.

Such contentions, and the case in which they arise, reach us at a very early stage in the litigation. In reviewing a demurrer, we ask only whether the plaintiff has alleged — or could allege — sufficient facts to state a cause of action against the defendant. (*Schifando v. City of Los Angeles* (2003) 31 Cal.4th 1074, 1081.) In our view, plaintiffs have indeed shown that they could allege a cause of action against Novartis for warning label liability. Because the same warning label must appear on the brand-name drug as well as its generic bioequivalent, a brand-name drug manufacturer owes a duty of reasonable care in ensuring that the label includes appropriate warnings, regardless of whether the end user has been dispensed the brand-name drug or its generic bioequivalent. If the person exposed to the generic drug can reasonably allege that the brand-name drug manufacturer's failure to update its warning label foreseeably and proximately caused physical injury, then the brand-name manufacturer's liability for its own negligence does not automatically terminate merely because the brand-name manufacturer transferred its rights in the brand-name drug to a successor manufacturer. We therefore affirm the Court of Appeal, which had directed the trial court to enter an order sustaining Novartis's demurrer with leave to amend plaintiffs' negligence and negligent misrepresentation causes of action.

I. BACKGROUND

From a certain perspective, the claim underlying this lawsuit is quite straightforward. Plaintiffs T.H and C.H., who are fraternal twins, sued defendant Novartis for negligence and negligent misrepresentation arising from Novartis's failure to warn of the risks of Brethine, an asthma drug sometimes prescribed "off label" to stop or slow preterm labor. Plaintiffs allege that Novartis knew or

should have known that Brethine carried a substantial risk of causing developmental and neurological damage to the fetus, yet failed to warn of this risk.

What removes this case from the realm of the ordinary is that plaintiffs' mother was never prescribed Brethine. Rather, she — like many pregnant women experiencing premature labor — was prescribed terbutaline sulfate (terbutaline), the generic bioequivalent drug. Moreover, Novartis stopped manufacturing Brethine and sold all rights to the drug in 2001, six years before plaintiffs' injury. During the period it was the brand-name manufacturer, however, Novartis had the legal duty to disclose Brethine's known and reasonably knowable risks in the drug's warning label. All generic manufacturers, in turn, had a specific legal responsibility regarding the label: to ensure the terbutaline label was identical to the Brethine label. We therefore examine plaintiffs' allegations against the backdrop of the distinctive legal framework governing labeling for brand-name and generic pharmaceuticals.

On review of a demurrer, we accept as true all properly pleaded facts. (*Shirk v. Vista Unified School Dist.* (2007) 42 Cal.4th 201, 205.) Where particular facts are set out below, they are those alleged in plaintiffs' first amended complaint.

A. Federal Regulation of Drug Labeling

The Food, Drug, and Cosmetic Act (FDCA; 21 U.S.C. § 301 et seq.) prohibits the marketing of a new brand-name drug unless the manufacturer has submitted a new drug application (NDA) and the Food and Drug Administration (FDA) has approved the drug as safe and effective for its intended use. (21 U.S.C. § 355(a).) The NDA must include an exemplar of the drug's proposed label (21 U.S.C. § 355(b)(1)(F)) describing the drug's indications and usage,

contraindications, warnings and precautions, and adverse reactions. (21 C.F.R. § 201.56(e)(1).)

In 1984, Congress enacted the Hatch-Waxman Act. (98 Stat. 1585, 1585-1597, codified as amended at 21 U.S.C. § 355.) This statute allows a prospective generic drug manufacturer to file an abbreviated new drug application (ANDA) asserting the generic drug's bioequivalence to an existing listed drug that has already been approved by the FDA. (*PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 612 (*PLIVA*), citing 21 U.S.C. § 355(j).) Such an application is typically filed as the brand-name drug's patent is about to expire. The streamlined application relieves the generic manufacturer of the need to duplicate the clinical trials previously submitted for the equivalent brand-name drug. (*Ibid*.) The generic manufacturer must nonetheless "show that the labeling proposed for the new drug is the same as the labeling approved for the listed drug." (21 U.S.C. § 355(j)(2)(A)(v).)

So under the federal scheme, "brand-name and generic drug manufacturers have different federal drug labeling duties." (*PLIVA, supra*, 564 U.S. at p. 613.) It is the brand-name manufacturer that bears responsibility for the accuracy and adequacy of its label "as long as the drug is on the market." (*Wyeth v. Levine* (2009) 555 U.S. 555, 570-571 (*Wyeth*).) The generic manufacturer, on the other hand, is responsible only for "an ongoing federal duty of 'sameness' " — that is, ensuring that its warning label is the same as the brand-name manufacturer's. (*PLIVA*, at p. 613.)

FDA regulations require the brand-name drug manufacturer to update the warning label "as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." (21 C.F.R. § 201.80(e); cf. *id*., § 314.80(b) [NDA holder "must promptly review all adverse drug experience information obtained or otherwise received by the

applicant from any source"].) A specific warning is required if the drug is commonly prescribed for a disease or condition, even when the drug has not yet been approved for that use, where "such usage is associated with serious risk or hazard." (*Id*., § 201.80(e).) Any manufacturer of the drug at issue may request a change in the label by submitting a "prior approval supplement" to the FDA, which decides whether to approve the requested change in the warning label. (21 C.F.R. § 314.70(b)(2)(v); FDA, Abbreviated New Drug Application Regulations, 57 Fed.Reg. 17950, 17961 (Apr. 28, 1992).) But a brand-name drug manufacturer, unlike a generic manufacturer, may *unilaterally* update a label, without waiting for FDA preapproval, "[t]o add or strengthen a contraindication, warning, precaution, or adverse reaction" under the "changes being effected" (CBE-0) regulation. (21 C.F.R. § 314.70(c)(6)(iii)(A); see *Wyeth*, *supra*, 555 U.S. at p. 568.) By contrast, a generic manufacturer may use the CBE-0 regulation only to conform its label to an updated brand-name label. (*PLIVA*, *supra*, 564 U.S. at p. 614.)

Because federal regulations preclude generic manufacturers from unilaterally altering the warning labels on their drugs (*PLIVA*, *supra*, 564 U.S. at p. 617), federal law preempts state tort claims against generic manufacturers for failure to provide adequate warnings. (*Id*. at p. 609.) State tort claims against a brand-name manufacturer based on a failure to warn, however, are not preempted. (*Id*. at p. 625.)

B. Terbutaline, Brethine, and Novartis

Terbutaline is a beta-adrenergic agonist, acting upon the beta2 receptors in smooth muscle tissue and causing muscles to relax. The drug was originally developed by Draco, a Swedish company, and released for use as a bronchodilator to treat asthma. In 1974, the FDA approved terbutaline as a treatment for asthma

in the United States. Astra AB (and later, AstraZeneca LP) licensed the right to manufacture and market terbutaline in its oral form to Ciba-Geigy (a predecessor to Novartis) under the brand name Brethine. Novartis owned the NDA for Brethine until 2001.

In 1976, a Swedish physician with ties to Draco published the results of a small study indicating that terbutaline was safe and effective as a tocolytic — a drug to suppress premature labor in pregnant women — on the theory that the drug could relax uterine smooth muscle tissue. Terbutaline subsequently gained wide acceptance as a tocolytic, but neither Novartis nor any other manufacturer sought FDA approval for this off-label use.[1] Later studies cast doubt on the safety and efficacy of terbutaline as a tocolytic.

In 1978, a study published in the British Journal of Obstetrics and Gynaecology questioned the validity and conclusions of the original Swedish report. According to plaintiffs' complaint, the British study warned that the benefits of this class of drugs on preterm labor was " 'not yet established,' " that the evidence was " 'too scanty to make conclusions about side effects possible,' " and that other data suggested " 'that labor inhibitors are potentially dangerous.' " A year later, a study published in the American Journal of Obstetrics and Gynecology reported adverse effects in both the pregnant mother and in the fetus following terbutaline exposure.

A team of American clinical investigators in 1982 sought to replicate the results of the 1976 Swedish study. They could not. In fact, the investigators were

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[1] Physicians may, in their professional judgment, prescribe a drug for a purpose other than that for which it has been approved by the FDA. (*Buckman Co. v. Plaintiffs' Leg. Com.* (2001) 531 U.S. 341, 351, fn. 5 [" 'Off-label use is widespread in the medical community' "].)

unable to find any benefit among the pregnant mothers who had been prescribed terbutaline as compared to those who received a placebo. A 1984 study published in the Journal of Reproductive Medicine similarly failed to confirm any benefits.

In 1985, Dr. Theodore Slotkin and a team of Duke University Medical Center researchers found that a single dose of terbutaline given to pregnant rats interfered with an enzyme necessary for neuronal development in the fetal brain. Dr. Slotkin's study showed that terbutaline can cross the placenta and fetal brain barrier in sufficient quantities to affect brain development. Other studies in the 1980s revealed that children born to mothers who had received a different beta-adrenergic agonist had poorer academic achievement and were more likely to have impairments in vision and language development than children born to mothers who did not receive such treatment.

In 1989 and 1990, Dr. Slotkin published studies showing that terbutaline may interfere with the fetus's neurobehavioral development, presumably through its effects on receptors in the fetal cerebellum. Shortly thereafter, in 1992, scientists from the University of Texas undertook a comprehensive and critical evaluation of the literature relating to terbutaline and concluded, in a study published in the American Journal of Obstetrics and Gynecology, that the drug had not been shown to arrest preterm labor and that chronic exposure may adversely affect the fetus. A 1995 meta-analysis by researchers from the University of Pennsylvania likewise concluded that the relevant literature did not support the claimed benefit from maintenance tocolytic therapy. The American College of Obstetricians and Gynecologists (ACOG) subsequently issued a "Technical Bulletin on Preterm Labor" to its more than 40,000 members, which noted the asserted benefit from maintenance tocolytic therapy lacked any evidentiary basis and warned that the potential risks of such therapy, to both the mother and the fetus, were well documented. ACOG's bulletin stated that the risk

associated with beta-mimetic agents (such as terbutaline) appeared greater than that associated with other tocolytic agents. In 1997, the FDA's Associate Commissioner for Health Affairs issued a "Dear Colleague" letter, which endorsed ACOG's assessment of the benefits and dangers of long-term tocolytic therapy.

In 2001, the German Central Institute of Mental Health issued a report concluding that children whose mothers had received beta-agonist tocolysis had a significantly higher rate of psychiatric disorders and psychopathology, and that such children scored lower on psychometric tests of cognitive development. Dr. Slotkin's Duke team released another study in October 2001, which revealed that beta2 receptors in the fetal brain, unlike those in mature brains, do not desensitize when exposed to continuous doses of terbutaline. Instead, the fetal receptors intensify their sensitivity to terbutaline and thus increase their response to the drug as the dosage increases (and the brain develops).

Over the years, researchers developed — and companies brought to market — newer and more effective bronchodilators and other asthma treatments. Novartis continued to manufacture and distribute Brethine with the intention that it be used as a tocolytic. By 2001, nearly half of all prescriptions for terbutaline were for tocolysis, even though the drug was never approved by the FDA for that purpose. In December 2001, Novartis transferred the NDA for Brethine to NeoSan Pharmaceuticals Inc., a wholly owned subsidiary of aaiPharma.

C. The Facts Underlying This Lawsuit

On September 5, 2007, plaintiffs' mother, J.H., was hospitalized because of concerns about premature labor. She was prescribed terbutaline, to be administered every six hours, and was discharged on September 25, 2007. While in the hospital, J.H. received a generic version that was manufactured by Lehigh Valley Technologies, Inc.; after discharge, she received a generic version that was

manufactured by Global Pharmaceuticals. J.H. continued taking terbutaline as directed until plaintiffs were born on October 9, 2007. Plaintiffs appeared to be normal until their pediatrician, during a routine checkup in December 2010, reported that the twins may have developmental delays. Despite specialized treatment for both children, a pediatric neurologist diagnosed them with autism in August 2012.

Plaintiffs' first amended complaint alleges that terbutaline passed through the placenta and the blood-brain barrier. As a result, plaintiffs contend, terbutaline caused them to suffer severe and permanent neurologic injuries, including an inability to speak and significant limitations and abnormalities in their motor skills. Plaintiffs further allege that Novartis knew or should have known that terbutaline was of questionable efficacy as a tocolytic agent, that terbutaline carried serious risks of side effects for newborns whose mothers received the drug during pregnancy, and that federal law required Novartis to report this information to the FDA and to update the warning label — something Novartis could have done unilaterally. (See 21 C.F.R. § 314.70(c)(6)(iii)(A).) Instead, Novartis falsely represented that terbutaline was safe and effective and would not cause serious side effects in newborns, and it intended for pregnant mothers and their physicians to rely on these representations. The complaint asserted causes of action for negligence and negligent misrepresentation, as well as strict liability, intentional misrepresentation, concealment, and medical negligence.

To support and place in factual context their negligence cause of action, plaintiffs made a variety of specific allegations regarding Novartis. They alleged that Novartis had a duty to update the label to warn of the drug's effects on fetal development, that Novartis knew or should have known of these effects, that J.H.'s physicians prescribed her terbutaline because of their erroneous belief that terbutaline was safe to use as a tocolytic, that plaintiffs suffered neurological

damage as a result of their exposure to terbutaline in utero, and that plaintiffs' injuries were foreseeable. Meanwhile, plaintiffs' negligent misrepresentation cause of action alleged that Novartis falsely represented that terbutaline was safe to use as a tocolytic, that Novartis had no reasonable basis for believing terbutaline was safe to use as a tocolytic, that Novartis intended for pregnant mothers and their physicians to rely on their false representations concerning the drug's safety as a tocolytic agent, that J.H. and her physicians relied on Novartis's representations, that plaintiffs suffered neurological damage as a result of their exposure to terbutaline in utero, and that plaintiffs' injuries were foreseeable.

Novartis's core assertion in its demurrer was that it had no duty to plaintiffs. To justify its position, the company offered two overarching rationales: It did not manufacture the terbutaline ingested by their mother; and it had transferred the Brethine NDA to another company in December 2001, nearly six years before plaintiffs' mother was prescribed terbutaline. In addition, Novartis argued that plaintiffs had failed to identify with specificity any misrepresentation by Novartis or allege that plaintiffs had relied on any such misrepresentation. In opposition to the demurrer, plaintiffs responded that Novartis had a duty to warn about the drug's effects on fetal development during the period it owned the NDA and manufactured Brethine; that the six-year gap between Novartis's divestiture of the NDA and plaintiffs' in utero exposure is relevant to causation (and not the existence of the duty); and that the first amended complaint adequately pleaded the misrepresentations with specificity, given that the specific misrepresentations are more likely to be within Novartis's knowledge, and adequately pleaded reliance on those misrepresentations.

The trial court sustained the demurrer without leave to amend. It concluded that Novartis owed plaintiffs no duty as a matter of law relating to claims arising from terbutaline exposure in 2007. Agreeing with Novartis, the court also found

that the fraud-based claims suffered from a lack of specificity and that this defect could not be remedied by allegations about Novartis's conduct prior to the 2001 NDA divestiture.

The Court of Appeal reversed and directed that the order sustaining the demurrer be modified to grant plaintiffs leave to amend their causes of action for negligence and negligent misrepresentation. The appellate court reasoned that if plaintiffs could allege that Novartis failed to warn about fetal risks it knew or should have known were associated with terbutaline when used as a maintenance tocolytic prior to its divestiture of the brand-name drug in 2001, that the warning would have remained on the label in 2007 had Novartis added a suitable warning to the label before divestiture in 2001, and that their mother's physician would not have prescribed terbutaline as a maintenance tocolytic had the drug been properly labeled, then their claims for negligence and negligent misrepresentation can survive demurrer.

We granted Novartis's petition for review to decide the existence and scope of warning label liability for brand-name drug manufacturers under California law.

II. DISCUSSION

The sole issue before us is whether the demurrer should have been sustained with respect to the negligence and negligent misrepresentation claims on the ground that Novartis owed no duty of care to plaintiffs. In reviewing an order sustaining a demurrer, we examine the operative complaint de novo to determine whether it alleges facts sufficient to state a cause of action under any legal theory. (*Lee v. Hanley* (2015) 61 Cal.4th 1225, 1230.) Where the demurrer was sustained without leave to amend, we consider whether the plaintiff could cure the defect by an amendment. The plaintiff bears the burden of proving an amendment could cure the defect. (*Blank v. Kirwan* (1985) 39 Cal.3d 311, 318.)

The gist of plaintiffs' warning label liability claim is that Novartis negligently failed to warn about the drug's risk to fetal brain development. They contend that the deficient label foreseeably and proximately caused harm not only to the children of women who were prescribed Brethine, but also to the children of women who were prescribed its generic bioequivalent, which was legally required to — and did — bear the same deficient label. Among other things, plaintiffs rely on section 311 of the Restatement Second of Torts (section 311), which addresses negligent misrepresentation involving physical harm. Under section 311(1), "[o]ne 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 [¶] . . . [¶] to such third persons as the actor should expect to be put in peril by the action taken."

Section 311's theory of liability is intended to be "somewhat broader" than that for mere pecuniary loss. (Rest.2d Torts, § 311, com. a.) It "finds particular application where it is a part of the actor's business or profession to give information upon which the safety of the recipient or a third person depends." (*Id.*, § 311, com. b; see also Prosser, *Misrepresentation and Third Persons* (1966) 19 Vand. L.Rev. 231, 254 [explaining that one has a duty not to make a false representation to "[t]hose to whom a public duty is found to have been created by statute, or pursuant to a statute . . . [and to] [t]hose members of a group or class whom he has special reason to expect to be influenced by the representation"].) This court applied and followed section 311 in *Randi W. v. Muroc Joint Unified School Dist.* (1997) 14 Cal.4th 1066 (*Randi W.*). There, we concluded that a school district's negligent misrepresentations about a former employee in a letter of recommendation could render the school district liable for the employee's molestation of a third person — a student at the employee's new school — even though the student had no special relationship with the former school district and

never received the misleading information. (*Id*. at p. 1081.) In accordance with the Restatement, we held "that the writer of a letter of recommendation owes to third persons a duty not to misrepresent the facts in describing the qualifications and character of a former employee, if making these misrepresentations would present a substantial, foreseeable risk of physical injury to the third persons." (*Ibid*.) Plaintiffs urge us to hold, in similar fashion, that a brand-name drug manufacturer owes a duty to third persons not to misrepresent the safety of its drug, if making those misrepresentations would present a substantial, foreseeable risk of physical injury to those third persons.

Duty is indeed the cornerstone of every negligence claim. In California, the general rule governing duty is codified in Civil Code section 1714, subdivision (a): "Everyone is responsible . . . for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person . . . ." Thus, "each person has a duty to use ordinary care and 'is liable for injuries caused by his failure to exercise reasonable care in the circumstances . . . .' " (*Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456, 472.) Whether a party has a duty of care in a particular case is a question of law for the court, which we review independently on appeal. (*Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1142 (*Kesner*).)

The conclusion that a duty exists in a particular case " 'is not sacrosanct in itself, but only an expression of the sum total of those considerations of policy which lead the law to say that the particular plaintiff is entitled to protection.' " (*Dillon v. Legg* (1968) 68 Cal.2d 728, 734, quoting Prosser, Law of Torts (3d ed. 1964) pp. 332-333.) We invoke the concept of duty to limit " ' " 'the otherwise potentially infinite liability which would follow from every negligent act,' " ' " yet we do so only where public policy clearly supports (or a statutory provision establishes) an exception to the general rule of Civil Code section 1714. (*Kesner*,

supra, 1 Cal.5th at p. 1143.) When considering whether to depart from the general rule, we balance a number of considerations, including "the foreseeability of harm to the plaintiff, the degree of certainty that the plaintiff suffered injury, the closeness of the connection between the defendant's conduct and the injury suffered, the moral blame attached to the defendant's conduct, the policy of preventing future harm, the extent of the burden to the defendant and consequences to the community of imposing a duty to exercise care with resulting liability for breach, and the availability, cost, and prevalence of insurance for the risk involved." (*Rowland v. Christian* (1968) 69 Cal.2d 108, 113 (*Rowland*).)

In the context of prescription drugs, a manufacturer's duty is to warn physicians about the risks known or reasonably known to the manufacturer. (*Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1112 (*Carlin*); see generally *Finn v. G.D. Searle & Co.* (1984) 35 Cal.3d 691, 699-700.) The manufacturer has no duty to warn of risks that are "merely speculative or conjectural, or so remote and insignificant as to be negligible." (*Carlin*, at p. 1116.) If the manufacturer provides an adequate warning to the prescribing physician, the manufacturer need not communicate a warning directly to the patient who uses the drug. (*Ibid*.)

In this case, plaintiffs allege that the terbutaline label failed to warn about the risks to fetal brain development and falsely represented that the drug was safe for use by pregnant women. They further claim that Novartis's control over the Brethine label rendered it responsible for any deficiencies in the terbutaline label, given that generic drug manufacturers are legally obligated to use the label crafted by the brand-name drug manufacturer. Novartis contends that it owed no duty to plaintiffs to update or maintain an accurate label because (1) it did not manufacture the terbutaline that caused plaintiffs' injuries; and (2) it had divested ownership of Brethine, the name-brand drug, several years before plaintiffs' mother was prescribed terbutaline.

To determine whether to create an exception to a brand-name drug manufacturer's duty to warn, we balance the constellation of factors set out in *Rowland, supra*, 69 Cal.2d at page 113. Three of those factors — foreseeability, the certainty of the injury, and the closeness of the connection between the plaintiff and the defendant — address the foreseeability of the relevant injury. (*Kesner, supra*, 1 Cal.5th at p. 1145.) The remaining four — moral blame, the policy of preventing future harm, the burden on the defendant and the general public, and the availability of insurance — focus on the public policy justifications for or against carving out an exception to the general duty in this category of cases. (*Ibid*.) Our task is to determine whether a brand-name manufacturer owes a duty of ordinary care to those who may be injured by deficiencies in its warning label, not whether Novartis acted reasonably under the particular circumstances here. (See *Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 772-774 (*Cabral*).)

A. Whether Plaintiffs Exposed to the Generic Bioequivalent Drug Can Assert Warning Label Liability Against Novartis, the Brand-name Drug Manufacturer

The first case to recognize warning label liability was *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89 (*Conte*). In *Conte* the court concluded that a brand-name drug manufacturer's common law duty of care when warning of the dangers of its drug extended not only to consumers of the brand-name drug, "but also to those whose doctors foreseeably rely on the name-brand manufacturer's product information when prescribing a medication, even if the prescription is filled with the generic version of the prescribed drug." (*Id*. at p. 94.) The Court of Appeal's holding predated by more than two years the United States Supreme Court's ruling that federal law requires generic drug manufacturers to conform their warning label to the label used by the brand-name manufacturer (*PLIVA, supra*, 564 U.S. at

p. 613), and its analysis referenced some — but not all — of the *Rowland* factors. (*Conte*, at pp. 105-107.)

Only a handful of courts have followed *Conte*. (See, e.g., *Dolin v. SmithKline Beecham Corp.* (N.D.Ill. 2014) 62 F.Supp.3d 705; *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; *Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649 (*Weeks*).) But our careful review of the federal regulatory scheme and analysis of all the *Rowland* factors persuades us that a brand-name drug manufacturer has the duty under California law to warn of the risks about which it knew or reasonably should have known, regardless of whether the consumer is prescribed the brand-name drug or its generic "bioequivalent." (See 21 U.S.C. § 355(j)(2)(A)(iv).)

1. Foreseeability and related factors

In determining whether to create an exception to the general statutory duty of care, the "major" (*Cabral, supra*, 51 Cal.4th at p. 771, fn. 2), and ultimately "most important" (*Kesner, supra*, 1 Cal.5th at p. 1145), consideration under California law is the foreseeability of physical harm. Novartis could reasonably have foreseen that deficiencies in its Brethine label could mislead physicians about the safety of terbutaline, Brethine's generic bioequivalent, which was legally required to bear an identical label.

A brand-name pharmaceutical manufacturer has a duty under federal law to draft, update, and maintain the warning label so that it provides adequate warning of the drug's potentially dangerous effects. (21 U.S.C. § 352(f)(2).) The FDA, as part of its premarket review process, must approve the text of the proposed label. (21 U.S.C. § 355; *Wyeth, supra*, 555 U.S. at p. 568.) Although the brand-name manufacturer generally must obtain FDA approval before making any change to the label, this category of manufacturers may use the "changes being effected"

(CBE-0) regulation (21 C.F.R. § 314.70(c)(3)) to "add or strengthen a contraindication, warning, precaution, or adverse reaction" immediately upon filing a supplemental application, without waiting for FDA approval. (*Id.*, § 314.70(c)(6)(iii)(A).)

The duty for a manufacturer of generic drugs, on the other hand, is to ensure that its warning label is identical to the label of the brand-name drug. (*PLIVA, supra*, 564 U.S. at p. 613.) In other words, generic manufacturers "have an ongoing federal duty of 'sameness.' " (*Ibid.*) A generic manufacturer may use the CBE-0 regulation to change its label only to match a revised brand-name label or otherwise comply with FDA instructions. (*Id.* at p. 614.)

What a brand-name manufacturer thus knows to a legal certainty is that any deficiencies in the label for its drug will be perpetuated in the label for its generic bioequivalent. A brand-name manufacturer will also be aware that although the warnings communicated in its drug label are designed for physicians — and are intended to influence a physician's decision whether to prescribe the drug (see *Stevens v. Parke, Davis & Co.*, *supra*, 9 Cal.3d at pp. 64-65) — it is often the pharmacist who actually decides whether the patient receives the brand-name drug or its generic bioequivalent. (Bus. & Prof. Code, § 4073.) Moreover, many insurance companies require the substitution of a generic drug for the brand-name drug as a matter of course, unless the physician justifies use of the branded drug. (*PLIVA, supra*, 564 U.S. at p. 628, fn. 2 (dis. opn. of Sotomayor, J.).) Accordingly, it is entirely foreseeable that the warnings included (or not included) on the brand-name drug label would influence the dispensing of the generic drug, either because the generic is substituted by the pharmacist or the insurance company *after* the physician has prescribed the brand-name drug, or because the warning label on the generic drug is legally required to be identical to the label on

the brand-name drug. (*Conte*, *supra*, 168 Cal.App.4th at p. 105; accord, *Weeks*, *supra*, 159 So.3d at p. 670.)

Under the second *Rowland* factor, we assess the degree of certainty that the plaintiff suffered injury. This factor, too, strengthens the case for finding a duty of care in these circumstances. Plaintiffs allege that they suffer from global neurological impairment, including autism and pervasive developmental delays. These are indisputably injuries and are compensable under the law. (See *Kesner*, *supra*, 1 Cal.5th at p. 1148.)

The third *Rowland* factor implicates the closeness of the connection between the defendant's conduct and the plaintiff's injury. The label for a generic drug is (and must be) the same as the label for the brand-name drug, so any deficiency in the brand-name label will be reflected in the generic label. Plaintiffs allege that the deficient Brethine label led their mother's physician to prescribe terbutaline, which caused their neurological injuries. This scenario describes a close connection between Novartis's allegedly negligent conduct and plaintiffs' injuries.

Novartis, meanwhile, relies on *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335 (*O'Neil*). This is a case we can distinguish. There, a naval seaman developed mesothelioma caused by asbestos exposure. Following his death, his family filed a wrongful death action asserting strict liability and negligence claims against several defendants, including the manufacturers of valves and pumps that were used in warships. (*Id*. at p. 346.) At the close of evidence, the defendant manufacturers moved for nonsuit, pointing out the plaintiffs' failure to show that the decedent had been exposed to asbestos from any of their products. Plaintiffs responded that even if the decedent was never exposed to asbestos from the defendants' products themselves, it was foreseeable that the defendants' valves and pumps would need to be replaced with new asbestos-containing components,

and that asbestos could be released into the air during the repair and replacement process. (*Ibid*.) In reinstating the trial court's judgment of nonsuit, we invoked the *Rowland* factors and noted, in particular, that the connection between the defendant manufacturers' conduct and the decedent's injury was "extremely remote" (*id*. at p. 365): Although component parts of the defendants' valves and pumps had been replaced "during routine maintenance" (*id*. at p. 344), the decedent did not begin to work in the vicinity of these valves and pumps until more than 20 years after they were installed — and did not suffer an injury for another 40 years. In addition, the defendant manufacturers did not produce, sell, or supply any of the asbestos-containing products that could have caused his mesothelioma. Because the defendants' asserted misconduct, according to the plaintiffs, was simply that they failed to warn about the potential dangers in replacement parts sold by other manufacturers — and there was "no reason to think a product manufacturer [would] be able to exert any control over the safety of replacement parts or companion products made by other companies" — we found that the connection between the alleged misconduct and the injury was too "attenuate[d]" to warrant imposition of a duty of care. (*Id*. at p. 365.)

Here, by contrast, federal regulations granted the brand-name drug manufacturer — and no other manufacturer — control over the active ingredients in the generic drug and the content of the warnings included in the generic's label.[2] In addition, the temporal connection between Novartis's allegedly

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[2] The FDA has been considering for some time a rule that would effectively abrogate *PLIVA* and enable generic drug manufacturers to update a drug's warning label unilaterally, even if the brand-name manufacturer had not yet done so. (See FDA, Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed.Reg. 67985 (Nov. 13, 2013); see Dept. of Health and Human Services, Regulatory Agenda, 82 Fed.Reg. 40277, 40279 (Aug. 24, 2017).) If adopted, the new rule "would create parity between NDA holders

negligent conduct, on the one hand, and plaintiffs' exposure to harm and subsequent injury, on the other, is much closer than was the case in *O'Neil*.

2. Considerations of public policy

Foreseeability alone, however, is not sufficient to justify a duty of care in every instance. (*Erlich v. Menezes* (1999) 21 Cal.4th 543, 552.) We will not recognize a duty of care even as to foreseeable injuries "where the social utility of the activity concerned is so great, and avoidance of the injuries so burdensome to society, as to outweigh the compensatory and cost-internalization values of negligence liability." (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 502.) Novartis contends that the circumstances here present such an exceptional case. We disagree.

Time and again we have recognized how " '[t]he overall policy of preventing future harm is ordinarily served, in tort law, by imposing the costs of negligent conduct upon those responsible.' " (*Kesner*, *supra*, 1 Cal.5th at p. 1150, quoting *Cabral*, *supra*, 51 Cal.4th at p. 781.) A brand-name drug manufacturer is not only in the best position to warn of a drug's harmful effects (*Sindell v. Abbott Laboratories* (1980) 26 Cal.3d 588, 611): It is also the *only* manufacturer with the unilateral authority under federal law to issue such a warning for the brand-name drug or its generic bioequivalent. Although federal regulations impose a continuing duty on the brand-name manufacturer to update and maintain an

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and ANDA holders with respect to submission of CBE-0 supplements for safety-related labeling changes based on newly acquired information" (78 Fed.Reg., *supra*, at p. 67989) and may conceivably justify reweighing of the *Rowland* factors and some reconsideration of the brand-name manufacturer's duty in this category of cases.

adequate warning label (see 21 C.F.R. § 201.80(e)), a brand-name manufacturer's incentive to comply with that duty declines once the patent expires and generic manufacturers enter the market, since the market share for the brand-name drug at that point "may drop substantially." (78 Fed.Reg., *supra*, at p. 67988 ["Among drugs for which a generic version is available, approximately 94 percent are dispensed as a generic"].) The possibility that any consumer injured by a deficient drug label, including those who were dispensed the generic bioequivalent drug, could assert a claim of warning label liability restores the brand-name manufacturer's incentive to update the warning label with the latest safety information, even as the brand-name drug's market share declines.

If the policy of preventing harm has special relevance to any particular endeavor, surely prescription drug labeling is one. (*Sindell v. Abbott Laboratories*, *supra*, 26 Cal.3d at p. 611.) A substantial body of state law serves to protect California consumers from the dangers posed by false, misleading, and inadequate labeling of prescription medications. (See, e.g., Bus. & Prof. Code, §§ 4070-4078.) The United States Supreme Court, too, has recognized the pivotal role of state tort actions "as a complementary form of drug regulation" with respect to drug labeling. (*Wyeth*, *supra*, 555 U.S. at p. 578; see *id*. at p. 579 ["State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times"]; accord, *Stevens v. Parke, Davis & Co.*, *supra*, 9 Cal.3d at p. 65 [recognizing that federal warning-label regulations alone may be insufficient to protect patient safety].)

The brand-name drug manufacturer is the only entity with the unilateral ability to strengthen the warning label. So a duty of care on behalf of all those who consume the brand-name drug or its bioequivalent ensures that the brand-name manufacturer has sufficient incentive to prevent a known or reasonably knowable harm. In *O'Neil*, by contrast, we found "no reason" to believe that the defendant valve and pump manufacturers would have any control over the safety of other companies' replacement parts or companion products (or even the Navy's purchasing choices or specifications). (*O'Neil*, *supra*, 53 Cal.4th at p. 365.) Our no-duty conclusion also rested explicitly on the fact that the replacement parts' "dangerous feature" — i.e., the asbestos — "was not integral to the product's design." (*Id*. at p. 343.) Here, on the other hand, the brand-name drug manufacturer exercised complete control over the contents of the generic drug label at the time of its alleged negligence, and the generic drug was legally required to be the brand-name drug's bioequivalent. We therefore conclude that warning label liability is likely to be effective in reducing the risk of harm to those who are prescribed (or are exposed to) the brand-name drug or its generic bioequivalent.

Against the public interest in preventing harm, we must balance the defendant's burden and the consequences to the community of imposing a duty of care. The burden that matters, though, is not the cost of compensating individuals for injuries that the defendant has actually and foreseeably caused. As we recently explained in *Kesner*, "shielding tortfeasors from the full magnitude of their liability for past wrongs is not a proper consideration in determining the existence of a duty. Rather, our duty analysis is forward-looking, and the most relevant burden is the cost to the defendants of upholding, not violating, the duty of ordinary care." (*Kesner*, *supra*, 1 Cal.5th at p. 1152.)

Strictly speaking, then, the burden on brand-name drug manufacturers of satisfying a common law duty of care to those who are prescribed the generic version of the drug is zero. Brand-name manufacturers *already* have a continuing duty to warn of potential risks "as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved." (21 C.F.R. § 201.80(e).) A brand-name manufacturer's burden to maintain an adequate warning label persists without regard to the happenstance that a given prescription for a brand-name drug may — because of insurance company cost-savings rules (*Meijer, Inc. v. Warner Chilcott Holdings Co. III Ltd.* (D.D.C. 2007) 246 F.R.D. 293, 297), or a pharmacist's discretion (Bus. & Prof. Code, § 4073, subd. (c)) — be filled with a generic bioequivalent. And where the brand-name manufacturer provides an adequate label, then it necessarily has also fulfilled its duty with respect to the generic bioequivalent.

Novartis complains that unless the ordinary duty of care is narrowed, the brand-name drug manufacturer would end up an insurer for the entire market. This would occur, Novartis contends, even though the brand-name manufacturer may hold only a small fraction of the combined sales of the brand-name drug and its generic bioequivalent. We disagree. A brand-name drug manufacturer would not be liable where, for example, the injury arose from a defect in the manufacturing process of the generic drug (see, e.g., *Fisher v. Pelstring* (D.S.C. 2012) 817 F.Supp.2d 791, 818), the generic manufacturer failed to conform its label to the brand-name drug's label (*Fulgenzi v. PLIVA, Inc.* (6th Cir. 2013) 711 F.3d 578, 582, 584; *Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, 356 (plur. opn. of Waterman, J.)), or the generic manufacturer was promoting a use that was inconsistent with the FDA-approved label (*Arters v. Sandoz, Inc.* (S.D. Ohio 2013) 921 F.Supp.2d 813, 819-820). Under warning label liability, the brand-name drug manufacturer is liable *only* in a narrow circumstance — when deficiencies in its

own label foreseeably and proximately caused injury. If instead tort law simply carved out those who were given the generic bioequivalent from obtaining otherwise available compensation for injuries attributable to the brand-name drug manufacturer's defective warning label, then consumers would insist on the brand-name drug over the cheaper bioequivalent, inflating health costs with no corresponding increase in safety and in contradiction to the stated federal policy of making low-cost generic drugs more available. (See H.R.Rep. No. 98-857, 2d Sess., p. 14 (1984), reprinted in 1984 U.S. Code Cong. & Admin. News, p. 2647.)

Novartis nonetheless predicts that unless we carve out an exception for those taking generic drugs, warning label liability will lead to overwarning — i.e., inclusion of a slew of speculative risks in the warning label — which would dilute the effectiveness of any individual warning. But why this would occur is far from clear. To recognize that the duty of care includes all those who would foreseeably be affected by a deficient brand-name drug label merely preserves the brand-name manufacturer's duty as it existed when its patent excluded all competitors from the market. Nor has Novartis identified any surge in overwarning since 2008, when *Conte* recognized warning label liability. (Cf. *Carlin*, *supra*, 13 Cal.4th at p. 1116, fn. 6 ["[T]here is no evidence that any such [overwarning] problem has emerged or that patients have suffered any detriment, despite the fact that strict liability has long been the rule in California"].) Plaintiffs further suggest that the consequences of overwarning on physicians' prescription decisions is uncertain (Steven Garber, RAND Institute for Civil Justice, Economic Effects of Product Liability and Other Litigation Involving the Safety and Effectiveness of Pharmaceuticals (2013) p. xiv ["That claim is controversial within the medical community, and there is no direct empirical evidence about it"]) and, in any event, can be solved through the FDA's power to reject a labeling change it deems unnecessary or counterproductive. (See *Wyeth*, *supra*, 555 U.S. at p. 571.)

Novartis cautions that warning label liability could perversely incentivize a brand-name manufacturer to withdraw its drug from the market, rather than expose itself to the risk of suit by those who — in reliance on the brand-name manufacturer's label — were prescribed the generic bioequivalent and suffered injury. Yet Novartis fails to explain why brand-name manufacturers would find it economically advantageous to withdraw drugs from the market rather than simply modify the warning labels to include the newly discovered risks. Nor does it offer any evidence that brand-name manufacturers have accelerated their withdrawal from the market in the nine years since *Conte* was decided. Moreover, a brand-name drug manufacturer cannot avoid its duty to update and maintain its warning label simply by unilaterally exiting the market. Under FDA regulations, a brand-name drug manufacturer's duty to update and maintain the warning label continues, even if the brand-name drug has been withdrawn from the market, until the FDA (having assured itself that the drug is safe, effective, and correctly labeled) withdraws approval of the NDA. (21 C.F.R. § 314.150(a)(2), (b)(3) & (c); FDA, *supra*, 78 Fed.Reg. at p. 67993.) A brand-name manufacturer that sought to exit the market but was unsure whether the FDA would determine that the drug was withdrawn "for reasons other than effectiveness or safety" thus would presumably go ahead and update the label. (Lasker et al., *Taking the "Product" Out of Product Liability: Litigation Risks and Business Implications of Innovator and Co-promoter Liability* (July 2015) 82 Def. Counsel J. 295, 306.)

Novartis complains next that it is unfair to subject a brand-name drug manufacturer to liability for harm caused by a competitor's product — a product from which the brand-name manufacturer derives no revenues or profit. But the plaintiffs' claim here is not that terbutaline is defectively designed or inherently dangerous. It is that terbutaline's warning label failed to mention the risk to fetal brain development, and that Novartis was responsible for the deficient label. So

the alleged fault here lies with Novartis, not with its generic competitors. The brand-name drug manufacturer's burden to adequately label its drug as a means of ensuring adequate warnings for the generic bioequivalent is more than offset by the substantial benefits federal law confers on the brand-name manufacturer: a monopoly over the market for the life of the patent, which can be extended for the time consumed by FDA review of the NDA (see 35 U.S.C. §§ 154, 156(a), (c)); an additional five-year exclusivity period if the brand-name drug contains a new chemical entity or an additional three years for a new use of a previously approved drug (see 21 U.S.C. § 355(c)(3)(E); 21 C.F.R. § 314.108(b)(2), (4), (5)); and the higher prices the brand-name drug can continue to command even after the exclusivity period expires. (See *Conte, supra*, 168 Cal.App.4th at p. 110.) Because federal law bundles — and indeed, only makes available — those benefits along with the responsibility to maintain an adequate warning label, it is as logical as it is reasonable for state common law to ensure the brand-name manufacturer holds up its end of the deal. (See *Wyeth, supra*, 555 U.S. at pp. 578-579; see generally Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation* (2005) 5 Yale J. Health Pol'y L. & Ethics 587, 605-606 ["The problem of insufficient resources persists, as does the [structural] concern that the FDA may be loath to move swiftly to address emerging safety issues"].) The public interest in adequate drug warnings, in short, is just as acute when the brand-name drug manufacturer has an effective monopoly over the *warning label* as it was when the brand-name manufacturer had a monopoly over the *entire market* for the drug. (See *Wyeth*, *supra*, 555 U.S. at p. 571 [noting that federal regulations "plac[e] responsibility for postmarketing surveillance on the manufacturer"].)

We are equally unpersuaded by Novartis's contention that warning label liability would stifle innovation by substantially raising drug costs and chilling the

development and marketing of new drugs. The logic buttressing this argument is far from self-evident. Warnings about a product's efficacy or danger may indeed risk diminishing its value to the manufacturer. Less obvious is the manufacturer's response to this predicament. One might just as easily assert that a drug company, after adding a new warning, will be incentivized to develop new and safer alternatives to the drug so that it can recapture the market for treatment of that disease. (See *Carlin*, *supra*, 13 Cal.4th at p. 1117.)

Indeed, the pharmaceutical industry raised a similar objection in *Carlin* to the imposition of strict liability for the failure to warn about the known or reasonably scientifically knowable dangers of a drug. We found "no clear or sufficient basis for concluding that research and development will inevitably decrease" as a consequence of imposing liability for failure to warn of known or knowable risks (*Carlin*, *supra*, 13 Cal.4th at p. 1117) — nor has Novartis offered any evidence that drug innovation has declined in the 21 years since *Carlin* was decided. *Carlin* therefore saw "no reason to depart from our conclusion . . . that the manufacturer should bear the costs, in terms of preventable injury or death, of its own failure to provide adequate warnings of known or reasonably scientifically knowable risks." (*Ibid*.)

The same is true here. When it comes to choosing whether the cost of an injury involving prescription medication should be borne by an innocent plaintiff or a negligent defendant, our case law has routinely held that the latter should bear the cost. (*Sindell v. Abbott Laboratories*, *supra*, 26 Cal.3d at pp. 610-611.) A brand-name drug manufacturer is in the best position to discover and cure deficiencies in its warning label, to bear the cost of injury resulting from its failure to update and maintain the warning label, to insure against the risk of liability, and to spread any increased cost widely among the public. (*Id*. at p. 611.) After all, the fault (if any) for a deficient label lies with the brand-name manufacturer alone.

(Cf. *Groll v. Shell Oil Co.* (1983) 148 Cal.App.3d 444, 449 [manufacturer of bulk fuel owed no duty to the ultimate consumer where the manufacturer provided adequate warnings to the distributor, "who subsequently packages, labels and markets the product," and the manufacturer thus "did not have the ability to prepare the warning"].) The balance of preventing harm and avoiding an undue burden on drug manufacturers and the public generally thus tips in favor of warning label liability.

Neither of the two remaining *Rowland* factors weighs in favor of an exception to the general duty of care. To wit: Significant moral blame attaches where a brand-name drug manufacturer fails to warn about the unsafe effects of its drug, when those effects are known or reasonably should have been known to the manufacturer. (See *Peterson v. San Francisco Community College Dist.* (1984) 36 Cal.3d 799, 814.) Blameworthiness would not depend on whether the pregnant woman, in reliance on the brand-name drug manufacturer's label, was dispensed the brand-name drug or its generic bioequivalent. Even those women who were prescribed the brand-name drug may nonetheless have received the generic version, either because the insurance company required it or because the pharmacist chose it. Moreover, both the pregnant woman and her physician would have relied on the brand-name drug manufacturer to warn of any serious hazards that were "associated" with the drug. (21 C.F.R. § 201.80(e).) Indeed, under federal law, no other manufacturer could have advised them of the drug's risks. In these circumstances, potential plaintiffs — the unborn — would be "particularly powerless," while the defendant brand-name drug manufacturer would have the best information about the drug's risks. (*Kesner, supra,* 1 Cal.5th at p. 1151.)

Although we declared in *O'Neil* that "little moral blame can attach to a failure to warn about dangerous aspects of *other* manufacturers' products and replacement parts" (*O'Neil*, *supra*, 53 Cal.4th at p. 365), the context of that

statement was a situation in which the valve and pump manufacturers had no control or influence over the design, manufacturing, or safety of those parts; the warning attached to them; or the consumer's decision whether to purchase such products. (*Ibid*.) Here, by contrast, the brand-name manufacturer legally controlled the label on the generic bioequivalent drug, and thus had significant influence on the decision whether to prescribe it.

Finally, Novartis offers no reason why a brand-name drug manufacturer would be unable to insure against the risk of warning label liability. Presumably, a brand-name manufacturer already insures against the risk of liability arising from a deficient warning label when a drug is introduced and the manufacturer has a monopoly over that market. It is far from clear why the brand-name drug manufacturer's exposure would become fatally uncertain merely because the brand-name manufacturer is sharing the market with generic manufacturers. (Cf. *O'Neil*, *supra*, 53 Cal.4th at p. 365 ["it is doubtful that manufacturers could insure against the 'unknowable risks and hazards' lurking in every product that could possibly be used with or in the manufacturer's product"].)

3. Out-of-state authorities

Novartis (and its amici curiae) rely in substantial part on what they call the "overwhelming" majority of courts that have declined to recognize warning label liability owed to those who were prescribed a generic version of the drug in reliance on the brand-name drug label. Although the decisions of our sister states and the lower federal courts may be instructive to the extent we find their analysis persuasive, they are neither binding nor controlling on matters of state law. (*People v. Gonzales and Soliz* (2011) 52 Cal.4th 254, 296.) We have respectfully considered the authorities cited by Novartis. We do not find them persuasive in analyzing California law.

The " 'leading case' " (*Strayhorn v. Wyeth Pharms., Inc.* (6th Cir. 2013) 737 F.3d 378, 401) for the proposition that a brand-name drug manufacturer owes no duty to warn patients who were dispensed the generic bioequivalent is *Foster v. American Home Products Corp.* (4th Cir. 1994) 29 F.3d 165 (*Foster*) — so we examine that case in some detail. In *Foster*, the decedent's pediatrician prescribed Phenergan, a brand-name antihistamine manufactured by the defendant which was sometimes used to treat colic. The pharmacist substituted promethazine, a generic bioequivalent. After being given promethazine several times over the next few days, six-week-old Brandy was found dead in her crib. A pediatrician specializing in sudden infant death syndrome at the University of Maryland opined that Brandy's death was caused by promethazine. (*Id*. at pp. 167-168.) The district court found the plaintiffs (Brandy's parents) had stated a claim for negligent misrepresentation, despite the fact that the defendant had not manufactured the drug ingested by Brandy, but subsequently granted summary judgment because of the plaintiffs' failure to demonstrate that their pediatrician had relied on the defendant's representations. When the plaintiffs appealed the grant of summary judgment and the defendant cross-appealed the district court's initial determination that a negligent misrepresentation claim could lie against the brand-name manufacturer for harm arising from the generic drug, the Fourth Circuit sustained the cross-appeal. (*Ibid*.)

Foster reasoned first that the negligent misrepresentation cause of action was in essence a claim of product liability, but "without meeting the requirements [Maryland] law imposes in products liability actions" — i.e., "that the defendant manufactured the product at issue." (*Foster*, *supra*, 29 F.3d at p. 168.) The court next addressed the peculiarities of the regulated pharmaceutical market, under which "any representations [the defendant] makes when advertising Phenergan also apply to generic promethazine"; a warning "will simply not be made" if the

brand-name manufacturer does not issue one; and a patient who is prescribed Phenergan "may actually receive generic promethazine." (*Id*. at p. 169.) In rejecting liability nonetheless, the *Foster* court assumed that although generic manufacturers "must include the same labeling information as the equivalent name brand drug, they are also permitted to add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval. . . . Manufacturers of generic drugs, like all other manufacturers, are responsible for the representations they make regarding their products." (*Id*. at p. 170.) The court also concluded that "to impose a duty in the circumstances of this case would be to stretch the concept of foreseeability too far" under Maryland law, which had recognized the tort of negligent misrepresentation only where " '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.' " (*Id*. at p. 171.) In the court's view, no such relationship could ever exist because Brandy "was injured by a product that [the defendant] did not manufacture." (*Ibid*.)

At the core of the *Foster* court's analysis is an erroneous assumption: that generic drug manufacturers may "add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval," and that they can be sued for their failure to do so. (*Foster*, *supra*, 29 F.3d at p. 170.) In reality, generic drug manufacturers are legally obligated to conform their drug label to the brand-name manufacturer's label (*PLIVA*, *supra*, 564 U.S. at p. 613) and, so long as they fulfill their "duty of 'sameness' " (*ibid*.), cannot be sued in tort for deficiencies in the label. (See *id*. at p. 624.) Fortunately, the Fourth Circuit has since recognized its error. Despite its categorical rejection of any duty in *Foster*, the court recently certified to the Supreme Court of Appeals of West Virginia the question "Whether West Virginia law permits a claim of failure to warn and negligent misrepresentation against a branded drug manufacturer when the drug

ingested was produced by a generic manufacturer." (*McNair v. Johnson & Johnson Corp.* (4th Cir. May 30, 2017, No. 15-1806) 2017 WL 2333843, *1.)[3]

Even on its own terms, though, *Foster*'s reasoning proves unhelpful in construing California law, and finds no support in it. First, California law does not conflate negligent misrepresentation and strict liability in the manner *Foster* believed was true of Maryland law. (*Conte*, *supra*, 168 Cal.App.4th at p. 108.) Under our state's law, there is no per se requirement in negligent misrepresentation actions that the misrepresentation be made by the product manufacturer. Consider *Hanberry v. Hearst Corp.* (1969) 276 Cal.App.2d 680, where the plaintiff alleged that defective shoes caused her injuries. (*Id*. at p. 682.) The Court of Appeal allowed the negligent misrepresentation claims to go forward against a nonmanufacturer — the publisher of Good Housekeeping magazine,

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[3] There is a sad coda to *Foster*. The Fourth Circuit's ruling relieved the brand-name manufacturer of any duty to warn of known or knowable risks of the drug when a plaintiff had been given the generic equivalent — and (contrary to *Foster*'s key assumption) the generic manufacturer had no ability to deviate from the brand-name manufacturer's label. As a result, it took until 2000 — six years after *Foster* was decided — for the FDA to modify the warning to recommend that promethazine not be given to children younger than two years old. (Starke et al., *Boxed Warning Added to Promethazine Labeling for Pediatric Use* (2005) 352 New Eng. J. Med. 2653, 2653.) Four years thereafter, following further review of all adverse events that had been reported, the FDA added a boxed warning — the strongest type of warning (21 C.F.R. § 201.57(c)(1)) — stating that the drug should not be given to children younger than two years old because of the potential for fatal respiratory depression. (Starke et al., *supra*, at p. 2653; Rostron, *Prescription for Fairness: A New Approach to Tort Liability of Brand-name and Generic Drug Manufacturers* (2011) 60 Duke L.J. 1123, 1146-1147.) This example underscores the reality that the FDA depends heavily on the brand-name drug manufacturer exercising its own unilateral ability to strengthen its warning label. (*Wyeth*, *supra*, 555 U.S. at p. 579; see generally *Weeks*, *supra*, 159 So.3d at p. 676 ["The FDA has limited resources to monitor the approximately 11,000 drugs on the market"].) Yet *Foster*'s rule seriously undermines the brand-name manufacturer's incentive to do so.

which had given the shoes its renowned seal of approval. (*Id*. at p. 683.) This seal appeared not only in the pages of its own magazine, but was used by the shoe manufacturer in its advertising as well as on the product and its packaging. (*Ibid*.) The court acknowledged that the defendant publisher was neither the seller nor the manufacturer of the shoes, but nonetheless recognized a duty of care because of the allegations that the publisher "held itself out as a disinterested third party which had examined the shoes, found them satisfactory, and gave its endorsement"; and the plaintiff reasonably relied on the endorsement and "purchased the shoes because of [it]." (*Id*. at pp. 686, 683.) As to the plaintiff's claim under strict liability, however, the court affirmed the trial court's dismissal — declining to extend strict liability "to a general endorser who makes no representation it has examined or tested each item marketed." (*Id*. at p. 688; see also *Conte, supra,* 168 Cal.App.4th at pp. 101-102 [similarly distinguishing between strict liability and negligent misrepresentation theories].)[4]

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[4] Novartis suggests that we recently conflated strict liability and negligence in *Webb v. Special Electric Co., Inc.* (2016) 63 Cal.4th 167 when we observed that " 'there is little functional difference between the two theories in the failure to warn context.' " (*Id*. at p. 187.) Not so. *Webb*'s observation was merely that the sophisticated user and sophisticated intermediary defenses applied to both theories of liability. (*Ibid*.) We did not categorically alter our longstanding recognition that "California law recognizes the differences between negligence and strict liability causes of action." (*Johnson v. American Standard , Inc.* (2008) 43 Cal.4th 56, 71; see *Saller v. Crown Cork & Seal Co., Inc.* (2010) 187 Cal.App.4th 1220, 1239 [" 'Negligence and strict products liability are separate and distinct bases for liability that do not automatically collapse into each other because the plaintiff might allege both when a product warning contributes to her injury' "].)

O'Neil did not erase the distinction between strict liability and negligence, either. Far from conflating the two theories, we said simply that "[t]he same policy considerations that militate against imposing strict liability *in this situation* apply with equal force in the context of negligence." (*O'Neil, supra*, 53 Cal.4th at p. 366, italics added.) As we have demonstrated above, *O'Neil* is soundly distinguishable from the situation here.

Second, California law places greater weight on the element of foreseeability in the duty analysis than does Maryland law. Indeed, this state treats foreseeability as "[t]he most important factor" (*Kesner, supra,* 1 Cal.5th at p. 1145), and we do not narrowly circumscribe the kinds of relationships that must exist between the plaintiff and the defendant as a predicate to imposing a duty on the defendant to prevent injuries arising from its own conduct. (*Id.* at p. 1163; see *Randi W., supra,* 14 Cal.4th at p. 1077 [one who negligently provides false information to another can owe a duty of care to a third person "who did not receive the information and who has no special relationship with the provider"].)[5] By contrast, *Foster* found that a "duty . . . arises" under Maryland law only "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.' " (*Foster, supra,* 29 F.3d at p. 171, quoting *Weisman v. Connors* (Md. 1988) 540 A.2d 783, 790.) *Foster* then summarily concluded that "[t]here is no such relationship between the parties to this case, as Brandy Foster was injured by a product that [defendant] did not manufacture." (*Foster,* at p. 171.) Even this explanation, though, seems to overlook the fact that there is never a direct relationship between a prescription drug manufacturer and the ultimate consumer. A consumer may obtain a prescription medication only through the physician as a

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[5] We therefore do not find persuasive those out-of-state cases discounting the role of foreseeability (see, e.g., *Huck v. Wyeth, Inc., supra,* 850 N.W.2d at p. 376 (plur. opn. of Waterman, J.) [" 'foreseeability should not enter into the duty calculus' "]) or requiring the existence of a specific type of relationship between the plaintiff and the defendant (see, e.g., *Moretti v. Wyeth, Inc.* (9th Cir. 2014) 579 Fed. Appx. 563, 564 [construing negligent misrepresentation, under Nevada law, to " 'require[], at a minimum, some form of relationship between the parties' "]; *Schrock v. Wyeth, Inc.* (10th Cir. 2013) 727 F.3d 1273, 1282 ["Oklahoma courts have also required a relationship between the defendant company and the product at issue for other theories of liability, including negligence"]).

learned intermediary. (See *Carlin*, *supra*, 13 Cal.4th at pp. 1116, 1126.) A physician, in turn, typically relies on the drug's warning label, the contents of which (regardless of whether the medication ultimately dispensed is the brand-name or generic bioequivalent) are controlled by the brand-name manufacturer. It is difficult to understand why the relationship between the brand-name manufacturer and the physician must be deemed to evaporate simply because an insurance company or pharmacist subsequently decides to dispense a generic version of the drug that bears the warning label crafted by the brand-name manufacturer.

Third, in one crucial respect, *Foster* is like the vast majority of the out-of-state cases on which Novartis relies: it arose in federal court under diversity jurisdiction. Federal courts sitting in diversity are "extremely cautious" about recognizing innovative theories under state law (*Combs v. Int'l Ins. Co.* (6th Cir. 2004) 354 F.3d 568, 578) and are bound to "apply the applicable state law as it now exists." (*Foster*, *supra*, 29 F.3d at p. 171; see generally Gluck, *Intersystemic Statutory Interpretation: Methodology as "Law" and the Erie Doctrine* (2011) 120 Yale L.J. 1898, 1939 [federal courts "pick the narrowest possible answer, usually the one that does the least to change the status quo, regardless of its predictions of what the state court would do"].) Because only a handful of jurisdictions have adopted the duty recognized in *Conte*, *supra*, and followed by the Court of Appeal here, it is not surprising that federal courts have been reluctant to interpret the law of various states to embrace it. But the task of this court is not to " 'opt for the interpretation that restricts liability, rather than expands it' " until someone else tells us otherwise. (*Travelers Indem. Co. v. Dammann & Co., Inc.* (3d Cir. 2010) 594 F.3d 238, 253; see also *Germain v. Teva Pharmaceuticals, USA, Inc. (In re Darvocet, Darvon, & Propoxyphene Products Litigation)* (6th Cir. 2014) 756 F.3d 917, 937 ["federal courts must be cautious"].) It is instead

emphatically the province of this court to declare what the law *is*. By contrast, Novartis's collection of federal decisions merely attempt to predict the law of other states, while operating under a presumption against expanding liability. (See *Schrock v. Wyeth, Inc.*, *supra*, 727 F.3d at p. 1290 ["As a federal court . . . we have limited authority to correct this potential injustice. It is for the state courts, rather than this panel, to engage in the delicate policy considerations predicate to the expansion of the scope of state tort law"].) They are of little use in discharging our task.

We likewise discount decisions from those jurisdictions that differ from California by categorically excluding from liability certain defendants (see, e.g., *Huck v. Wyeth, Inc.*, *supra*, 850 N.W.2d at p. 371 (plur. opn. of Waterman, J.) ["the tort of negligent misrepresentation does not apply to sellers of products but rather is limited to those in the business or profession of supplying information for the guidance of others"]) or certain injuries (see, e.g., *Flynn v. American Home Products Corp.* (Minn.Ct.App. 2001) 627 N.W.2d 342, 351 ["the Minnesota Supreme Court has recognized negligent misrepresentation involving damages only for pecuniary loss, and has expressly declined to recognize the tort of negligent misrepresentation involving the risk of physical harm"]) from the tort of negligent misrepresentation. And we find unhelpful the views of those jurisdictions that (federal courts predict) will recharacterize under their product liability act or similar rule all claims against a product manufacturer, no matter the theory, as product liability actions, which can be asserted only against the manufacturer of the product. (See, e.g., *Germain*, *supra*, 756 F.3d at pp. 941-954 [construing the laws of Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Maryland, Mississippi, Nebraska, New York, North Carolina, Ohio, Texas, Washington, and West Virginia]; *Phelps v. Wyeth, Inc.* (D.Or. 2012) 857 F.Supp.2d 1114, 1121 [Oregon law]; *Stanley v. Wyeth, Inc.*

(La.Ct.App. 2008) 991 So.2d 31, 33-34 [noting the "numerous cases where the negligent misrepresentation claims were . . . preempted by . . . a state's enactment of products liability law"].)

At core, what Novartis seems to want is more than just an exception to the general duty of care applicable in California — an exception constructed to avoid liability where a biologically equivalent product is sold and the warning label used is required by federal law to be the label that the brand-name manufacturer controls. Perhaps because there is no logical basis to justify such an exception, Novartis instead seeks a more categorical result, though one no easier to justify — i.e., an unequivocal declaration that California law relieves a manufacturer of any failure-to-warn liability relating to another manufacturer's products. True: An exception to California's general duty of care *is* ordinarily applicable to relieve a manufacturer of the duty to warn consumers about a product's risks where the product is that of another manufacturer. (*O'Neil*, *supra*, 53 Cal.4th at pp. 364-366.) For good reason: A product manufacturer ordinarily will have no control over the design or safety of another manufacturer's product, the other manufacturer's use of dangerous materials, or any warnings the other manufacturer might place on the product. (*Id*. at pp. 350, 365.) Nor would there be any reason to think that a manufacturer has the ability to influence a customer's decision to buy another manufacturer's product. (*Id*. at p. 365.) Without such predicate connections between one manufacturer and another, it would be difficult, if not impossible, for a manufacturer to foresee the dangers lurking in the seemingly limitless number of other products that might be used with or in its product. (*Ibid*.) But prescription drug markets are different. They present the unusual situation where one entity's misrepresentations about its own product foreseeably and legally "contributed substantially to the harm" caused by another entity's product (i.e., the generic drug bearing the warning label drafted by the

brand-name manufacturer). (*O'Neil*, at p. 362.) That key circumstance distinguishes the situation here from those involving the general run of products.

The negligence causes of action are potentially viable because of the allegedly deficient representations in Novartis's warning label. Novartis is not being sued for dangers inherent in the generic terbutaline manufactured by some other entity. Nor do plaintiffs claim that any product manufactured by Novartis caused them harm. They claim instead that allegedly deficient representations and omissions in Novartis's warning label caused them harm. The fact that Novartis *also* manufactured a product is extrinsic to the analysis and does not insulate it from liability for its alleged misrepresentations. (See *Conte*, *supra*, 168 Cal.App.4th at pp. 109-110; accord, *Weeks*, *supra*, 159 So.3d at p. 672 ["the [tort] claims are not based on the manufacturing of the product but instead allege that the label — drafted by the brand-name manufacturer and required by federal law to be replicated verbatim on the generic version of the medication — failed to warn"].)

B. Whether Warning Label Liability Was Extinguished as a Matter of Law When Novartis Divested Ownership of Brethine

We have determined that Novartis owed a duty of care to those who were prescribed Brethine or its generic bioequivalent in reliance on Novartis's warning label. Novartis claims that the demurrer should nonetheless be sustained without leave to amend on the ground that it sold the Brethine NDA to aaiPharma in 2001 and no longer had control over its warning label in 2007, when plaintiffs' mother was prescribed terbutaline. So we now consider whether Novartis should be relieved of all liability for its allegedly negligent failure to update the label as a matter of law, despite the fact that aaiPharma continued using the label Novartis had crafted.

Plaintiffs fault Novartis. But they do not claim the company was responsible for any negligent acts or omissions after the transfer of ownership. After all, under FDA regulations, only the current NDA holder has the authority to unilaterally modify the drug's warning label. Plaintiffs claim instead that they were harmed by Novartis's failure to update the label prior to transferring the NDA to aaiPharma, in that aaiPharma continued to use the same warning label until at least 2007, when their mother was prescribed terbutaline. In effect, plaintiffs claim that the Brethine warning label was deficient *at the time* Novartis transferred the NDA — and it was reasonably foreseeable that it would remain deficient, given the incentives facing any successor manufacturer.

To address this aspect of plaintiffs' claim, we must determine whether to recognize an exception to a brand-name manufacturer's duty to warn. Is a brand-name drug manufacturer's duty to warn extinguished simply because the deficiency in the label caused the injured plaintiff to be exposed to the drug *after* the manufacturer had transferred the NDA to a successor? Foreseeablity of harm is the touchstone of our duty analysis. (*Kesner*, *supra*, 1 Cal.5th at p. 1148.) Plaintiffs allege (or claim they can allege) that Novartis negligently provided inaccurate and incomplete warnings about the safety of its drug, that it was foreseeable the new NDA holder (aaiPharma) would continue to use Novartis's warning label without modification, that their mother's physician relied on the deficient warning label drafted by Novartis and reiterated by aaiPharma in prescribing terbutaline, and that they were harmed in utero by the terbutaline ingested by their pregnant mother. Whether aaiPharma would *also* be liable for any deficiencies in its warning label should not, in plaintiffs' view, automatically negate Novartis's culpability.

1. Foreseeability and related factors

We explained above why it was foreseeable that Novartis's failure to update the Brethine warning label could affect fetuses exposed to the generic version of the drug in utero. And there is no dispute that plaintiffs have alleged injury. Although Novartis was no longer responsible for updating the warning label at the time plaintiffs' mother was prescribed the drug, aaiPharma was using the same label it had inherited from Novartis. According to plaintiffs, neither NDA holder had sufficient financial incentive to update the label: Nearly half of all prescriptions for Brethine or its generic equivalent were to slow preterm labor. Under the circumstances, it was certainly foreseeable that aaiPharma would be no more conscientious about updating the warning label than Novartis allegedly had been.

Novartis contends the connection between its alleged negligence and plaintiffs' injury was extremely remote, as it had ceased producing the drug six years before the injury. But it is not clear why liability should turn on Novartis's role in the manufacturing process. What warning label liability stems from is Novartis's failure to warn about a drug's risks, not its production of a defective drug. The complaint alleges that Novartis and aaiPharma were concurrent tortfeasors whose liability stemmed from failure to warn, because each negligently failed to update the warning label.

We agree that Novartis's failure to update the warning label could foreseeably cause harm to plaintiffs. Under the circumstances arising from the federal regulatory regime for prescription drugs, a successor manufacturer's negligent failure to update the warning label is foreseeable. According to federal regulatory rules, a successor brand-name drug manufacturer has no choice but to use the former manufacturer's warning label — or a warning label at least as strong as the one used by the previous brand-name manufacturer — unless

directed otherwise by the FDA. (*Wyeth, supra*, 555 U.S. at p. 568 ["Generally speaking, a manufacturer may only change a drug label after the FDA approves a supplemental application"]; see 21 C.F.R. §§ 314.70(b)(2)(v), (c)(6)(iii), 314.72(b).) Unlike other product manufacturers (cf. conc. & dis. opn., *post*, at pp. 2-3), a brand-name drug manufacturer knows that, without FDA action, a successor manufacturer will produce a drug identical to the original in ingredients and design, and bearing an identical warning label (or a label that is at least as strong as the one used by the former manufacturer). (Cf. *Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513, 516 [affirming summary judgment in favor of a former asbestos insulation manufacturer where there was no evidence the manufacturer "had an actual connection with the design, manufacture or distribution" of the product causing harm]; *id.* at p. 520 [distinguishing cases where "the maker of the misrepresentation reasonably foresaw that the intermediary would repeat the misrepresentation to another person"].)[6] Because nearly half of all terbutaline prescriptions at the time of sale were written to prevent premature labor, it was also reasonably foreseeable that aaiPharma would be reluctant to add warnings about the risks to fetal brain development. In sum, a successor drug manufacturer's negligent conduct can be " 'derivative of [the brand-name drug manufacturer's] allegedly negligent conduct' " and thus foreseeable. (*Kesner, supra*, 1 Cal.5th at p. 1148.)

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6 Nor can the concurring and dissenting opinion derive any support from the scattering of federal district court cases involving a challenge to the adequacy of a medical device label. Federal law preempts state tort actions based on deficient warnings for medical devices. (*Riegel v. Medtronic, Inc.* (2008) 552 U.S. 312, 329; cf. *Wyeth, supra*, 555 U.S. at p. 574 ["despite its 1976 enactment of an express pre-emption provision for medical devices, [citation], Congress has not enacted such a provision for prescription drugs"].)

Novartis highlights the six years that elapsed between its surrender of the NDA for the drug at issue in this case and the decision to prescribe terbutaline to plaintiffs' mother. Yet the gap between the transfer of this particular NDA and the time at which plaintiffs' mother was prescribed terbutaline does not bear on the question of duty, "which must be addressed at a higher level of generality." (*Kesner*, *supra*, 1 Cal.5th at p. 1158.) In determining whether to create an exception to a brand-name drug manufacturer's duty of care, we do not evaluate " 'whether a *particular* plaintiff's injury was reasonably foreseeable in light of a *particular* defendant's conduct,' " but " 'whether the category of negligent conduct at issue is sufficiently likely to result in the kind of harm experienced that liability may appropriately be imposed . . . .' " (*Cabral*, *supra*, 51 Cal.4th at p. 772.) So the relevant inquiry is whether a successor drug manufacturer is sufficiently likely to continue using the warning label it inherited from the prior brand-name manufacturer, even when that label was deficient at the time the NDA was transferred.

It is true enough that a successor drug manufacturer has an obligation, under state as well as federal law, to ensure adequacy of the warning label. But the scenario at issue here implicates whether a successor drug manufacturer is sufficiently likely — as a matter of law — to modify the warning label when the brand-name manufacturer, which labored under an identical obligation, negligently failed to do so. In such circumstances, it is at least plausible that a successor manufacturer may choose to undertake only a cursory investigation of the medical literature, on the assumption that the prior manufacturer must have done a more thorough inquiry during the period that *it* was responsible for maintaining the warning label. This option will seem especially attractive when the prior manufacturer has greater resources or expertise than its successor. A successor manufacturer may also undertake an adequate inquiry but make no

changes to the label in close cases, partially or entirely trusting the judgment of the prior manufacturer. Or a successor manufacturer, like the prior manufacturer, may fear an adequate warning would damage the market share for the drug and balance its lost revenue and potential exposure in the same way as the prior manufacturer. Indeed, plaintiffs claim that neither NDA holder wanted to jeopardize Brethine's use as a tocolytic, which accounted for almost half of the drug's market share. Any or all of these factors could explain why a drug's warning label may prove "stickier" than what is optimal to protect public safety at a reasonable cost, and why a successor drug manufacturer would not be categorically distinguishable from the prior manufacturer in its likelihood of being conscientious about its obligations to disclose relevant risks.

Under the "general" rule, " ' "every person has a right to presume that every other person will perform his duty and obey the law." ' " (*Webb v. Special Electric Co., Inc.*, *supra*, 63 Cal.4th at p. 191.) But we have never allowed a defendant to excuse its own negligence as a matter of law simply by asserting that *someone else* should have picked up the slack and discharged the duty at issue. (See *Stewart v. Cox* (1961) 55 Cal.2d 857, 864 ["The fact that a third person does not perform his duty to protect the plaintiff from harm, either because he makes no effort or through his negligence does not succeed, is not a superseding cause"].) Nor have we permitted a negligent actor to evade liability simply because another party may also be liable for a similar tort. (See, e.g., *Beacon Residential Community Assn. v. Skidmore, Owings & Merrill LLP* (2014) 59 Cal.4th 568, 583 (*Beacon*); accord, *Humble Oil & Refining Co. v. Martin* (Tex. 1949) 222 S.W.2d 995, 1001 ["there is a distinction between the general axiom that a person is not bound to anticipate the negligence of others and the idea that one may always discharge a duty of due care to the public by relying on performance by another of the same duty owed by the latter"].) So while " '[a] person who, *himself*, is

exercising ordinary care, has a right to assume that others, too, will perform their duty under the law' " — and thus may not be negligent in failing to anticipate injury that results " ' *only* from a violation of law or duty by another' " — the general rule does not apply when " 'it is *reasonably apparent* to one, or *in the exercise of ordinary care would be apparent* to him, that another is not going to perform his duty.' " (*Stickel v. San Diego Elec. Ry. Co.* (1948) 32 Cal.2d 157, 166, first and second italics added; see *id*. at pp. 166-167 ["It is but a statement as to that common type of negligence, the unreasonable failure to observe what is going on about one, including the negligence of others. 'One may not continue to assume that the law is being observed after knowing or having an opportunity, by the use of reasonable care, to know that it is not being observed' "]; *Harris v. Johnson* (1916) 174 Cal. 55, 58 [" 'The general rule . . . that every person has a right to presume that every person will perform his duty' " applies only " 'in the absence of reasonable ground to think otherwise' "].) Few if any entities would be in a position to know better that the law " 'is not being observed' " (*Stickel*, at p. 167) than a brand-name drug manufacturer that *itself* had negligently failed to update the label. So the assumption underlying the brand-name drug manufacturer's duty is not at all "that successor corporations will *routinely* ignore th[eir] duty." (Conc. & dis. opn., *post*, at p. 5, italics added.) It's that when a brand-name drug manufacturer has ignored its *own* duty, there is a risk that the successor manufacturer will adopt the same strategy. Under these circumstances, categorically justifying a manufacturer's neglect of that risk requires heroic, and ultimately unreasonable, assumptions distinguishing an original brand-name manufacturer's behavior from that of its successors. For these reasons, we find it reasonably foreseeable that a successor drug manufacturer could continue to use the same label it inherited, even when the label was deficient.

2. Considerations of public policy

According to Novartis, the policy of preventing future harm would not be advanced by subjecting the brand-name drug manufacturer to liability after it has already divested itself of the drug and no longer has control over the warning label. But in examining the prevention of future harm, we undertake the duty analysis "look[ing] to the time when the duty was assertedly owed." (*Kesner*, *supra*, 1 Cal.5th at p. 1150.) It is during the time Novartis owned the drug that both its legal duty and its power to discharge that duty converge. At that point, Novartis *did* have control over the warning label and could have modified it, without waiting for FDA approval, to warn of the risks to fetal brain development. Recognizing a brand-name drug manufacturer's potential responsibility for injuries proximately caused by deficiencies in its warning label — regardless of whether the injury occurred before or after divestment — provides a further incentive to the brand-name manufacturer to update the label as soon as it knows (or should have known) of the unwarned risks. Consider, on the other hand, the implications of allowing the brand-name manufacturer to shield itself from liability as soon as it transfers ownership to another manufacturer, as Novartis proposes. What such a rule would do is encourage an economically rational brand-name manufacturer to transfer the NDA, rather than add a warning to the label, since an updated label would diminish the utility (and thus the value) of the drug.[7] Such a scenario obviously poses greater risks to consumer safety relative to the alternative.

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[7] This case does not present the question, and we do not decide, whether a brand-name manufacturer would remain liable for deficiencies in its warning label when the FDA has formally withdrawn its approval of the NDA and has determined "that the drug was voluntarily withdrawn from sale for reasons other than effectiveness or safety." (Lasker, *supra*, 82 Def. Counsel J. at p. 306; see 21 C.F.R. § 314.150; 78 Fed.Reg., *supra*, at p. 67993.)

Novartis counters with a different scenario. It claims that under plaintiffs' regime, a successor brand-name drug manufacturer would have an incentive to maintain the identical label without change so that the former brand-name manufacturer would be forced to share in any liability. We are skeptical. When it is economically rational for the manufacturer to update the label, it will update the label — regardless of the prospect that a prior manufacturer might share in the liability for its own negligent failure to update the label. Even in a marginal case, though, it does not seem especially likely that a successor drug manufacturer which knows or should know of an unwarned risk would choose to leave a warning label unchanged simply to preserve the possibility that — if the label remained the same as under the former manufacturer — the former manufacturer could be a codefendant in a future tort action. It seems implausible that a successor manufacturer would take that gamble if its proportional share of fault would be ever increasing as medical research became more confident about the link between the drug and some adverse effect. After all, the successor manufacturer could avoid liability *altogether* by updating the label to warn about the risk.

The more substantial danger is that *neither* manufacturer will have sufficient incentive to update the label. Unless there is warning label liability, it will be economically rational in some circumstances for a brand-name manufacturer to offload the drug to a successor rather than update the warning label. And if the brand-name manufacturer fails to update the label to disclose a known or knowable risk, economic interests and simple inertia may lead the successor manufacturer to the same strategy. (See *ante*, at pp. 44-45.) The better rule is to provide appropriate incentives for the brand-name manufacturer to update the warning label at the earliest possible time, given that the successor manufacturer cannot remove any aspect of the warning without FDA approval.

To determine how best to incentivize a drug manufacturer to provide prompt warnings, we turn to the very factors on which Novartis trains its attention: the extent of the duty's burden on the defendant and the consequences to the community. Novartis complains first that plaintiffs' proposed rule would lead to immeasurable and perpetual liability for brand-name drug manufacturers. This appears to be an overstatement. Only during the time it holds the NDA does the brand-name drug manufacturer have a duty of care. Although a breach of that duty can have enduring effects — effects that do not magically disappear merely because the brand-name manufacturer no longer holds the NDA — a plaintiff would still need to prove that the injury was foreseeable at the time the brand-name manufacturer held the NDA, that the brand-name manufacturer's deficient label proximately caused the injury, and that the prescribing physician relied on the brand-name manufacturer's misrepresentations or omissions. The passage of time would naturally tend to undermine a plaintiff's ability to prove that an injury was foreseeable at that earlier stage,[8] that the physician actually relied on the defendant's warning label, or that the defendant's negligence proximately caused injury. (See *Beacon*, *supra*, 59 Cal.4th at p. 583.) An extended period of time also presupposes a lengthy latency period before an injury (or its connection to the drug) manifested itself, further complicating the showing of foreseeability, reliance, or causation. (Cf. *PLIVA*, *supra*, 564 U.S. at p. 625, fn. 9 ["the FDA

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[8] Indeed, approximately half of the studies cited in the first amended complaint to demonstrate a link between terbutaline exposure in pregnancy and fetal brain development postdated Novartis's sale to aaiPharma. To avoid the distortion caused by hindsight bias, trial courts should be careful to protect the jury from needlessly being exposed to or considering scientific studies connecting a drug to some harm where those studies postdate transfer of the NDA.

informs us that '[a]s a practical matter, genuinely new information about drugs in long use . . . appears infrequently' "].)

Yet the question before us involves neither causation nor these other elements of negligence. What role the six-year gap between Novartis's transfer of the NDA to aaiPharma and plaintiffs' exposure to terbutaline might play in plaintiffs' ability to prove these remaining elements is beyond the scope of this proceeding. We granted review to decide only the threshold question of a brand-name drug manufacturer's duty of care and therefore have no occasion to address other arguments Novartis might advance to defeat liability. (See *Kesner*, *supra*, 1 Cal.5th at p. 1157.)[9] But we reject Novartis's contention that a finding of duty will result in perpetual liability for brand-name drug manufacturers as well as the burden of a trial to address every claim of harm. Time's effect on causation, while

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[9] Recognizing a brand-name drug manufacturer's duty of care in these circumstances does not prevent the manufacturer from arguing in a given case that it did not breach its duty given the scientific knowledge at the time; that its label could not have proximately caused the harm given the passage of time between the transfer of the NDA and the plaintiff's exposure to the drug, as well as the successor's exclusive responsibility for promoting the assertedly dangerous off-label use of the drug (see *Lyman v. Pfizer, Inc.* (D.Vt. July 20, 2012, No. 2:09-CV-262) 2012 WL 2970627, *17); or that its disclosure of the unwarned risks to the successor manufacturer severed any link between its own label and the harm. But our task here is not to decide whether there should be "an exception to the general duty of reasonable care on the facts of the particular case before us, but whether carving out an entire category of cases from that general duty rule is justified by clear considerations of policy." (*Cabral*, *supra*, 51 Cal.4th at p. 772.)

The concurring and dissenting opinion finds "perhaps most troubling" the court's unwillingness to "predict" when the gap between transfer of the NDA and exposure to the drug will be so remote as to preclude a finding of proximate cause. (Conc. & dis. opn., *post*, at p. 9.) But neither party has briefed the issue of proximate cause, nor is proximate cause fairly encompassed within the issue presented — indeed, the issue presented involves exclusively the tort law element of *duty*. Novartis remains free to contest the existence of proximate cause — as well as any of the other elements of negligence and negligent misrepresentation.

ordinarily a question of fact, becomes a question of law " 'where the facts are such that the only reasonable conclusion is an absence of causation.' " (*State Dept. of State Hospitals v. Superior Court* (2015) 61 Cal.4th 339, 353; see *id.* at p. 357 [sustaining demurrer where the theory of causation was "conjectural, depending on a long series of determinations"]; accord, *Lyman v. Pfizer, Inc., supra,* 2012 WL 2970627 at p. *17 [affirming grant of summary judgment to a former brand-name drug manufacturer on causation grounds].) Similarly, the question of breach can be decided as a matter of law where "no reasonable jury could find the defendant failed to act with reasonable prudence under the circumstances." (*Cabral, supra*, 51 Cal.4th at p. 773.) The burden of a potential trial on a brand-name drug manufacturer that, under the facts presented, acted unreasonably in failing to update the warning label before transferring the NDA — and whose negligence proximately caused harm to those exposed to the drug — is not a compelling justification for carving out an entire category of cases from the general duty of reasonable care. (See *id.* at p. 772.)

Moreover, the greater the gap between transfer of the NDA and the plaintiffs' exposure to the drug, the greater the likelihood that the NDA would have been transferred to yet another manufacturer, which would multiply the number of potential defendants available to share responsibility for damages. Because a defendant's liability for noneconomic damages is not joint but several (Civ. Code, § 1431.2, subd. (a)), a negligent brand-name manufacturer would be liable for noneconomic damages only in an amount that was directly proportional to its percentage of fault. (*Ibid.*)

Indeed, a brand-name manufacturer could entirely avoid the prospect of extended exposure by including an indemnification provision when it transferred ownership of the NDA. (See, e.g., *Conte, supra*, 168 Cal.App.4th at p. 95, fn. 1.) This might lower the sales price of the brand-name drug in the transaction, but not

in any way that fails to reflect the true costs and benefits of being the NDA holder or that is unfair to the seller. Meanwhile, an indemnification provision may have the salutary effect of focusing both the seller and the purchaser, at a critical time, on the existence of any known or knowable risks not reflected in the warning label. And, as before, Novartis identifies no reason why it could not insure against the effects of any negligence related to the warning label for its drug. (See *Vasilenko v. Grace Family Church* (2017) 3 Cal.5th 1077, 1091.) Commercial general liability insurance policies cover injuries that accrue from multiple occurrences over a period of years (see *Montrose Chemical Corp. v. Admiral Ins. Co.* (1995) 10 Cal.4th 645), and tail coverage is available for injuries caused by the insured that did not manifest themselves until well after the manufacturer either sold the product or shut down its operations. (See *State of California v. Continental Ins. Co.* (2012) 55 Cal.4th 186, 195-196.)

A somewhat analogous situation lay at the heart of a case the court addressed recently. In *Centinela Freeman Emergency Medical Associates v. Health Net of California, Inc.* (2016) 1 Cal.5th 994 (*Centinela Freeman*), we considered the circumstances under which a health care service plan could transfer its financial responsibility to pay for its enrollees' emergency medical services to its contracting medical providers. Under state and federal law, licensed hospitals are required to provide emergency medical care to anyone, regardless of the patient's ability to pay. A health care service plan, in turn, is required to reimburse a noncontracting emergency service provider for necessary services, but may delegate this responsibility to another entity, such as an individual practice association (IPA). (*Id.* at pp. 1000-1001.) The health care service plans in *Centinela Freeman* delegated their financial responsibility for emergency services to their contracting IPAs, which were (or became) financially insolvent and eventually went out of business. (*Id.* at p. 1001.) When the IPAs failed to

reimburse the plaintiff emergency service providers for the care they had provided to enrollees of the defendant health care services plans, the plaintiffs sued the health plans for payment. (*Ibid*.)

The defendant health care service plans made an argument that echoed what Novartis argues here: that they had lawfully transferred their legal responsibilities to another entity and had therefore terminated any duty of care. We unanimously rejected the argument that the delegation of financial responsibility to an IPA necessarily relieved the health care service plans of any obligation to pay for its enrollees' covered emergency care. (*Centinela Freeman*, *supra*, 1 Cal.5th at p. 1001-1002.) What we held instead was that a health care service plan owes certain duties to noncontracting emergency service providers: first, a duty at the outset not to delegate its financial responsibility to an IPA "that it knew or should have known would not be able to pay for emergency service and care provided to the health plan's enrollees" (*id*. at p. 1002); and second, a duty not to continue or renew a delegation to an IPA "when it knows or should know that there can be no reasonable expectation that its delegate will be able to reimburse noncontracting emergency service providers for their covered claims." (*Ibid*.)

Centinela Freeman tends to undermine Novartis's absolutist position that a lawful transfer of its duty to another entity necessarily terminated its liability for its own negligence. Under our ruling in *Centinela Freeman*, a health care service plan remains responsible for the costs of its enrollees' emergency medical care, despite a lawful delegation of that financial responsibility, if the plan knows or should know the IPA would be unable to fulfill that financial responsibility. (*Centinela Freeman*, *supra*, 1 Cal.5th at pp. 1001-1002.) Here, we find that a brand-name drug manufacturer can be liable for the effects of its deficient warning label, despite transferring the NDA to a successor, if the harm is reasonably foreseeable and is proximately caused by the label.

Novartis's argument echoes the position we rejected in *Centinela Freeman*. Although some differences exist between these two scenarios, they do not undermine our conclusion that a brand-name drug manufacturer owes a duty to all those who may foreseeably and proximately be harmed by its deficient warning label. Unlike the duty we recognized in *Centinela Freeman*, warning label liability does not constitute a *continuing* duty of care. (See *Centinela Freeman*, *supra*, 1 Cal.5th at p. 1019 ["We agree that a health care service plan has a continuing duty of care to noncontracting emergency service providers"].) The conduct giving rise to a brand-name drug manufacturer's liability can occur only during the period that it holds the NDA. Negligent conduct during that period may have *effects* that extend beyond the transfer of the NDA, but a brand-name manufacturer is not subject to liability for any of its actions that occur after transfer of the NDA. Moreover, in this case, unlike in *Centinela Freeman*, we are analyzing a duty to prevent physical harm. Such a duty is broader than the duty to prevent pecuniary loss. (Rest.2d Torts § 311, com. a.)

Novartis renews its claim that warning label liability would severely chill both the innovation and marketing of new drugs if imposed after the brand-name manufacturer exits the market. Yet once again, it offers neither evidence nor a persuasive rationale to support its contention — and no reason for us to prefer some unknown increment of drug development over the urgent need to compensate a victim whose injury was foreseeably and proximately caused by a brand-name manufacturer's negligence. (See *Carlin*, *supra*, 13 Cal.4th at p. 1117 ["Upjohn offers no clear or sufficient basis for concluding that research and development will inevitably decrease" because of failure-to-warn claims]; *id.* at p. 1116, fn. 6 [discounting the risk of overwarning because of the lack of evidence]; cf. *Kesner*, *supra*, 1 Cal.5th at p. 1156 [noting the defendants "cite no evidence to suggest such [preventive] measures would have been unreasonably costly"].)

After all, the duty imposed here merely reinforces the brand-name drug manufacturer's existing duty to update and maintain the warning label. It does not require a brand-name drug manufacturer to do anything new.

We explained earlier why significant moral blame attaches to the failure to warn about a drug's risks when the brand-name drug manufacturer knew or should have known about those risks. The fact that the brand-name manufacturer has since exited the market does not alter the calculus. Under plaintiffs' theory, the actionable conduct occurred while the manufacturer still had control over the warning label. Had Novartis updated the warning label before surrendering the NDA, the federal regulations make it very likely that the warning would have remained on the label in 2007. (See *Wyeth*, *supra*, 555 U.S. at p. 568.) Although it can be difficult to assess the full extent of moral blame before a factual record has been developed (*Kesner*, *supra*, 1 Cal.5th at p. 1151), concealment of a drug's effects on the fetal brain for the purpose of preserving the drug's share of the premature labor drug market and thus inflating the sales price of the NDA would be especially objectionable. So Novartis fails to show how " 'clear considerations of policy' " justify a categorical exception to the duty of care. (*Kesner*, *supra*, 1 Cal.5th at p. 1144.) What the *Rowland* factors support instead is the conclusion that Novartis had a duty to warn about the potential risks of its drug, regardless of whether the consumer received the brand-name or generic bioequivalent, and that liability for the asserted breach of that duty did not end as a matter of law at the moment Novartis sold its rights to aaiPharma, an allegedly concurrent tortfeasor. A contrary rule would convey to Novartis and to similarly situated drug manufacturers the unjustified benefit of an exception to the general duty of care, incentivizing brand-name drug manufacturers that know or should know of unwarned risks to unload a problematic drug on another entity instead of modifying the drug's warning label to include those hazards.

The concurring and dissenting opinion makes much of the fact that no other jurisdiction has yet recognized a brand-name drug manufacturer's duty to maintain a warning label in these circumstances. The legal landscape was just as bare when the Court of Appeal recognized a brand-name drug manufacturer's duty to consumers of the generic bioequivalent drug (see *Conte, supra,* 168 Cal.App.4th at p. 101) — a duty we unanimously affirm here. Rarely, if ever, do jurisdictions face precisely the same jurisprudential questions at the same time, nor is our system premised on the idea that law congeals across jurisdictions. To the contrary, the common law incorporates the possibility of change as a foundational premise: "[t]he law of torts is anything but static, and the limits of its development are never set. When it becomes clear that the plaintiff's interests are entitled to legal protection against the conduct of the defendant, the mere fact that the claim is novel will not of itself operate as a bar to the remedy." (Prosser & Keeton, Torts (5th ed. 1984) § 1, p. 4.) Indeed, even if we acknowledge the value of reducing uncertainty where possible, what is critical in common law adjudication is not that all jurisdictions rapidly converge on a particular understanding of tort liability. Instead a court must carefully weigh whether an existing rule should apply in a particular context under current conditions. Applying the *Rowland* factors to address that context, we conclude that brand-name drug manufacturers owe a duty to those whose injuries are foreseeably and proximately caused by the manufacturer's deficient warning label.

III. CONCLUSION

We do not doubt the wisdom of crowds in some settings. But the value of an idea conveyed by or through a crowd depends not on how loudly it is proclaimed or how often it is repeated, but on its underlying merit relative to the specific issue at hand. Despite the impressive case authority Novartis has collected on its behalf, none of it purports to interpret California law. Yet it is California law that we must construe and apply in this case.

In doing so, we find that brand-name drug manufacturers have a duty to use ordinary care in warning about the safety risks of their drugs, regardless of whether the injured party (in reliance on the brand-name manufacturer's warning) was dispensed the brand-name or generic version of the drug. We also conclude that a brand-name manufacturer's sale of the rights to a drug does not, as a matter of law, terminate its liability for injuries foreseeably and proximately caused by deficiencies present in the warning label prior to the sale. We therefore affirm the Court of Appeal.

CUÉLLAR, J.

WE CONCUR:

CHIN, J.
LIU, J.
MAURO, J.*

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* Associate Justice of the Court of Appeal, Third Appellate District, assigned by the Chief Justice pursuant to article VI, section 6 of the California Constitution.

CONCURRING AND DISSENTING OPINION BY CORRIGAN, J.

I accept the majority's holding that a brand-name drug manufacturer's duty to warn extends to consumers of a generic bioequivalent, but only because federal regulations currently require that generic drugs carry the same warning label as appears on the brand-name product. (See 21 C.F.R. § 314.94(a)(8)(iv); *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 613 (*PLIVA*).) This special feature of pharmaceutical law, which gives the brand-name manufacturer sole and complete control over the warning label, justifies making generic drugs an exception to our observation in *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 342 (*O'Neil*) that a manufacturer is generally not liable for injuries caused by another manufacturer's product.[1]

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[1] However, the pertinent regulations are now under review and subject to imminent change. In November 2013, the Food and Drug Administration (FDA) proposed rule changes that would allow generic drug makers to revise their product warning labels, and depart from the labeling of the brand-name drug, using the "changes being effected" process. (Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products, 78 Fed.Reg. 67985 (Nov. 13, 2013) (Supplemental Applications).) In view of the Supreme Court's preemption decisions, the FDA explained it sought to "create parity" between brand-name and generic manufacturers. (*Id.* at p. 67989.) Moreover, the change was needed to ensure postmarket safety surveillance, because the FDA had found that safety-related labeling changes are typically required many years after a drug's initial approval, when generic versions are widely prescribed and the original brand-name manufacturer may have left the market. (*Id.* at p. 67988.) In 2015, the FDA reopened the comment period and scheduled a public meeting on the proposed rule change. (80 Fed.Reg. 8577 (Feb.

The majority's second holding, however, would extend indefinitely a drug manufacturer's duty to warn the customers of its successor, even after sale of the product line. No special feature of FDA law or practice warrants this rule. Plaintiffs' theory of "predecessor liability" represents a substantial and unprecedented expansion of tort duties. The majority cites no case holding a predecessor manufacturer liable for failing to warn about injuries caused by its successor's product. Indeed, it appears that predecessor liability for failure to warn has never before been recognized by *any* court, in any jurisdiction. To the extent the theory has been raised, courts across the country have universally rejected it.

For example, in the silicone breast implant litigation, some plaintiffs whose implants were manufactured by McGhan Medical Corporation (McGhan) sought to sue the Minnesota Mining and Manufacturing Company (3M) on the theory that 3M was the original designer. (See, e.g., *In re Minnesota Breast Implant Litigation* (D.Minn. 1998) 36 F.Supp.2d 863, 873.) 3M had sold this product line to McGhan in 1984 after patients began complaining of problems. (*Id*. at p. 870.) In addition to rejecting strict liability claims, published federal decisions uniformly held that 3M had no negligence-based duty to warn about the risks of a product it no longer manufactured or supplied. (*Id*. at p. 874; see *Christian v. Minnesota Min. & Mfg. Co.* (D.Md. 2001) 126 F.Supp.2d 951, 958-959; *McConkey v. McGhan Medical Corp.* (E.D.Tenn. 2000) 144 F.Supp.2d 958, 963-964.) Attempts to impose negligence liability on predecessor manufacturers have failed in other contexts as well. (See *Cadlo v. Owens-Illinois, Inc.* (2004) 125 Cal.App.4th 513, 520-521 [asbestos insulation]; *Potwora ex rel. Gray v. Grip* (N.J.Super.Ct.App.Div. 1999) 725 A.2d 697, 703-704 [motorcycle helmet]; *Fricke*

18, 2015).) If this regulatory change is implemented, our decision to allow suits against brand-name manufacturers for injuries caused by generic equivalents will need to be reevaluated because the rationale supporting it will be largely, if not entirely, undermined. (See maj. opn. *ante*, at pp. 20-21, fn. 2.)

v. Owens-Corning Fiberglas Corp. (La.Ct.App. 1993) 618 So.2d 473, 474-475 [vinegar].)

The majority insists pharmaceutical drugs are different from other products. However, both courts that have considered the issue have refused to extend tort liability to drug manufacturers after transfer of the product's New Drug Application (NDA) to a successor company. In *In re Darvocet, Darvon and Propoxyphene Products Liability Litigation* (E.D.Ky. Mar. 7, 2012, MDL Docket No. 2226) 2012 WL 767595, plaintiffs who had taken painkillers containing propoxyphene sued the drug's original manufacturer, Eli Lilly and Company (Lilly), for negligence and misrepresentation. Lilly had sold the NDA to another company in 2002 and stopped manufacturing the drug altogether in 2004. (*Id*. at p. *1.) The district court concluded Lilly had no liability for claims arising after the divestiture (*id*. at pp. *3, *9), and its decision was affirmed on appeal. (*In re Darvocet, Darvon, and Propoxyphene Products* (6th Cir. 2014) 756 F.3d 917, 940-941.) Another federal court reached the same conclusion in *Lyman v. Pfizer, Inc.* (D.Vt. July 20, 2012, No. 2:09-cv-262) 2012 WL 2970627. Defendant Wyeth LLC (Wyeth) had sold its rights to the drug Reglan almost two years before the plaintiff took her first dose. (*Id*. at pp. *1, *5.) By that time, "Wyeth could not have delivered a stronger warning regarding the drug, or have changed its design in any way." (*Id*. at p. *16). Assuming for sake of argument that Wyeth owed a legal duty to the customers of its successor and breached that duty by, among other things, failing to update Reglan's label, the court concluded any negligence was too remote as a matter of law to be the proximate cause of the plaintiff's injury. (*Id*. at p. *17.)

O'Neil, *supra*, 53 Cal.4th at pages 363-366, held that a manufacturer has no negligence-based duty to warn about the risks of another manufacturer's product. There, we were addressing risks posed by replacement components used in and around the manufacturer's product. Although it was foreseeable that the product's original components would be replaced with asbestos-containing parts, we stressed

that " 'foreseeability alone is not sufficient to create an independent tort duty.' " (*Id*. at p. 364.) Instead, weighing the other *Rowland*[2] factors, we concluded strong policy considerations counseled against imposing a duty of care. (*O'Neil*, at pp. 364-365; see *Taylor v. Elliott Turbomachinery Co. Inc.* (2009) 171 Cal.App.4th 564, 583.)

The majority attempts to distinguish *O'Neil* as applied to a brand-name manufacturer's liability for generic bioequivalents. (See maj. opn. *ante*, at pp. 19-20.) The distinction does not hold when applied to predecessor liability. In the generic drug context, public policy supports imposing a duty of care on brand-name manufacturers because the brand-name manufacturer is the *only* party with the practical and legal ability to warn about product risks. Generic manufacturers cannot write their own labels. Their products are legally required to carry the same warnings as appear on their brand-name counterparts. (21 U.S.C. § 355(j)(2)(A)(v), (4)(G); see *PLIVA*, *supra*, 564 U.S. at p. 613.) Placing a duty of care on brand-name manufacturers thus allocates the costs of compensating drug-related injuries on the party that is best-situated to prevent the harm. (See *Kesner v. Superior Court* (2016) 1 Cal.5th 1132, 1153 (*Kesner*).) In the predecessor liability context, however, the opposite is true. Imposing a duty on predecessor manufacturers to warn about potential injuries that could result from successors' products allocates costs to a party that has *no ability* to change the product's labeling and thus no effective way to control the warnings given to consumers. After divestiture, *only* the successor manufacturer has the ability to warn its customers about hazards. (21 C.F.R. §§ 314.71(a), 314.72(a)(2).) The same considerations led this court to unanimously reject a duty of care in *O'Neil*. As we explained, "[t]here is no reason to think a product manufacturer will be able to exert any control over the safety of replacement parts or companion products made by other companies." (*O'Neil*, *supra*, 53 Cal.4th at p. 365.) The *O'Neil* rule is

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[2] *Rowland v. Christian* (1968) 69 Cal.2d 108.

consistent with the Restatement of Torts, which advocates liability for post-sale failure to warn only if the seller has the ability to identify and communicate effectively with those at risk. (Rest.3d Torts, Products Liability, § 10.)

When a drug manufacturer acquires a new product line, it assumes the responsibility to update the warning label if and when reasonable evidence demonstrates a link to a serious health hazard. (21 C.F.R. § 201.80(e).) Predecessor manufacturers have a right to presume successors will perform their duty and follow the law. (See *Webb v. Special Electric Co., Inc.* (2016) 63 Cal.4th 167, 191; *Harris v. Johnson* (1916) 174 Cal. 55, 58.) The majority's foreseeability analysis glosses over this important legal obligation, noting that the successor would have no financial incentive to make a labeling change. (See maj. opn. *ante*, at pp. 43-45.) However, the prospect of negative publicity, fines, and tort liability gives all manufacturers substantial reason to disclose the adverse effects of a drug they sell. Updating the warning label to disclose risks *as they become known*, and ensuring warnings remain adequate, is a drug manufacturer's legal duty. (*Wyeth v. Levine* (2009) 555 U.S. 555, 570-571.) The majority's assumption that successor corporations will routinely ignore this duty, simply because their predecessors may have done so, is unfounded.

Moreover, the accumulation of scientific studies will often make the correlation with a health risk *more* clear over time. The majority's analysis elides this important feature of pharmaceutical practice. Adverse effects from a drug typically appear first in anecdotal case reports. It can take several years for epidemiological studies, the gold standard for establishing causation, to be conducted and published. Indeed, a 2013 FDA study found that the "most critical safety-related label changes, boxed warnings and contraindications, occurred a median 10 and 13 years after drug approval (and the range spanned from 2 to 63 years after approval)." (Lester et al., *Evaluation of FDA Safety-related Drug Label Changes in 2010* (2013) 22 Pharmacoepidemiology & Drug Safety 302, 304.) A connection to adverse effects that appears reasonably clear when a

successor produces a drug may well have been more tenuous, perhaps not even rising to the FDA's "reasonable evidence" standard, when it was the predecessor's product. Scientific evidence may not demonstrate the link to a health risk until after divestiture. Yet, at that point there is little to nothing a predecessor manufacturer can do to warn about the harm.

This case demonstrates the point. The majority concedes that "approximately half" of the studies plaintiffs cite to show terbutaline's impact on fetal brain development *postdated* Novartis's sale of the product line. (Maj. opn. *ante*, at p. 48, fn. 8.) But this summary does not tell the full tale. A few rat studies in the 1980s showed that terbutaline could cross the placenta and affect fetal brain development, and effects in human children were beginning to be documented. But most of the early studies were focused on the drug's effectiveness, or lack thereof, at preventing preterm labor. The first long-term study cited in plaintiffs' complaint that demonstrates a potential impact on human development was published in 2001, the same year Novartis sold the Brethine NDA to aaiPharma. It is undisputed that after 2001 Novartis had no ability to change the drug's warning label. Moreover, the scientific link between terbutaline and autism remains questionable. In 2011, four years after plaintiffs' mother was given terbutaline and nearly 10 years after Novartis's divestiture, the FDA reviewed the scientific literature investigating this link and concluded the studies did not constitute " 'positive evidence' " of a risk to fetal health. (Food & Drug Admin., letter to James P. Reichmann responding to citizen petition, Feb. 17, 2011, Docket No. FDA-2008-P-0358, p. 12.)

I discuss these developments not to express a view on the merits of plaintiffs' suit, but simply to point out that the scientific investigation of an alleged harmful effect takes time. Anecdotal case reports, in vivo studies, or animal studies that initially suggest an association are sometimes discredited by later

epidemiological studies, which are more authoritative but take longer to conduct.[3] Yet the majority's new duty rule makes it nearly imperative for manufacturers to issue warnings in advance of the science if they are selling a drug's NDA. In the normal course, a responsible drug manufacturer can monitor scientific developments and work with the FDA to determine when additional warnings are warranted. It loses this ability after transferring the NDA to another company. By holding that such a manufacturer owes a duty to warn its successor's customers even many years later, the majority creates an incentive for manufacturers to warn about every conceivable harm before transferring an NDA, lest their successors fail to include appropriate warnings when a risk is later validated.

It is certainly possible to foresee that a successor manufacturer will shirk its legal obligation to warn. That a harm is foreseeable does not necessarily mean we should recognize a duty of care, however. On "clear judicial days . . . a court can foresee forever." (*Thing v. La Chusa* (1989) 48 Cal.3d 644, 668.) As the majority opinion recognizes, an analysis of the *Rowland* factors requires us to balance foreseeability against considerations of public policy. Several policy reasons strongly counsel against imposing a duty of care on predecessor companies to warn about risks in products manufactured and sold by their successors.

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[3] One example of tort liability leapfrogging scientific knowledge occurred in the Bendectin litigation. Several cases alleging the anti-nausea drug Bendectin caused birth defects went to trial in the 1980s, leading the manufacturer to withdraw the drug from the market. (Sanders, *From Science to Evidence: The Testimony on Causation in the Bendectin Cases* (1993) 46 Stan. L.Rev. 1, 4-7.) However, later scientific studies demonstrated the safety of Bendectin, and its active ingredient is now used in several over-the-counter medications. (*Id*. at pp. 9-10.) A similar phenomenon occurred in the early 1990s with breast implants. Despite little scientific evidence of an association, thousands of suits were filed across the country alleging silicone breast implants caused autoimmune disorders. (Bernstein, *The Breast Implant Fiasco* (1999) 87 Cal. L.Rev. 457, 477.) Eventually, several large-scale epidemiological studies conclusively refuted this proposition, finding no link between implants and systemic disease. (*Id*. at pp. 480-484.)

First, as noted, a predecessor manufacturer has no control over the successor's product warnings. Only the current NDA holder has the power to change a drug's warning label. (21 C.F.R. §§ 314.71(a), 314.72(a)(2).) The majority therefore imposes a duty of care that is *impossible* for predecessor companies to discharge. Although this result might increase compensation for claims of drug-related injury, it disserves the tort policy of deterring negligent behavior. As this court recently observed, the "goal of products liability law is not merely to spread risk but also 'to "induce conduct that is capable of being performed." ' " (*Webb v. Special Electric Co., Inc.*, *supra*, 63 Cal.4th at p. 187.) Until today, a defendant's ability to control product warnings has been understood, even taken for granted, as an essential prerequisite to imposing liability for failure to warn. Indeed, this *very same* logic underlies the Supreme Court's preemption holding in *PLIVA*: It is unfair to subject generic manufacturers to failure-to-warn liability under state law when federal law gives them no ability to alter a drug's warning label. (See *PLIVA*, *supra*, 564 U.S. at p. 624.) It is no answer to say that a predecessor need only ensure that its own warnings are complete and accurate. The immediate and efficient cause of plaintiffs' alleged injury here was their mother's ingestion of (a generic version of) aaiPharma's drug. The warnings Novartis gave for the product it sold *six years earlier* are extremely remote from this event.

Second, the majority's holding will likely encourage over-warning by drug manufacturers. Drug manufacturers are already under a duty to update their warning labels, and they already face the risk of suit from their own customers if they fail to comply with that duty. The knowledge that they will still be subject to liability years in the future, even after divesting a product line, might well cause companies to seek the FDA's permission to add warnings about potential adverse effects that have only the barest support in evolving scientific literature. We have noted before that overabundant product warnings breed consumer disregard. (See, e.g., *O'Neil*, *supra*, 53 Cal.4th at p. 365.) Such a problem seems especially acute

in the pharmaceutical drug context, where product inserts and advertising frequently include mind-numbing lists of potential side effects.

Third, the majority's rule could conceivably have the perverse effect of diminishing successor corporations' incentive to update labels as scientific evidence develops. Current product manufacturers already have a disincentive to add warnings that may lower their profits. By holding that predecessor companies must potentially share liability for injuries caused by a successor's product, the court effectively reduces successor companies' exposure to tort liability. Aware that the cost of tort suits can be shared with their predecessors, some successor companies may decide to delay or perhaps even forgo additional warnings.

Fourth, and perhaps most troubling, creating a broad duty of care to consumers of a successor's product will expose pharmaceutical companies to liability in perpetuity. There is no logical stopping point for such a duty. The majority asserts that injuries will eventually become too remote for proximate causation to be established. It, however, declines to predict when that time might be reached and ventures no opinion about whether the *six-year* gap in this case is long enough. (But cf. *Lyman v. Pfizer, Inc.*, *supra*, 2012 WL 2970627 at p. *17 [finding any negligence of predecessor company too remote as a matter of law for a drug ingested less than two years after transfer of the NDA].) Without any limiting principles to guide the proximate cause analysis, the majority's reassurance fails to reassure.

Absent some such limiting principle, a proximate cause inquiry cannot reliably prevent excessive liability because proximate cause is ordinarily a question of fact for the jury. (*Lacy v. Pacific Gas & Electric Co.* (1934) 220 Cal. 97, 101.) The issue cannot be decided as a matter of law unless the only reasonable conclusion from the facts is an absence of causation. (*State Dept. of State Hospitals v. Superior Court* (2015) 61 Cal.4th 339, 353.) Thus, in all but the most extreme cases, predecessor liability claims are likely to reach a jury, with costly and unpredictable results. Duty, by contrast, is a question of law for the

court to decide. (*Cabral v. Ralphs Grocery Co.* (2011) 51 Cal.4th 764, 770 (*Cabral*).) This court has traditionally relied on *duty* rules to limit liability, even for foreseeable injuries. (E.g., *Kesner*, *supra*, 1 Cal.5th at pp. 1154-1155; *O'Neil*, *supra*, 53 Cal.4th at pp. 364-366; *Parsons v. Crown Disposal Co.* (1997) 15 Cal.4th 456, 476-478.) In *Kesner*, for example, we limited the duty to prevent take-home asbestos exposure to members of the worker's household, even though this limit excluded other individuals in close contact with the worker who would be foreseeably harmed. (*Kesner*, at pp. 1154-1155) This court has acknowledged the importance of limits to avoid potentially infinite expansions of tort duty. The majority's opinion here proposes none.

Exposing drug manufacturers to broad liability with no predictable end point has the clear potential to destabilize the pharmaceutical industry and chill innovation. Although the majority contends no evidence has been presented to support this prediction (maj. opn. *ante*, at p. 53), we do not typically demand evidence on the *Rowland* factors. The *Rowland* analysis is inherently predictive, not evidence-based. (Cf. *Cabral*, *supra*, 51 Cal.4th at p. 772 [*Rowland* factors are evaluated at a broad level of generality and not tied to facts of a particular case].) It stands to reason that expanding a drug manufacturer's exposure to tort liability will likely increase the drug's price. It may also delay the release of new drugs or even keep some beneficial drugs off the market. "Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering." (*Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1063.) We have previously proceeded with caution in this area, recognizing this broad public interest in the availability of affordable drugs. (See, e.g., *id.* at pp. 1065-1066, 1069 [rejecting strict liability for injuries caused by prescription drugs].) The majority reverses this course. It imposes a more expansive, enduring liability on drug manufacturers than has been recognized elsewhere in tort law.

Fifth, there is no reason to think the majority's predecessor liability holding will be limited to the pharmaceutical industry, or even to immediate predecessors. Despite its suggestion that pharmaceutical drugs are somehow different, the majority opinion identifies no specific feature of drug regulation that makes an extension of duty especially desirable or necessary in this context. What is now to stop users of any product from suing a former manufacturer, arguing it was foreseeable the successor would fail to update the product's warnings? The path of least resistance for all successor companies is to continue the product warnings used by their predecessors. It will generally be against a successor's financial interest to add warnings, no matter what the product. The majority's rule thus opens the door to predecessor liability for *all* products. It is also unclear exactly how far back this liability would extend. Some amicus briefs advised that product line acquisitions are common in the pharmaceutical industry. If a product line has changed hands two or three times, do all of these manufacturers have a duty of care toward the eventual plaintiff? Apparently they do, given the majority's remarks on joint and several liability. (See maj. opn. *ante*, at p. 50.) Again, however, this reasoning suggests no logical stopping point.

Sixth, it is not clear that an expanded duty of care is needed to prevent drug manufacturers from concealing risks when their product line is acquired. These transactions involve highly sophisticated parties, and acquiring companies can be expected to discover a drug's known risks when conducting due diligence. Plaintiffs here never alleged that Novartis hid risks from aaiPharma. Moreover, the appropriate remedy for this wrong is not an overbroad duty rule, but a fraud or breach of contract lawsuit from the acquiring company. A lawsuit related to the acquisition offers a more immediate and effective deterrent than the prospect of future tort claims by the acquirer's customers. Such an approach would make clear the duties of full disclosure and due diligence. It would also encourage successor companies to remain attentive to the evolving science relating to their acquisitions.

In discussing *Centinela Freeman Emergency Medical Associates v. Health Net of California, Inc.* (2016) 1 Cal.5th 994 (*Centinela Freeman*), a completely distinguishable case, the majority implicitly assumes that drug companies commonly sell off product lines to undercapitalized entities in order to "unload" (maj. opn. *ante*, at p. 54) products found to be dangerous. It cites no evidence or authority for these assumptions. In contrast, we *do* know it is common for brand-name manufacturers to stop selling a drug after their exclusivity period ends and generic competitors are allowed to enter the market. (See Supplemental Applications, *supra*, 78 Fed.Reg. at p. 67988; *PLIVA*, *supra*, 564 U.S. at p. 644 (dis. opn. of Sotomayor, J.).) Because the brand-name drug's market share inevitably declines with the entry of generic equivalents, these transactions may make good business sense and have nothing to do with the risks or benefits of the product itself. With respect to this case in particular, plaintiffs did not allege that Novartis hid health risks of terbutaline from aaiPharma or committed any wrongdoing in connection with the transfer of Brethine's NDA. Nor is there a basis for speculating that Novartis deliberately sold Brethine to an undercapitalized company, or that such transactions are typical. Plaintiffs' complaint includes no allegations to this effect, and aaiPharma's bankruptcy did not occur until four years after the NDA transfer.[4]

The majority also suggests that an extended duty of care is needed because successor manufacturers may simply rely on their predecessor's review of the medical literature or may trust their predecessor's judgment of whether a warning

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[4] Moreover, the court's holding in *Centinela Freeman* included a scienter requirement, specifying that health care plans may be liable for negligent delegation of financial responsibility if they "knew or should have known" the transferee would not be able to pay. (*Centinela Freeman*, *supra*, 1 Cal.5th at pp. 1001-1002.) Yet the majority's analysis here accords no such significance to details surrounding the transfer of an NDA. Novartis would be equally responsible under the majority's duty rule if it had sold Brethine's NDA to another multinational, highly capitalized company.

is required. (Maj. opn. *ante*, at p. 43.) This speculation rests on the mistaken assumption that due diligence is a static event, occurring only when an NDA is transferred. But, with the transfer, the new manufacturer assumes the sole and *continuing* responsibility to monitor the drug's safety and labeling. (21 C.F.R. § 314.72(b).) To fulfill this duty, the successor manufacturer must regularly monitor research developments as well as consumer feedback related to the drug. If the successor fails to update the drug's warnings to include newly documented risks, it may face products liability suits from its customers. Predecessor liability is not necessary to give these injured customers a remedy. The majority's holding is a solution in search of a problem.

Seventh, with respect to moral blame, the majority focuses too narrowly on the facts of this specific case. The broader question is what moral blame attaches to a manufacturer's failure to warn its successor's customers about a product defect. A predecessor manufacturer's share of moral blame may well be lower than that of a successor company that fails to update warnings, especially if scientific knowledge has advanced over time to provide stronger evidence of the product's link to an adverse effect.

Eighth, and finally, despite the majority's blithe assurance that drug manufacturers can "entirely avoid" perpetual liability through insurance or indemnity agreements (maj. opn. *ante*, at p. 50), there is no precedent for coverage against claims arising from *another company*'s product. None of the cases cited in the majority opinion addressed this unusual scenario. While insurance might be available in theory, the policy would have to cover a potentially enormous future risk that the insured would have no ability to mitigate. At the very least, the coverage would be difficult to manage and extremely costly. Defining the covered events could also be difficult, given that the potential plaintiffs would have no relationship with the insured. Even if appropriate insurance does become available, the majority's holding will require that pharmaceutical companies maintain it on all drugs for several years after they have stopped selling the

products and realizing a profit. The high cost of insuring against the majority's extension of the liability will almost certainly drive up the prices for prescription drugs.[5]

For all these reasons, although I join the majority's decision to affirm *Conte v. Wyeth, Inc.* (2008) 168 Cal.App.4th 89, I dissent from its holding that predecessor manufacturers have a duty to warn their successors' customers about risks of a product they no longer make or sell.

CORRIGAN, J.

WE CONCUR:

CANTIL-SAKAUYE, C. J.
KRUGER, J.

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[5] Nor are indemnity agreements a satisfactory answer. After today's holding, drug companies subject to suit in California will undoubtedly include indemnity provisions in all NDA transfer contracts. Such provisions could effectively put the burden of liability back where it rightfully belongs, i.e., on the actual manufacturer of the product used by the plaintiff. But they would not necessarily relieve the predecessor of all costs related to future claims. Indemnification rights may be capped or may exclude costs in defending the underlying lawsuits. There may also be costs if the predecessor must sue to enforce the indemnity agreement.

See last page for addresses and telephone numbers for counsel who argued in Supreme Court.

Name of Opinion T.H. v. Novartis Pharmaceuticals Corporation

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