No. S233898

IN THE SUPREME COURT OF THE STATE OF CALIFORNIA

T.H., a Minor, *et al.*,
Plaintiffs and Appellants,

v.

Novartis Pharmaceuticals Corporation,
Defendant and Respondent.

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

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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INTERESTS OF *AMICUS CURIAE*

Washington Legal Foundation (WLF) is a nonprofit, public-interest law firm and policy center with supporters in all 50 states, including many in California. WLF devotes a substantial portion of its resources to promoting free enterprise, individual rights, a limited and accountable government, and the rule of law. To that end, WLF has appeared as *amicus curiae* before this Court in a variety of cases concerning the proper scope of liability for prescription drug manufacturers. (See, e.g., *In re Cipro Cases I & II* (2015) 61 Cal.4th 116; *City of Hope Nat'l Med. Ctr. v. Genentech Inc.* (2008) 43 Cal.4th 375.)

In addition, WLF's Legal Studies Division, the publishing arm of WLF, regularly publishes articles concerning pharmaceutical liability, including the novel theory of "innovator liability" at issue in this case. (See, e.g., John J. Park, Jr., *Law Rejecting "Innovator Liability" Theory Restores Civil Justice Sanity to Alabama*, WLF Legal Opinion Letter (June 19, 2015); Victor E. Schwartz & Phil Goldberg, *Iowa High Court Exposes Pharma "Innovator Liability" for What it Is: Deep-Pocket Jurisprudence*, WLF Legal Opinion Letter (Sept. 12, 2014).)

WLF believes that individual freedom and American prosperity both suffer when state law, including state tort law, imposes upon industry an

unnecessary layer of liability that frustrates the objectives or operation of specific regulatory regimes, such as (in this case) the Food, Drug, and Cosmetic Act (FDCA) administered by the Food and Drug Administration (FDA). The FDCA establishes a comprehensive scheme of safety and disclosure requirements as part of the approval process for *any* prescription drug. By allowing plaintiffs to manipulate state-law tort duties as a means of second-guessing those federal regulatory requirements, the decision below undermines the very goals of public health and safety that the Court of Appeal purportedly desires to further.

WLF agrees with Novartis that the Court of Appeal's decision in this case marks a sharp and unwarranted break from longstanding principles of tort law. By holding that Novartis may be held liable for injuries caused by a drug that it did not manufacture—and that it no longer even sells—the Court of Appeal's decision places California squarely at odds with every other jurisdiction in the country. Rather than repeat those arguments here, WLF writes separately to rebut Plaintiffs' underlying contention that federal preemption of state-law tort claims against generic manufacturers somehow justifies the radical imposition of liability on former branded manufacturers of the same drug.

INTRODUCTION

This appeal arises from a suit on behalf of fraternal twin minors who allege that their autism was caused by their prenatal exposure to generic

versions of the drug terbutaline. Although terbutaline is a prescription bronchodilator approved by FDA to treat asthma, Plaintiffs allege it was prescribed to their mother for off-label use as a tocolytic (to suppress premature labor). Plaintiffs sued the hospital where they were born, the physician who prescribed the drug, and Lehigh Valley Technologies, Inc. and Global Pharmaceuticals—the alleged manufacturers of the generic versions of the drug ingested by Plaintiffs' mother.

Plaintiffs also sued several current and former branded manufacturers of terbutaline, including Defendant Novartis Pharmaceuticals Corporation (Novartis), which manufactured *neither* of the generic versions of terbutaline that allegedly caused Plaintiffs' injuries. In fact, Novartis had completely divested from its branded terbutaline drug, Brethine, *six years before* Plaintiffs' alleged prenatal exposure. Accordingly, the trial court sustained Novartis's demurrer (1AA:101), explaining that "Novartis owed Plaintiffs no duty as a matter of law" for claims arising from generic versions of terbutaline that Novartis never manufactured. But the Court of Appeal reversed, holding that a former branded manufacturer of a prescription drug owes a legal duty of care to consumers injured by a generic manufacturer's subsequent bioequivalent version of that drug.

Plaintiffs' answer brief reveals (ABOM: 42-43) that a major impetus for their attempt to shift liability for their injuries from generic terbutaline

to former branded manufacturers of terbutaline is to counter the unfairness they perceive in the U.S. Supreme Court's holdings in *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 618, and *Mutual Pharmaceutical Co. v. Bartlett* (2013) 133 S.Ct. 2466, 2470, that most state-law tort claims against generic drug manufacturers are preempted under the Supremacy Clause. Yet because it is impossible for generic manufacturers to satisfy *both* a state-law duty to change their product's label *and* their federal-law duty under the FDCA to keep that label unchanged, preemption is necessary to accomplish Congress's regulatory aims.

Preempting such suits is not only the "law of the land," but it also embodies sound and wise policy in its own right. Congress adopted the Hatch-Waxman Act in 1984 to facilitate the development of low-cost, generic versions of FDA-approved drugs following expiration of the branded manufacturer's patent. But permitting state-law tort suits against generic manufacturers would undoubtedly make generic drugs less affordable to patients, as the costs of defending against product-liability suits and satisfying large jury verdicts would substantially increase the retail prices of all generic drugs.

In any event, it is not for the Judiciary to fashion a remedy for Plaintiffs by distorting existing law, particularly in the context of a comprehensive federal regulatory scheme. Only Congress has the institutional capacity to fully accommodate the myriad of competing

interests that are implicated in regulating prescription drugs, and it delegated to FDA the responsibility for undertaking the careful balancing process necessary to determine which drugs are safe and which labels are adequate. Allowing non-expert judges and juries to second-guess that careful balance would severely undermine Congress's preferred policy aims. This Court should therefore decline to embrace the Court of Appeal's novel legal theory that would shift liability to branded drug manufacturers any time plaintiffs are injured by generic drugs.

Notwithstanding Plaintiffs' bare assertion, a decision by this Court in favor of Novartis would not leave consumers injured by a drug manufacturer's negligence entirely without legal recourse. To the contrary, injured plaintiffs may continue to assert failure-to-warn claims against branded drug manufacturers *whose products allegedly caused plaintiffs' injuries*. Likewise, if a plaintiff can demonstrate that he or she was injured by a branded or generic drug that was manufactured in a negligent manner (and thus contained impurities), nothing would prevent a state-law tort suit against that drug's manufacturer from proceeding. And if, as alleged here, the prescribing physician failed to consult the product label before prescribing the drug in question, the injured patient can always sue that physician for negligence.

ARGUMENT

I. PREEMPTION OF STATE-LAW TORT CLAIMS AGAINST GENERIC DRUG MANUFACTURERS IS NECESSARY TO ACCOMPLISH CONGRESS'S POLICY OBJECTIVES

Plaintiffs urge the Court to drastically expand state tort law by imposing a duty of care on former *branded* drug manufacturers to future consumers of *generic* drugs in order to counteract what Plaintiffs view as the unfairness resulting from congressional and FDA policy judgments. (ABOM: 7-12, 37-44.) But preemption is settled law—the Constitution commands it, and sound public policy commends it.

A. The Federal Regulatory Scheme for Generic Drugs

Congress adopted the FDCA (21 U.S.C. § 301 et seq.) to regulate the sale and distribution of all prescription drugs to the public. Section 352(f) provides that every approved drug must bear "adequate directions for use." (*Id.* § 352(f).) FDA does not approve the marketing of a new drug unless it is satisfied that, among other things, the drug is safe, effective, and adequately labeled for its intended use. (*Id.* § 355(d).)

In 1984, Congress amended the FDCA by adopting the Hatch-Waxman Act (Pub. L. No. 98-417, 98 Stat. 1585), which streamlined the approval of generic versions of previously-approved branded drugs whose exclusive patent protection had expired. Hatch-Waxman created the Abbreviated New Drug Application (ANDA) process to facilitate quicker market entry by lower-priced drugs following expiration of the original

New Drug Application (NDA) applicant's exclusive marketing period. Under that process, companies seeking to market a generic version of a previously-approved drug can rely on the safety and effectiveness data in the original NDA filing. (21 U.S.C. § 355(j).) The only significant scientific information that must be included in an ANDA is evidence that the applicant's generic drug is "bioequivalent" to the original branded drug. (*Id.* § 355(j)(2)(A)(iv).)

If bioequivalence is demonstrated, Congress assumed that the generic drug shares the branded drug's safety and effectiveness. That assumption significantly reduces the cost of developing, manufacturing, and marketing generic drugs. Likewise, as amended by Hatch-Waxman, the FDCA provides that an ANDA submitted by a generic company must "show that the labeling proposed for the new drug is the same as the labeling approved for" the branded drug. (*Id.* § 355(j)(2)(A)(v).) It further provides that FDA may not approve the ANDA unless the application demonstrates that the labeling "is the same." (*Id.* § 355(j)(4)(G).)

Soon after Congress amended the FDCA with the Hatch-Waxman Act, FDA adopted regulations confirming both that a generic manufacturer must ensure at all times that its product's labeling is identical to its branded counterpart and that this "sameness" requirement prohibits generics from unilaterally changing that label. For the past three decades, FDA regulations have required a generic drug to maintain the same labeling as

the branded drug throughout the lifecycle of the generic drug. (See 21 C.F.R. § 314.150(b)(10).) If a generic manufacturer "believes new safety information should be added to a product's labeling, it should contact FDA, and FDA will determine whether the labeling for the generic and [branded] drugs should be revised." (57 Fed. Reg. 17950, 17961 (Apr. 28, 1992).)

B. Preemption of State-Law Tort Claims Against Generic Drug Manufacturers Furthers Congress's Regulatory Aims

Under the Supremacy Clause of the U.S. Constitution, state law is preempted whenever it conflicts with federal law. (U.S. Const., art. VI cl. 2.) Because it is impossible for generic manufacturers "to comply with both their state-law duty to change the label and their federal law duty to keep the label the same," the U.S. Supreme Court has determined that Congress intended to preempt all state-law failure-to-warn claims against generic manufacturers. (*PLIVA*, *supra*, 564 U.S. at p. 618.) As the Court in *PLIVA* explained, "when a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." (*Id.* at pp. 623-624.)

Such preemption is entirely consistent with Congress's determination that generic drugs can be marketed without additional safety and effectiveness testing precisely because they are bioequivalent to, and bear labeling identical to, the branded drug. Indeed, it is this "special, and

different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public." (*Id.* at p. 626.) Permitting failure-to-warn or misrepresentation claims to proceed against generic manufacturers, however, would undercut Congress's desire that generic drugs serve as a low-cost alternative to branded drugs.

Exposing generic manufacturers to widespread tort liability would undoubtedly lead to increased prices (and potential shortages) for generic drugs, which inevitably would become less affordable to patients—precisely the opposite of Congress's aim when it adopted the Hatch-Waxman Act. (See, e.g., *Carlin v. Superior Court* (1996) 13 Cal.4th 1104, 1127 ["[T]he imposition of excessive liability on prescription drug manufacturers may discourage the development and availability of life-sustaining and lifesaving drugs."]; *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1062-1063 [explaining that "the consuming public ... will pay a higher price for the product to reflect the increased expense of insurance to the manufacturer resulting from its greater exposure to liability"].)

Faced with the prospect of multi-million-dollar tort judgments, risk-averse generic manufacturers could no longer afford to accept at face value FDA's determination that a bioequivalent drug's benefits outweigh its safety risks. Instead, to ensure that selling a given drug with a fixed label would not expose the company to potentially ruinous liability, a generic

manufacturer would need to undertake extensive clinical trials of their own—often at a cost of hundreds of millions of dollars—to satisfy themselves that a given drug is safe and its label adequate. That is a burden generic manufacturers could not bear. The vast majority of generic manufacturers undoubtedly would be forced to exit the market altogether, while any remaining firms invariably would have to incorporate the enormous expense of tort liability exposure (and higher insurance premiums) into a drug's retail price, ensuring that generic drugs would no longer be available as the affordable alternative contemplated by Congress when it adopted the Hatch-Waxman Act.

The Hatch-Waxman Act's legislative history is replete with statements showing that Congress fully expected that generic drugs would, in fact, be produced at minimal costs and thus be made available for sale at very low prices. (See, e.g., H.R. Rep. 98-857, pt. 1, at p. 17 ["The availability of generic versions of pioneer drugs approved after 1962 would save American consumers $920 million over the next 12 years."]; *id.* at p. 18 ["Enactment of the legislation, however, will result in significant cost savings to the Federal government. Unlike the costs of H.R. 3605, *these savings are certain*."] [emphasis added].) Congress could be "certain" that the cost savings from generic drugs would remain significant only if generic manufacturers' prices would not need to reflect the prohibitive costs associated with onerous tort liability and clinical testing but instead

could reasonably rely on FDA findings that FDA-approved drugs are safe and that FDA-mandated labels are adequate.

Moreover, Congress was adamant that generic manufacturers should *not* undertake their own clinical studies, not only because they were deemed "unnecessary and wasteful," but also because Congress considered them "unethical":

> The only difference between a NDA and an ANDA is that the generic manufacturer is not required to conduct human clinical trials. FDA considers such retesting to be unnecessary and wasteful because the drug has already been determined to be safe and effective. Moreover, such retesting is unethical because it requires that some sick patients take placebos and be denied treatment known to be effective.

(*Id.* at p. 16.) The same Congress that deemed additional safety testing of FDA-approved drugs so unnecessary as to be "wasteful" and "unethical" cannot reasonably be understood to have simultaneously contemplated that state tort law would serve as a complementary regime of drug regulation, whereby juries are invited to second-guess whether FDA-mandated labeling is inadequate.

II. THIS COURT SHOULD REJECT PLAINTIFFS' INVITATION TO DISTORT EXISTING LAW BY IMPOSING A TORT DUTY ON FORMER BRANDED DRUG MANUFACTURERS

The Supremacy Clause commands that state law must give way when federal policymakers have spoken. This Court therefore must accept Congress's decision to preempt claims against generic manufacturers. In doing so, however, this Court should also resist the impulse to "turn

somersaults to create" (*Riegel v. Medtronic* (2008) 552 U.S. 312, 325) a novel legal theory of liability for branded drug manufacturers simply because plaintiffs allege they were injured by ingesting generic drugs.

In recognition of courts' lack of technical expertise,[1] Congress delegated to FDA the responsibility for undertaking the careful balancing process necessary to determine which drugs are safe and which labels are adequate. And Congress enacted the Hatch-Waxman Act "in an effort to strike a balance between two conflicting policy objectives: to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." (*aaiPharma Inc. v. Thompson* (4th Cir. 2002) 296 F.3d 227, 230, internal quotation marks and citations omitted.)

Allowing non-expert judges and juries to second-guess that delicate balance would severely undermine Congress's carefully calibrated policy aims. (See, e.g., *United States v. Oakland Cannabis Buyers' Cooperative* (2001) 532 U.S. 483, 497 [explaining that courts can neither "override Congress's policy choice, articulated in a statute" nor "reject the balance

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[1] As the U.S. Supreme Court has recognized, "[e]valuation of conflicting reports as to the reputation of drugs among experts in the field is not a matter well left to a court without chemical or medical background." (*Weinberger v. Bentex Pharms., Inc.* (1973) 412 U.S. 645, 654, internal citations omitted.)

that Congress has struck in a statute"].) But that is precisely what Plaintiffs urge the Court to do in this case.

Federal law is quite clear that upon the sale of its NDA for Brethine, Novartis was precluded from any further involvement in the drug's labeling. Indeed, Novartis was prohibited under federal law from communicating *any* warnings about terbutaline or making *any* statements contrary to the FDA-approved labeling maintained by the new NDA holder. (21 U.S.C. § 352(n) [prohibiting as misbranding any communications regarding side effects for prescription drugs that are contrary to FDA-required labeling]; 21 C.F.R. § 100,1(d)(1) [providing that communications must mirror the language on the FDA-approved label].)

Accordingly, imposing a duty on former branded manufacturers contradicts the very rationale for federal preemption of state-law claims against generic manufacturers announced in *PLIVA*: impossibility. Indeed, a former branded manufacturer like Novartis, which has completely divested from an NDA, can no more change its former drug's label than can a generic manufacturer. Lacking any ability to cure alleged labeling defects, former branded manufacturers simply cannot be held liable for them. Even if an independent state-law duty to future generic consumers existed, the logic of *PLIVA* makes clear that any state-law remedy is preempted.

Moreover, extending liability to branded manufacturers for harms caused by generic drugs would drastically distort existing tort law.

Although federal law preempts the *remedy* that injured plaintiffs may seek under state law against generic manufacturers, such preemption does not alter the general *duty* such manufacturers owe to consumers of their products. Even Plaintiffs concede that, notwithstanding federal preemption of certain remedies, generic manufacturers have an independent duty to monitor drug and safety seek labeling changes when necessary. (ABOM: 10.)

Because the existence of a duty is wholly distinct from the availability of a remedy, shifting a generic manufacturer's *duty* to a former branded manufacturer makes no sense. Plaintiffs' response—that mere foreseeability of injury is an adequate basis for imposing a negligence duty on Novartis—is contrary to California law. As this Court has recognized, "foreseeability alone is not sufficient to create an independent tort duty." (*O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, 364, internal citations omitted.) Nonetheless, the Court of Appeal imposed a duty on Novartis based not on "the foreseeable result of the brand manufacturers' conduct, but [based on] the [federal] laws over which the brand manufacturers have no control." (*In re Darvocet, Darvon, & Propoxyphene Products Liability Litigation* (6th Cir. 2014) 756 F.3d 917, 944.) As the Sixth Circuit has cogently explained, "[u]sing federal ... laws designed to increase the availability of generic drugs as the basis of supplying the duty element for tort liability stretches foreseeability too far." (*Id.* at p. 947.)

For these reasons, "an overwhelming majority of courts, in at least fifty-five decisions from twenty-two states, have rejected the contention that a name brand manufacturer's statement regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug." (*In re Darvocet*, *supra*, 756 F.3d at p. 938, internal citations and quotation marks omitted.) Indeed, "the overwhelming national consensus ... is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of [its generic counterpart.]" (*Guarino v. Wyeth, LLC* (11th Cir. 2013) 719 F.3d 1245, 1252.)

Unlike Congress, state courts sitting in adversary proceedings are confined to rendering opinions on the basis of the limited evidentiary record before them and cannot commission independent studies, hire policy experts, conduct public hearings, balance the competing interests of stakeholders, or make policy judgments on the basis of legislative facts. As this Court has noted, "[i]t is not the judiciary's function ... to reweigh the 'legislative facts' underlying a legislative enactment." (*Am. Bank & Trust Co. v. Cmty. Hosp.* (1984) 36 Cal.3d 359, 372.)

In *PLIVA*, the U.S. Supreme Court rejected a similar invitation to "distort" existing law by allowing generic drug consumers to seek common-law remedies under state law. (*PLIVA*, *supra*, 564 U.S. at pp. 623-626.) In particular, *PLIVA* observed that "'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or

even bizarre.'" (*Id.* at pp. 625-626, quoting *Cuomo v. Clearing House Ass'n, LLC* (2009) 557 U.S. 519, 556 (conc. opn. of Thomas, J.).) Refusing to "distort the Supremacy Clause in order to" guarantee a legal remedy for every injured plaintiff, the Court in *PLIVA* reiterated that "[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire." (*Id.* at p. 626.)

Similarly, while acknowledging that "[r]espondent's situation is tragic and evokes deep sympathy," the Court in *Bartlett* nonetheless concluded that "a straightforward application of pre-emption law requires that the judgment below be reversed." (*Bartlett, supra*, 133 S.Ct. at p. 2480.) Resisting the temptation to jettison settled law to achieve a particular policy outcome, the Court reaffirmed that "sympathy for [a party] does not relieve us of the responsibility of following the law." (*Id.* at p. 2478.) So too here.

The appropriate role of the judiciary is to interpret the law, not to rewrite the law. (See, e.g., *People v. Rubalcava* (2000) 23 Cal.4th 322, 333 ["The role of the judiciary is not to rewrite legislation to satisfy the court's, rather than the Legislature's, sense of balance and order"] quoting *People v. Carter* (1997) 58 Cal.App.4th 128, 134, internal quotation marks omitted.) Of course, the corollary to the rule that courts should not manipulate existing law to create remedies out of whole cloth is that the political branches can do so when necessary. The Judiciary, however, is ill-suited to

address complex policy concerns that are best left to the political branches. (See, e.g., *Grossmont Union High School Dist. v. California Dep't of Educ.* (2008) 169 Cal.App.4th 869, 892 ["The quandary described in the complaint is lamentable, but the remedy lies squarely with the Legislature, not the judiciary"].) Accordingly, any change in the law to address the "unfortunate hand that federal drug regulation has dealt" to Plaintiffs (*PLIVA*, *supra*, 564 U.S. at p. 625) must be undertaken by Congress, not this Court.

In sum, the principle that the Judiciary should not distort existing law to engineer a remedy for a sympathetic plaintiff applies directly to this case. Because "courts are not institutionally qualified to balance the complex, interrelated, and divergent policy considerations in determining labeling and liability obligations of brand and generic pharmaceuticals" (*Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, 377), this Court should resist any temptation to fashion a sui generis legal remedy for Plaintiffs in this case.

III. A FINDING FOR NOVARTIS HERE WOULD NOT LEAVE INJURED CONSUMERS WITHOUT LEGAL RECOURSE

Plaintiffs contend that a failure to extend common-law tort liability to a former branded drug manufacturer—which manufactured *none* of the generic drugs that allegedly injured Plaintiffs—would somehow "strip generic-drug victims of their ability to seek compensation for their

injuries." (ABOM: 42.) Indeed, according to Plaintiffs, this Court's refusal to adopt the expansive theory of tort liability embraced by the Court of Appeal would effectively "prevent[ ] consumers of dangerously mislabeled drugs from receiving any compensation at all." (ABOM: 43.) Not so.

Of course, this Court has never grounded its tort-law jurisprudence in a "sporting chance" rationale, whereby every allegedly injured plaintiff is entitled to have at least one shot at obtaining a monetary recovery for his or her alleged injuries. More fundamentally, a decision favoring Novartis in this case would *not* leave consumers without legal recourse for their injuries. To begin with, the U.S. Supreme Court has clarified that injured plaintiffs may always assert failure-to-warn claims against those branded drug companies *whose products allegedly caused plaintiffs' injuries.* (*Wyeth v. Levine* (2009) 555 U.S. 555.) And WLF is unaware of precedent from any court in any jurisdiction that holds that a manufacturing-defect claim (a claim for injuries caused by pharmaceutical drugs that were improperly made or somehow became tainted) is preempted by federal law or otherwise barred—whether the defendant is a branded or generic drug manufacturer.

Moreover, nothing prevents an injured patient from bringing suit against the prescribing physician if that physician was negligent in writing the prescription. Indeed, Plaintiffs' own complaint includes medical negligence claims against the physician who prescribed the drugs, that

physician's employer, and the hospital where Plaintiffs were born. None of those claims have been dismissed. If, as alleged here, a prescribing physician allegedly failed to "ensure that the drug was safe and effective as a tocolytic agent by, for example, consulting Terbutaline's drug label, package insert, or the corresponding entry in the *Physician's Desk Reference*" (AA053), he or she may be a prime candidate for liability. (See, e.g., *Wyeth*, *supra*, 555 U.S. at p. 605 (dis. opn. of Alito, J.,) [observing that "it is unclear how a 'stronger' warning could have helped respondent" given that "the physician's assistant who treated [the plaintiff] disregarded at least six separate warnings that are already on Phenergan's labeling"].)

Plaintiffs also concede that their "off-label" claim against generic manufacturer Global Pharmaceuticals remains viable after surviving demurrer in the trial court below. (ABOM: 44, fn.17.) Specifically, Plaintiffs alleged that Global "violated federal laws that prohibit the promotion of off-label uses" by delivering generic terbutaline to the "facility where Plaintiffs' mother was treated for pre-term labor." (*Ibid.*) Plaintiffs further alleged that Global "knew or should have known that the pills it was furnishing to that facility would be put to a non-approved use." (*Ibid.*) In light of this ongoing claim (the merits of which WLF expresses no view), Plaintiffs' curious insistence that a decision by this Court in favor of Novartis would somehow "strip generic-drug victims of their ability to seek compensation for their injuries" (ABOM: 42) strains credulity.

In any event, nothing supports Plaintiffs' histrionic claim that, were the Court to find for Novartis in this case, injured consumers of prescription drugs would be left with no legal recourse. Of course, even if Plaintiffs were left with no recourse, that fact standing alone would not provide a plausible legal basis for imposing liability on Novartis for a drug that it did not manufacture and whose branded version it has not sold for six years. Accordingly, the Court should reject the unprecedented expansion of tort liability sought by Plaintiffs (and adopted by the Court of Appeal) and reverse the decision below.

CONCLUSION

WLF respectfully requests that the Court of Appeal's opinion be reversed.

Dated: December 7, 2016

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

As required by Rule 8.520(c)(1) of the California Rules of Court, I certify that, according to the word-count feature in Microsoft Word, the foregoing Brief of Washington Legal Foundation as *Amicus Curie* in Support of Respondent contains 4,399 words, including footnotes, but excluding any content excepted by Rule 8.520(c)(3).

Dated: December 7, 2016

/s/ Gregory Herbers