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 DECISION BY THE COURT OF APPEAL,
FOURTH APPELLATE DISTRICT, DIVISION ONE
Case No. D067839

APPLICATION OF AARP AND AARP FOUNDATION FOR LEAVE TO FILE AMICI CURIAE BRIEF IN SUPPORT OF PLAINTIFFS AND APPELLANTS T.H., ET AL. AND PROPOSED BRIEF IN SUPPORT OF PLAINTIFFS AND APPELLANTS T.H., ET AL.

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APPLICATION OF AARP AND AARP FOUNDATION FOR LEAVE TO FILE AMICI CURIAE BRIEF AND PROPOSED BRIEF IN SUPPORT OF PLAINTIFFS & APPELLANTS T.H., ET AL.

To the Honorable Chief Justice Cantil-Sakauye and Associate Justices of the California Supreme Court:

Pursuant to California Rules of Court, rule 8.520(f), AARP and AARP Foundation respectfully apply to this Court for leave to file the accompanying Brief of Amici Curiae in support of Plaintiffs and Appellants, T.H., et al. (hereinafter "Appellants").

Amici have a strong interest in the issues before this Court. In various ways, including legal advocacy as amici curiae, AARP and AARP Foundation support patient-centered drug labels that emphasize the most important details for safe and effective use. Amici are familiar with all of the briefs that have been filed in this case and seek to provide additional context and perspective, as demonstrated below. Specifically, this brief will provide insight as to the harms that consumers will likely experience, should this Court rule in Respondent's favor.[1]

STATEMENT OF INTEREST OF AMICI CURIAE

AARP is a nonprofit, nonpartisan organization dedicated to fulfilling the needs and representing the interests of people age fifty and older.

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[1] No party or counsel for any party authored any portion of the brief. No party or counsel for any party made a monetary contribution intended to fund the preparation or submission of the brief. No person or entity other than amici curiae, their members and their counsel made a monetary contribution intended to fund the preparation or submission of the brief. Cal. R. Ct. 8.520(f)(4).

AARP fights to protect older people's financial security, health, and well-being. AARP's charitable affiliate, AARP Foundation, creates and advances effective solutions that help low-income individuals fifty and older secure the essentials. Among other things, AARP and AARP Foundation advocate for access to safe and affordable health care services, prescription drugs, and medical devices. *See e.g.*, *Levine, et al. v. Ventura Convalescent Hospital*, No. 56-2011-00406713 (Ventura Co. Sup. Ct. Nov. 14, 2011) *and* Brief of AARP, et al. as Amici Curiae in Support of Respondent, *Nevarrez v. San Marino Skilled Nursing and Wellness Centre*, No. B235372 (Cal. Ct. App. June 20, 2013). Access to safe prescription drugs is particularly important to older adults because they have the highest rates of prescription drug use and higher rates of chronic health conditions. National Center for Health Statistics, *Health, United States, 2015*, Tables 39 and 79 (May 2016), http://www.cdc.gov/nchs/data/hus/hus15.pdf.

AARP and AARP Foundation submit this brief because the Court of Appeals decision below allowing Appellants to bring a claim against a former manufacturer of a drug correctly permits a name-brand drug manufacturer to be held accountable for the foreseeable consequences of its failure to advise consumers of known risks of the drug, when it had the duty and power to do so.

INTRODUCTION AND SUMMARY OF ARGUMENT

Eight years ago, in its amicus brief to the U.S. Supreme Court in *Wyeth v. Levine*, AARP expressed concern about the eradication of "the traditional role played by the tort system" as a "protector of the American public with regard to drug safety." Brief of AARP et al. as Amici Curiae in Support of Respondent at 2, *Wyeth v. Levine*, 555 U.S. 555 (2009) (No. 06-1249). Consistent with our brief, the Court declined to hold that the federal Food, Drug and Cosmetics Act preempted innumerable state tort claims for injuries caused by inadequate labeling of prescription drugs. *Wyeth v. Levine*, 555 U.S. 555, 581 (2009).

Three years later, the Court again considered the preemptive impact of federal law—in this case, the Hatch-Waxman Act—on state tort claims for failure to warn consumers of harms caused by generic versions of name-brand prescription drugs. *PLIVA v. Mensing*, 564 U.S. 604 (2011). Again, AARP expressed its concern that "a statute intended to provide consumers with increased access to *safe* generic drugs will be used to deny consumers necessary protections against *unsafe* ones." Brief of AARP et al. as Amici Curiae in Support of Respondents, at 3, *PLIVA v. Mensing*, 564 U.S. 604 (2011) (No. 09-993) (emphasis in original).

The Court's ruling in *PLIVA* finds that, while it would be "impossible" for generics manufacturers to comply with "both their state-law duty to change the label and their federal-law duty to keep the label the

same," name-brand manufacturers face no such dilemma. *PLIVA*, 564 U.S. at 618-20. Critically, the Court did *not* overturn its prior ruling in *Wyeth* because, unlike generics manufacturers, the name-brand manufacturer has the power "to *unilaterally* strengthen its warning" without prior approval from the Food and Drug Administration (FDA). *Id.* at 624 (emphasis added). In the post-PLIVA landscape, it is clear that name-brand manufacturers, and *only* name-brand manufacturers, can be held liable under state tort law for failing to update the labels on their own products that would "add or strengthen a contraindication, warning, precaution, or adverse reaction." *Wyeth*, 555 U.S. at 568 (*citing* 21 C.F.R. §§ 314.70 (c)(6)(iii)(A), (C)).

This case simply represents a logical extension of the Court's prior rulings in *Wyeth* and *PLIVA*: Could manufacturers of name-brand drugs, under any set of circumstances, ever be liable under state law for the foreseeable consequences of their failure to update the label *when* they had the duty to unilaterally update the label but chose not to do so? AARP believes that this question should be answered in the affirmative. AARP does not opine as to whether Novartis' breach of its duty to warn caused injury to Appellants. Appellants should be allowed to proceed to discovery on that question.

ARGUMENT

I. NAME-BRAND DRUG MANUFACTURERS HAVE A DUTY TO WARN CONSUMERS OF RISKS OF WHICH THEY HAVE ACTUAL OR CONSTRUCTIVE KNOWLEDGE

A drug is considered "misbranded" when its label fails to include "such adequate warnings...where its use may be dangerous to health...in such manner and form, as are necessary for the protection of users." 21 U.S.C. § 352(f) (2016). Federal law imposes a duty on drug manufacturers to update the label "to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug." 21 C.F.R. § 201.80(e) (2016). In order to trigger a drug manufacturer's duty to update the labels on their products, it is not necessary to show a causal connection between the drug and the hazard. *Id.*

Until 1985, the FDA was charged with approval of most proposed updates to prescription drug labels. Public Citizen, *Comment on Updating ANDA Labeling After the Marketing Application for the Reference List Drug Has Been Withdrawn: Draft Guidance for Industry, Docket No. FDA-2016-D-1673*, 2 (September 9, 2016), http://www.citizen.org/documents/2334.pdf. At that time, due in part to the urging of the pharmaceutical industry, the FDA expanded the ability of drug manufacturers to unilaterally make changes to a label that would "add or strengthen a contraindication [or] warning." *New Drug and Antibiotic Regulations*, 47 Fed. Reg. 46622 (Oct. 19, 1982).

As a practical matter, the safety of new drugs "cannot be known with certainty until a drug has been on the market for many years." Karen E. Lasser, et al., *Timing of New Black Box Warnings and Withdrawal for Prescription Medications*, 287 JAMA 2215, 2215 (2002). A recent study on the frequency and timing of the discovery of adverse drug reactions (ADRs) that require black-box warnings or drug withdrawal from the market concluded that "only half of newly discovered serious ADRs are detected and documented in the Physicians' Desk Reference within 7 years after drug approval." *Id.* at 2218. In some cases, ADRs to a particular drug were not detected until more than 15 years after the FDA's approval of the name-brand drug's New Drug Application (NDA). *Id.* at 2217-18.

On some occasions, by the time that public awareness was raised about the risks of a drug, the market for the name-brand and generic versions of the drugs numbered in the millions. *See, e.g.*, Sidney M. Wolfe, *Testimony on Propoxyphene (Darvon) Before FDA's Anesthetic, Analgesic and Rheumatologic Drugs and Drug Safety and Risk Management Advisory Committees* (Jan. 30, 2009), www.citizen.org/Page.aspx?pid=537 (discussing the risks and enduring market of the drug Darvon, originally approved in the 1950s). The record in this case reinforces the fact that the mere passage of time between the initial approval of the name-brand drug and the approval of the generic drug does not ensure the drug's safety or that its current label contains adequate warnings. According to the Court of

Appeals, the risks of Brethine to fetal development did not appear to become widely known until at least a decade after its approval by the FDA, at a time when Novartis still owned the drug's NDA. *T.H., et al. v. Novartis Pharm. Corp.*, 245 Cal. App. 4th 589, 595-97 (Mar. 9, 2016).

Because risks often do not become apparent until long after FDA approval, it is vital that drug manufacturers continue to monitor the safety of their products and respond to safety risks as they become known. As the U.S. Supreme Court recognized in *Wyeth*, manufacturers have "superior access to information" about their own products. *Wyeth*, 555 U.S. at 578-79 (footnote omitted). Therefore, it has been "a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label. . . [and] ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 570-71. Where the label of a prescription drug does not adequately disclose its risks, the public's exposure to those risks does not disappear simply because the owner of that drug offloads its rights to a third party.

Although the Food and Drug Administration Amendments Act of 2007 gave the FDA additional resources for drug safety and new authority to compel manufacturers to make labeling changes, Congress continued to recognize in its passage that "the resources of the drug industry to collect and analyze postmarket safety data vastly exceed the resources of the FDA, and no matter what we do, [drug manufacturers] will always have vastly

greater resources to monitor the safety of their products than the FDA does." 153 Cong. Rec. S11832 (daily ed. Sept. 20, 2007) (statement of Sen. Kennedy). It follows that the onus of updating the labels must fall principally on those who produce the drugs when they have the ability to do so.

A. There is no evidence that remedying a breach of this duty as to former name-brand manufacturers would result in higher-priced brand drugs.

Novartis baldly asserts that adopting the theory of liability proposed by Appellants and adopted by the Court of Appeals would result in higher priced brand drugs. Reply Br. of Resp. at 29, *T.H., et al. v. Novartis Pharms. Corp.*, No. S233898 (Cal. Nov. 7, 2016) (hereinafter "Reply Br."). Novartis provides no empirical evidence to support this claim, inviting this Court to assume that a tort claim theoretically available to consumers under state law would inevitably cause manufacturers to increase their prices. Even if this Court were to make that assumption, due to a general lack of general transparency in how drug manufacturers set prices, there is no evidence that the Court's adoption of Appellants' theory of recovery would have any significant impact on prices.

The rapid increase in drug prices paid by U.S. consumers has been the subject of intense public debate and analysis in recent years. *See, e.g.*, CBS News, *What's behind the sharp rise in prescription drug prices?* (Aug. 24, 2016), http://www.cbsnews.com/news/whats-behind-the-sharp-rise-in-

prescription-drug-prices/ (summarizing recent highly-publicized price increases for EpiPen, Daraprim, and hepatitis C drugs). Various stakeholders offer multiple explanations as to the cause of ever-increasing drug prices. Consumer Reports, *Is There a Cure for High Drug Prices?* (July 29, 2016), http://www.consumerreports.org/drugs/cure-for-high-drug-prices/.

Some commenters identify limited competition in the drug marketplace as a key driver of heightened drug prices. Alfred Engelberg, *How Government Policy Promotes High Drug Prices* (Oct. 29, 2015), http://healthaffairs.org/blog/2015/10/29/how-government-policy-promotes-high-drug-prices/. Other commenters argue that the lack of transparency in how manufacturers set drug prices is a major factor contributing to the cost of prescription drugs. American College of Physicians, *Stemming the Escalating Cost of Prescription Drugs: A Position Paper* (July 5, 2016), http://annals.org/aim/article/2506848/stemming-escalating-cost-prescription-drugs-position-paper-american-college-physicians.

While name-brand prescription drug manufacturers claim that pricing is based on some combination of costs from "research and development...and innovation," *id.*, they fail to provide public access to information explaining how these various factors, along with any mitigating factors—including public funding of development costs—ultimately factor into the drug's final price. Without greater access to information as to how

drug prices are calculated, it is impossible for the Court to discern whether the impact of this case on drug prices is significant, minimal, or nonexistent. Drug manufacturers cannot take advantage of this ambiguity while at the same time broadly identifying the type of liability pled in this case as having some unspecified effect on the prices of its products.

B. Manufacturers can foresee that future consumers may be injured by the risks that they knew about but failed to disclose while they manufactured the drug.

Novartis argues that *only* present NDA holders have "the most up-to-date safety information about the drug" and, therefore, a "former drug manufacturer should not reasonably foresee that the subsequent NDA holder will violate its tort law and FDA regulatory obligations to properly label its drug." Reply Br. at 24. This argument misses the point: whether, *at the time* of Novartis's divestiture of its Brethine NDA, it could foresee that its failure to update the drug's label could cause harm to consumers, particularly absent subsequent changes to the warning label by the NDA's purchaser. The issue here is merely whether a former manufacturer can be charged with knowledge of safety information available to it *at or before* the time of divestiture, not whether it could be held responsible for knowing about *subsequent, post-divestiture* studies of the drug's safety.

As the Court of Appeals' opinion illustrates, there are multiple factual allegations that, if proven, would tend to show that the harms experienced by Appellants were a foreseeable result of Novartis's failure to

update the labels when Novartis had the power and duty to do so. *T.H.*, 245 Cal. App. 4th at 605 ("[Appellants] allege it was foreseeable physicians and their patients would continue to rely on Novartis's product label for adequate warnings. They also allege it was foreseeable a subsequent manufacturer would not change the label information..."). Whether Appellants have adequately demonstrated these allegations, or whether Novartis's failure to update the label caused Appellants' injuries, are not proper issues for the court to decide at this stage of the litigation.

Novartis further argues that *only* the current holder of the New Drug Application has any ability to alter the content on a drug's label, and that former holders of the NDA are "powerless to cure" any deficiency in the label. Reply Br. at 25. Novartis was hardly powerless to act when it owned the NDA for Brethine, and the parties do not appear to dispute that, when Novartis owned the rights to market Brethine, it had at least some obligation to update its label upon learning about subsequently discovered risks posed by the drug. *Compare* Opening Br. of Resp. at 14, *T.H., et al. v. Novartis Pharms. Corp.*, No. S233898 (Cal. August 8, 2016) (stating that the holder of an NDA "assumes continuing responsibilities under federal law...to update the drug labels with any necessary warnings") *and* Answer Br. of Appellants at 11, *T.H., et al. v. Novartis Pharms. Corp.*, No. S233898 (Cal. Oct. 11, 2016) (hereinafter "Answer Br.") (stating that "both [federal drug law and state tort law] permitted, and indeed *compelled*, drug

manufacturers to update their labels as soon as a deficiency in the warnings was identified"). When it owned the rights to market name-brand Brethine, Novartis had every opportunity to update the label of risks it knew or should know about and, according to Appellants, chose not to. It cannot evade liability for any foreseeable consequences of its failure to update the label at that time simply by divesting itself of those rights.

Both during and after its ownership, Novartis could have and should have disclosed the known risks of Brethine to the FDA and to the public at large. Even after its divestiture of the Brethine NDA, Novartis could have taken steps to remedy any problems with its label. For example, any person—whether an individual consumer, a public safety watchdog group, or a name-brand or generic drug manufacturer—can file a petition requesting that the FDA "issue, amend, or revoke a regulation or order," or "take or refrain from taking any other form of administrative action." 21 C.F.R. §§ 10.3, 10.25, & 10.30. The record in this case demonstrates that the label for Brethine was only updated in response to one of these petitions. Food and Drug Administration, *FDA Response to Citizen Petition on Terbutaline*, Docket No. FDA-2008-P-0358 (Feb. 17, 2011), http://www.fda.gov/downloads/drugs/drugsafety/ucm243797.pdf.

If a name-brand manufacturer is truly concerned about what it sees as an inadequate label on one of its former products, it still has the option of filing a citizen petition asking the FDA to update the label. Knowing that

doing so might have a negative impact on its business relationships—or that doing so might be construed as an admission of its failure to update the label in the first place—the former manufacturer may *choose* not to employ this option, but that does not mean that it is "powerless" to do so.

II. DRUG LABELS MUST BE KEPT CURRENT AS A PRIMARY SOURCE OF INFORMATION FOR CONSUMERS

The value of clear, current information on the label of a prescription drug cannot be overstated. A recent study by Consumer Reports concluded that "most patients rely on the information printed directly on their medication containers," as opposed to lengthier instructions or warnings that may be contained within the drug's packaging. Consumer Reports, *Can You Read this Drug Label?* (June 2011), http://www.consumerreports.org/cro/2011/06/can-you-read-this-drug-label/index.htm. While many patients would prefer to receive information about a drug's potential risks directly from their physicians, as a practical matter, such conversations "occur infrequently and are often quite limited." William H. Shrank and Jerry Avorn, *Educating Patients About Their Medications: The Potential And Limitations Of Written Drug Information*, 26 Health Aff. 731 (May/June 2007). The instructions on drug labeling become the default source of information about a drug's safety and efficacy for many consumers.

Due to their importance in preventing medication errors, some observers have called for simplified labels that use more explicit language to support greater patient understanding of information about the drug. Michael S. Wolf, *Improving Prescription Drug Warnings to Promote Patient Comprehension*, Arch. Internal Med. (January 11, 2010), at 6 (finding that "[s]imple, explicit language on warning labels can increase patient understanding"). On the other hand, the absence of clear, unequivocal language on the label advising patients of known risks of the drug leaves consumers without the critical information they need to make informed decisions about their care.

III. STATE LAW TORT CLAIMS PROVIDE AN INCENTIVE FOR DRUG MANUFACTURERS TO PROVIDE CLEAR AND ACCURATE INFORMATION DISCLOSING THE KNOWN RISKS OF A DRUG

One of the fundamental purposes of tort law is to deter tortious behavior. *Klein v. Children's Hospital Medical Center*, 46 Cal. App. 4th 889, 898 (1996). As the Supreme Court of New Jersey recently recognized, "to the extent that state tort suits uncover unknown drug hazards, they provide incentives for drug manufacturers to disclose safety risks promptly." *In Re: Reglan Lit.*, 226 N.J. 315, 337 (Aug. 22, 2016). In one of the few empirical studies of the effect of punitive damages, of "more than five hundred companies assessed, all respond at some level to punitive damages, with just under half responding fairly aggressively." Andrew F.

Popper, *In Defense of Deterrence*, 75 Alb. L. Rev. 181, 193 (2011) (*citing* Michael L. Rustad, *How the Common Good is Served by the Remedy of Punitive Damages*, 64 Tenn. L. Rev. 793, 795 (1997)).

A. A ruling in Respondent's favor would categorically exclude "former" drug manufacturers from state tort claims alleging a failure to warn consumers of harms that were foreseeable at the time of the manufacturer's ownership.

Conversely, an unconditional *exemption* of a tortfeasor from liability would frustrate one of the general functions of tort law. As some commenters have observed, "the operating assumption of courts is not just that they will be there to...compensate an injured party, but that they will be sending a message heard clearly by those engaged in similar market practices." Popper, *supra* at 191. The total exemption of a tortfeasor from liability stifles that message.

The rule proposed by Novartis would allow former manufacturers to evade liability, regardless of (a) whether the former manufacturer had actual or constructive knowledge of the drug's hazards at the time it sold its rights to the drug; and (b) when the injury to a consumer taking a generic version of its drug occurred—whether 6 days, 6 months, or 6 years after the sale of the NDA. If the Court adopts the standard proposed by Novartis, name-brand drug manufacturers, knowing that their liability would be cut off simply by selling their interest without regard to their pre-divestiture knowledge or actions, would have less of an incentive to aid in public

safety by updating the labels on their products and a greater incentive to pass the "hot potato" to a fully-informed and willing buyer. Answer Br. at 6. While the purchaser presumably would share any liability for its ongoing failure to update the label, there is no basis for the former manufacturer to entirely absolve itself of any and all foreseeable consequences of its past failure to update the label.

The "foreseeability" test suggested by Appellants would permit a more flexible analysis and empower a fact-finder to decide what, if any, harms were foreseeable for a name-brand manufacturer upon failing to update a label to advise consumers of known risks. Again, that fact-intensive question cannot be resolved merely on a demurrer; Appellants are at least entitled to discovery to determine exactly what risks to patients, if any, Novartis knew or should have known at the time that it sold its rights to Brethine to AaiPharma.

B. Appellants' proposed rule would not nullify federal law.

Novartis argues that the rule proposed by Appellants would "nullify" or "counteract" certain unspecified "federal statutory and regulatory judgments." Reply Br. at 29-30. Appellant's specious comparisons between this case and various state efforts to resist implementation of federal civil rights legislation in the 1960s—and, more recently, the Affordable Care Act—illustrate the emptiness of this argument. Reply Br. at 30-31.

In fact, Appellants' theory of liability acts alongside existing federal statutory schemes intended to ensure patient safety. As the U.S. Supreme Court noted in *Wyeth*, "failure to warn" claims similar to Appellants' claims actually "lend force to the [Food, Drug, and Cosmetics Act's] premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling..." *Wyeth*, 555 U.S. at 579. Congress further "determined that widely available state rights of action provided appropriate relief for injured consumers" and "may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.* at 574.

Without a doubt, the federal Hatch-Waxman Act sought to "make available more low cost generic drugs." H.R. Rep. No. 98-857, pt. 1, at 14 (June 21, 1984). However, Congress did not seek to risk patient safety in fulfillment of that goal. Rather, the policy objective was to get "*safe and effective* generic substitutes on the market as quickly as possible." H.R. Rep. No. 98-857, pt. 2, at 9 (June 21, 1984) (emphasis added). The Hatch-Waxman Act was also intended to be a win for both consumers and drug manufacturers in which generic drugs would be approved more quickly with no decrease in safety or effectiveness. In drafting the Hatch-Waxman Act, Congress focused entirely on the initial market entry of generics, not on post-entry regulation or monitoring. The Hatch-Waxman Act does not

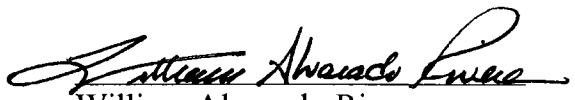
detail drug manufacturers' duties after the drug is approved or absolves them of responsibility for the safety of the drugs that they manufacture.

CONCLUSION

For the foregoing reasons, the judgment of the Court of Appeal should be affirmed.

Dated: December 6, 2016

Respectfully submitted,



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CERTIFICATE OF WORD COUNT

As required by California Rules of Court, Rule 8.520(c)(1), I certify that, according to the word count feature in Microsoft Word, the enclosed Application for Leave to File Amici Curiae Brief and Proposed Amici Curiae Brief was produced using Times New Roman 13-point type style and contains 4,021 words including footnotes, but excluding any content identified in rule 8.520(c)(3).

Dated: December 6, 2016

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I, Donna J. Wolf, am employed in the city of Cincinnati, Ohio. I am over the age of 18 and not a party to the within suit; my business address is 8790 Governor's Hill Drive, Suite 102, Cincinnati, Ohio 45249.

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

Donna Wolf