**IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA**

No. 17-0519

---

**KIMMY McNAIR AND LARRY McNAIR**

*Plaintiffs - Appellants,*

V.

**JOHNSON & JOHNSON, JANSSEN PHARMACEUTICALS, INC., AND ORTHO-MCNEIL PHARMACEUTICAL, INC.,**

*Defendants - Appellees.*

---

On Certified Question from the U.S. Court of Appeal
For the Fourth Circuit,
Case No. 15-1806

---

# BRIEF OF AMICI CURIAE AARP AND AARP FOUNDATION IN SUPPORT OF APPELLANTS, KIMMY McNAIR AND LARRY McNAIR

---

Anthony J. Majestro (W.Va. Bar No. 5165)
Powell & Majestro, PLLC
405 Capitol Street, Suite P-1200
Charleston, WV 25301
(304) 346-2889; Fax (304) 346-2895
amajestro@powellmajestro.com

Attorney for Amici Curiae AARP
and AARP Foundation

October 30, 2017

## TABLE OF CONTENTS

## TABLE OF AUTHORITIES

**Cases**



**Statutes and Regulations**



**Legislative History**

**Other Authorities**

## STATEMENT OF INTEREST OF AMICI CURIAE[1]

AARP is a nonprofit, nonpartisan organization dedicated to fulfilling the needs and representing the interests of people age fifty and older. 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. 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 amicus brief[2] because the District Court's decision below dismissing Appellants' claim against the brand-name manufacturer incorrectly prohibits the injured persons from seeking to hold the brand-name manufacturer accountable for the foreseeable consequences of its failure to advise consumers of known risks of the drug, when it had the duty and sole 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

[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. West Virginia Rules of Appellate Procedure 30(e)(5).
[2] All parties have consented to AARP and AARP Foundation's participation as amici in this matter. West Virginia Rules of Appellate Procedure Rule 30(a).

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 in *PLIVA* held that, because generic drug manufacturers have a "duty of sameness" to adopt verbatim the labels written by the brand-name manufacturer of the drug, it would be "impossible for [generic drug manufacturers] to comply with both their state-law duty to change the label and their federal-law duty to keep the label the same." *PLIVA*, 564 U.S. at 616-18. The Court also made clear that name-brand manufacturers face no such dilemma. 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 brand-name 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," and that would be copied verbatim by manufacturers of the generic version of the drug. *Wyeth*, 555 U.S. at 568 (*citing* 21 C.F.R. §§ 314.70 (c)(6)(iii)(A), (C)).

The differing federal law drug labeling obligations imposed on brand-name and generic drug manufacturers as articulated in *Wyeth* and *PLIVA* has left open questions regarding how a state's tort law intersects with those obligations and has, thus, raised the question before this Court: whether West Virginia 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. AARP believes that, when an injured consumer alleges that the brand-name drug manufacturer knew or should have foreseen the risks associated with the drug and failed to update the drug's label, it may be liable for failure to warn even if the generic version of the drug was actually ingested. Such an approach is consistent with the federal law regarding drug labeling, West Virginia's tort law, and the purposes and policy considerations animating both.

Federal law is clear that when risks associated with a drug are either known or foreseeable to the brand-manufacturer, it has a duty to update the label to warn of those risks. *See* 21 C.F.R. § 201.80(e); *see also Wyeth v. Levine*, 555, 568 (2009) (brand-name manufacturers can update labels to add or strengthen the warnings without FDA prior authorization). Appellees, who are the brand-name manufacturers, are fully aware that

the generic manufacturer of its drug must use the exact same label that it writes for the brand-name drug and that the label can be updated *only* by brand-name manufacturer. *See PLIVA*, 564 U.S. at 618. Because the generic version of the drug must be biologically equivalent to the brand-name drug, if the brand-name manufacturer does not update the label to warn of risks and hazards discovered after FDA approval of the label, it will result in both the brand-name and generic version being misbranded and unsafe. *See* 21 U.S.C. § 352(f) (2016) (defining "misbranded" drug). Thus, it is not only foreseeable, but inevitable that any injury caused by the generic version of the drug may be traced back in the causal chain to a failure to give adequate warning of known and foreseeable risks associated with the brand-name drug. AARP does not opine as to whether Appellees' breach of its duty to warn caused injury to Appellants, but rather, that Appellants should be allowed to proceed to discovery on that question.

## ARGUMENT

### I. BRAND-NAME DRUG MANUFACTURERS HAVE A DUTY TO WARN CONSUMERS OF RISKS OF WHICH THEY HAVE ACTUAL OR CONSTRUCTIVE KNOWLEDGE FOR AS LONG AS THE DRUG REMAINS ON THE MARKET

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.* 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).

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.

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 post-market 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. Indeed, under the current federal drug labeling scheme, brand-name manufacturers provide the *only* prescribing information that doctors, pharmacists, and consumers receive about brand-name drugs and their generic versions.

### A. *Recognizing potential liability of the brand-name manufacturer for failure to warn of generic drug risks is fair because the brand-name manufacturer can foresee that consumers may be injured by the risks associated with use of the biologically equivalent generic that they knew about but failed to disclose.*

Appellees may argue that it is unfair to hold the brand-name manufacturer liable for injuries caused by a drug that it did not manufacture. This argument, however, misses the critically important point that the brand manufacturer's duty to warn is *already* mandated by federal law and that this duty *extends* to knowledge of risks associated with the generic versions of the drug. Here, Appellants alleged that the brand-name manufacturer knew that acute respiratory distress syndrome had been linked to the use of levofloxacin, but negligently failed to update the warning label on its brand-name counterpart Levaquin. *See McNair v. Johnson & Johnson*, 694 F. App'x 115, *3 (4th Cir. 2017). The generic manufacturer must use the exact same label as the brand-name drug, so the Appellees knew that omission of safety information on Levaquin's label would result in the same omission on the label of the biologically equivalent generic levofloxacin that Kimmy McNair ingested. *Id.* at *2. Because the brand-name manufacturer knew that it had exclusive control of the information about the drug that

could go out to the public and health care providers, it could foresee that its failure to update the drug's label could cause harm to consumers. *Id.* These factual allegations, if proven, would show that the harms experienced by Appellants were a foreseeable result of Janssen's failure to update the labels when Janssen had the power and duty to do so.

### B. *A ruling in favor of Appellees would leave prescription drug consumers in West Virginia and all across the country without recourse if they are injured by a misbranded and unsafe generic drug.*

The cost of prescription drugs has long been a concern for consumers and policymakers in the U.S. *See, e.g.*, CBS News, *What's behind the sharp rise in prescription drug prices?* (Aug. 24, 2016), https://goo.gl/29hKRM (summarizing recent highly-publicized price increases for EpiPen, Daraprim, and hepatitis C drugs). High drug prices are the direct result of the 20-year patent protected monopoly in which brand-name drug manufacturers can raise the price of drugs without limitation and according to its demand. *See* AARP Bulletin, *Why Drugs Cost So Much*, p. 3 (May 2017); *see also* Alfred Engelberg, *How Government Policy Promotes High Drug Prices* (Oct. 29, 2015), https://goo.gl/FQ4BvX . Creating a faster pathway for generic drugs to enter the market and incentives for generic drug manufacturers to challenge the patents of brand-name drugs, the Hatch-Waxman Act of 1984 was one federal response to the rising costs of prescription drugs. *See* Jordan Paradise, *The Legal and Regulatory Status of Biosimilars: How Product Naming and State Substitution Laws May Impact the United States Healthcare System*, 41 Am. J. L. and Med. 49, 53-54 (2015).

As part of state efforts to stem the rise in prescription drug costs, all 50 states have passed laws that either permit or require pharmacists to substitute a prescribed brand-name drug with its generic equivalent. *Id.* at 74-75 (noting that 36 states allow generic substitution in the absence of a specific brand request by the prescriber and that 14 states mandate the generic substitution). In West Virginia, pharmacists are required to fill a prescription for a brand-name drug with its generic version, unless the pharmacist or the prescribing doctor specifically forbids the substitution. *See* W. Va. Code § 30-5-12b(b). In this case, it appears just that happened—Kimmy McNair was prescribed Levaquin, but the pharmacist filled the order with levofloxacin. *See McNair v. Johnson & Johnson*, Civil Action No. 2:14-17463, 2015 U.S. Dist. LEXIS 83181, *1, *5 (S.D. W. Va. June 26, 2015). Given this nationwide statutory preference for dispensing generic drugs and the Supreme Court's rulings in *Wyeth* and *PLIVA*, a ruling in favor of Appellees would insulate both the brand-name and generic manufacturers from any liability for failure to warn whenever a generic drug is ingested. Not only would this result be wrong as a matter of West Virginia tort law, as noted in the Appellants' brief, but it would be disastrous as a matter of public policy. In exchange for their efforts to reduce the cost of prescription drugs, Consumers and the American healthcare system would be penalized with toothless patient safety and tort laws.

## II. 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 breaches of duty of care that will harm others. *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 Appellees' favor would categorically exclude brand-name drug manufacturers from state tort claims alleging a failure to warn consumers of harms that are known or foreseeable.*

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 silences that message.

The rule proposed by Appellees would allow brand-name manufacturers to evade liability, regardless of (a) whether the brand-name manufacturer had actual or constructive knowledge of the drug's hazards at the time its exclusive right to sell/manufacture the drug ended; and (b) when the injury to a consumer taking a generic version of its drug occurred. If the Court adopts the standard proposed by Appellees,

name-brand drug manufacturers, knowing that their liability would be cut off simply by waiting for patent exclusivity to expire without regard to their pre-expiration knowledge or actions, would have less of an incentive to aid in public safety by updating the labels on their products. Consequently, the consumer would have no recourse because the generic drug manufacturer, according to the holding in *PLIVA*, is also absolved of any duty to update the label. However, there is no basis for the brand-name manufacturer to entirely absolve itself of any and all foreseeable consequences of its failure to update the label when such duty arises under federal drug labeling law.

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 on the pleadings; Appellants are at least entitled to discovery to determine exactly what risks to patients, if any, Janssen knew or should have known at the time that levofloxacin was sold to Kimmy McNair.

### B. *Appellants' proposed rule is consistent with and complementary to existing federal drug safety law.*

Appellants' theory of liability is consistent with and complementary to 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 absolve them of responsibility for the safety of the drugs that they manufacture.

## III. DRUG LABELS MUST BE KEPT CURRENT, AS THEY ARE THE 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.

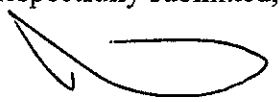
## CONCLUSION

For the foregoing reasons and those articulated in Appellants' brief, amici AARP and AARP Foundation urge the Court to hold that West Virginia tort 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. A ruling to the contrary would nullify tort law protections for West Virginians who use generic drugs, without

regard to whether the drug is actually safe or whether they were adequately warned of its risks; but simply because they were dispensed a generic drug to reduce the high cost of prescription drugs for them, insurance companies, and the state of West Virginia.

Dated: October 30, 2017.

Respectfully submitted,



Anthony J. Majestro (WV Bar No. 5165)
Powell & Majestro, PLLC
405 Capitol Street, Suite P-1200
Charleston, WV 25301
(304) 346-2889; Fax (304) 346-2895
amajestro@powellmajestro.com

Attorney for Amici Curiae AARP
and AARP Foundation

## CERTIFICATE OF SERVICE AND FILING

I, Anthony J. Majestro, do hereby certify that service of the foregoing Brief of Amici Curiae AARP and AARP Foundation in Support of Appellants, Kimmy McNair and Larry McNair was made upon the parties listed below by depositing a true copy of the same by first-class on each party and person required to be served, as follows:

***Counsel for Petitioner:***

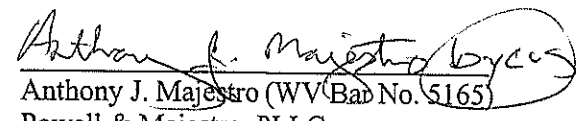
Leslie A. Brueckner, Esq.
Senior Attorney
Public Justice
555 12th Street, Suite 1230
Oakland, CA 94607
510-622-8150
510-622-8156
lbruechner@publicjustice.net

Richard D. Lindsay, Esq.
Tabor Lindsay & Associates
1223 Virginia Street, E
Charleston, WV 25301
304-344-5156
304-344-5188

***Counsel for Respondents:***

Philip J. Combs, Esq.
Daniel R. Higginbotham, Esq.
David B. Thomas, Esq.
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
Charleston WV 25301
304-414-1800

John Winter, Esq.
Patterson Belknap Webb & Tyler LLP
1133 Avenue of the Americas
New York, NY 10036-6710



Anthony J. Majestro (WV Bar No. 5165)
Powell & Majestro, PLLC
405 Capitol Street, Suite P-1200
Charleston, WV 25301
(304) 346-2889; Fax (304) 346-2895
amajestro@powellmajestro.com

Attorney for Amici Curiae AARP
and AARP Foundation