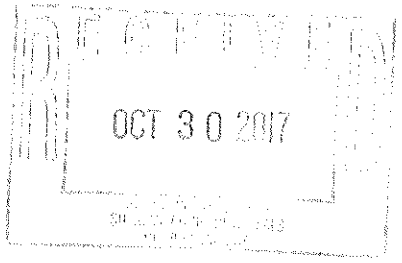

SUPREME COURT OF APPEALS
OF WEST VIRGINIA

No. 17-0519

KIMMY MCNAIR and LARRY MCNAIR,
Plaintiffs-Appellants,

v.

JOHNSON & JOHNSON, A FOREIGN CORPORATION;
JANSSEN PHARMACEUTICALS, INC., A FOREIGN CORPORATION;
AND ORTHO-MCNEIL PHARMACEUTICAL, INC., A FOREIGN CORPORATION,
Defendants-Appellees.

On certified question from the United States Court of Appeals
for the Fourth Circuit
Case No. 15-1806

BRIEF OF AMICUS CURIAE PUBLIC CITIZEN, INC.

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October 30, 2017

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INTEREST OF AMICUS CURIAE[1]

Public Citizen is a non-profit consumer advocacy organization with members and supporters in every state, including West Virginia. Since its founding in 1971, Public Citizen has assessed the safety and efficacy of drugs, provided information on drug safety to the public, and advocated before the Food and Drug Administration (FDA) for product labeling and regulation to reduce safety risks. In June 2013, a Public Citizen report compiled a list of drugs for which black-box warnings—the most serious contraindications and warnings—were added after a generic equivalent entered the market. Looking at a five-year period, the report identified 53 drugs for which a black-box warning calling attention to serious or life-threatening risks was added after generic market entry. The data underscore the public health imperative of requiring pharmaceutical companies to maintain active surveillance of safety, even after a drug is also marketed in generic form.[2]

Public Citizen has participated as amicus in many cases brought by patients injured by drugs that carried inadequate warnings, including *PLIVA, Inc. v. Mensing*, 564 U.S. 605 (2011). In *PLIVA*, the United States Supreme Court held that federal law preempts failure-to-warn claims against generic drug manufacturers because FDA regulations prohibit generic manufacturers from updating labeling except to mimic brand-name labeling changes or as ordered by the FDA. Public Citizen responded by petitioning the FDA to allow generic drug manufacturers to revise product labeling through the procedures already available to brand-name manufacturers. In November

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[1] No party's counsel authored this brief in whole or in part, and no party or party's counsel made a monetary contribution specifically intended to fund the preparation or submission of this brief. No person or entity other than amicus curiae made such a monetary contribution. West Virginia Rules of Appellate Procedure 30(e)(5). Amicus gave all parties notice of the filing of this brief at least five days in advance of filing, and all parties have consented to the filing of this brief. West Virginia Rules of Appellate Procedure 30(a).

[2] The report is available at www.citizen.org/documents/2138.pdf.

2013, the FDA granted Public Citizen's petition in part by issuing a proposed rule, 78 Fed. Reg. 67985 (Nov. 13, 2013). The FDA, however, has yet to issue a final rule. Until it does so, and unlike brand-name manufacturers, generic drug manufacturers cannot initiate safety updates to product labeling. Patients and physicians therefore depend on brand-name manufacturers to provide adequate warnings for both brand-name and generic drugs. Allowing patients to pursue tort claims against brand-name manufacturers for injuries caused by inadequate warnings is important as both an incentive to be vigilant about product safety and to provide accountability to patients. For this reason, this case has important implications for all West Virginians that go well beyond the interests of the parties.

INTRODUCTION AND SUMMARY OF ARGUMENT

The issue presented in this case—whether a brand-name drug manufacturer can be held liable for injuries caused by inadequately labeled generic drugs—is of significant and growing importance to patients. Following passage of the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585, commonly referred to as the Hatch-Waxman Amendments, sales of generic drugs have grown dramatically, fundamentally reshaping the pharmaceutical market. The increased availability of generic drugs has made many prescription drugs more affordable for patients. In 1983, only 35 percent of top-selling drugs with expired patents had generic equivalents; by 1998, nearly all did.[3] And when generics compete, they typically capture a significant part of market share and profit.[4] As of 2010, 90 percent of

[3] *How Increased Competition From Generic Drugs Has Affected Prices and Return in the Pharmaceutical Industry*, Congressional Budget Office, p. xii (1998), https://www.cbo.gov/sites/default/files/105th-congress-1997-1998/reports/pharm.pdf.

[4] *See Research and Development in the Pharmaceutical Industry*, Congressional Budget Office, pp. 16–17 (2006), https://www.cbo.gov/sites/default/files/cbofiles/ftpdocs/76xx/doc7615/10-02-drugr-d.pdf.

prescriptions for drugs with generic versions were filled with generics rather than brand-name drugs[5]—a development spurred by state laws authorizing pharmacists to substitute generic drugs when filling prescriptions.[6] Some states have gone further and now mandate generic substitution where available.[7] From 2009 through 2012, generic prescriptions' share of the prescription drug market increased to 84 percent of all U.S. prescriptions.[8] In 2010, generics captured more than 80 percent of the market within six months of expiration of a brand-name's patent (as compared to 55 percent in 2006).[9]

Despite these market changes, the law places responsibility for labeling firmly on brand-name manufacturers. Generic drug manufacturers cannot initiate labeling updates; the labeling of generic drugs must mirror that of the brand-name products. A patient's reliance on the brand-name labeling, regardless of whether the patient took the branded or the generic version of the drug, is thus intended by the regulatory scheme. In light of this unusual fact—that one manufacturer is required to copy the safety information provided by another—patients should be able to hold brand-name drug manufacturers accountable for injuries resulting from misrepresentations about the safety of their drugs, even if those injuries are caused by a generic version of the drug. As

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[5] *ASPE Issue Brief: Expanding the Use of Generic Drugs*, HHS, pp. 3–4 (Dec. 2010), https://aspe.hhs.gov/basic-report/expanding-use-generic-drugs.

[6] *See Drug Product Selection: Legal Issues*, Thomas P. Christensen et al., 41 J. Am. Pharm. Ass'n 868 (2001).

[7] *State Generic Substitution Laws Can Lower Drug Outlays Under Medicaid*, William H. Shrank et al., 29 Health Affairs 1383 (July 2010).

[8] *Declining Medicine Use and Costs: For Better or Worse?*, IMS Institute for Healthcare Informatics (May 2013), http://static.correofarmaceutico.com/docs/2013/05/20/usareport.pdf; *The Use of Medicines in the United States: Review of 2010*, IMS Institute for Healthcare Informatics, pp. 11, 15, 22 (Apr. 2011), https://www.imshealth.com/files/web/IMSH%20Institute/Reports/The%20Use%20of%20Medicines%20in%20the%20United%20States%202010/Use_of_Meds_in_the_U.S._Review_of_2010.pdf (IMS 2011 Report).

[9] IMS 2011 Report, *supra* note 8, at p. 21.

discussed below, allowing patients to do so makes sense under traditional tort law principles and as a matter of policy.

ARGUMENT

I. Safety concerns often do not come to light until years after a drug first comes on the market, and only brand-name manufacturers can promptly update labeling in light of newly discovered risks.

Before a manufacturer can market a drug in the United States, it must obtain FDA marketing approval. 21 U.S.C. § 355. Although the FDA evaluates the drug's safety and effectiveness for its intended use before granting approval, the importance of post-approval monitoring for ensuring drug safety is well-recognized. As an article in the *Journal of the American Medical Association* explained:

> Even though the evaluation of new drugs and devices is technically rigorous, the current approach of basing drug approval decisions on clinical trials of efficacy that include relatively small numbers of patients virtually guarantees that the full risks and complete safety profile of these drugs will not be identified at the time of approval. Rather, the full safety profile and effectiveness only manifest as each drug is used in the wider population of patients who are less carefully selected than participants in clinical trials.[10]

The limitations in pre-approval testing are especially salient when a drug's significant adverse effects are relatively rare or have long latency periods—forms of risk that the FDA approval process is not designed to uncover. Examples of drugs whose substantial risks were only discovered post-approval abound in the medical literature.[11] A 2013 article authored jointly by three FDA staff members and two academics reported that "[t]he most critical safety-related label

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[10] *Prescription Drugs, Products Liability, and Preemption of Tort Litigation*, Catherine D. DeAngelis & Phil B. Fontanarosa, 300 J. Am. Med. Ass'n 1939, 1939 (2008).

[11] *See, e.g.*, Brief of the Am. Med. Ass'n et al. as Amici Curiae Supporting Resp'ts, 2011 WL 794118, *PLIVA, Inc. v. Mensing* (2011) 131 S. Ct. 2567 (Nos. 09-993, 09-1039, 09-1501), at 12–17 (discussing examples of fenfluramine, propoxyphene, ibuprofen, terbutaline sulfate, and metoclopramide).

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)."[12] This conclusion is consistent with an earlier study's finding that "[o]nly half of newly discovered serious [adverse drug reactions] are detected and documented in the *Physicians' Desk Reference* within 7 years after drug approval."[13]

Because safety risks are commonly not identified until years after a drug comes on the market, and even after generic versions of the drug come on the market, ongoing monitoring and labeling updates are crucial for safe use of medications. Yet as the Supreme Court recognized in *Wyeth v. Levine*, 555 U.S. 555 (2009), "[t]he FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge." *Id.* at 578-79 (footnote omitted). It has therefore been "a central premise of federal drug regulation that the manufacturer bears responsibility for the content of its label at all times ... [and] ensuring that its warnings remain adequate as long as the drug is on the market." *Id.* at 570-71. The need for manufacturers to play a significant role is heightened by funding and staff shortages at the FDA that have prompted the Government Accountability Office (GAO) repeatedly to express concern about post-approval drug safety monitoring.[14]

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[12] *Evaluation of FDA safety-related drug label changes in 2010*, Jean Lester, et al., 22 Pharmacoepidemiology and Drug Safety 302, 304 (2013).

[13] *Timing of New Black Box Warnings and Withdrawals for Prescription Medications*, Karen E. Lasser, et al., 287 J. Am. Med. Ass'n 2215, 2218 (2002).

[14] *See, e.g., High-Risk Series: An Update* 271, GAO (Feb. 2015), http://www.gao.gov/assets/670/668415.pdf (expressing concern that FDA lacks resources to adequately inspect drug manufacturing facilities); *High-Risk Series: An Update* 116-17, GAO (Feb. 2011), http://www.gao.gov/assets/320/315725.pdf ("FDA staff have expressed concern about their ability to meet a growing postmarket workload, with some maintaining that their premarket responsibilities are considered a higher priority."); *Drug Safety: FDA Has Begun Efforts to Enhance Postmarket Safety, But Additional Actions Are Needed*, GAO (Nov. 2009),

To ensure the post-approval safety of their drugs, manufacturers must "promptly review all adverse drug experience information obtained or otherwise received by the [manufacturer] from any source, foreign or domestic, including information derived from commercial marketing experience, post-marketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b). To ensure that labeling is kept up to date as information accumulates, FDA regulations require that the labeling of both brand-name and generic drugs "must be revised to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a causal association with a drug; a causal relationship need not have been definitely established." *Id.* § 201.57(c)(6)(i) (implementing 21 U.S.C. § 352(f)(2), which provides that a drug lacking "adequate warnings" is misbranded). At the same time, the FDA significantly restricts generic manufacturers' ability to do so, in ways that absolve generic manufacturers of responsibility for labeling updates and that reinforce the brand-name manufacturers' responsibility.

Brand-name manufacturers, who market drugs approved through the new drug application (NDA) process, may seek review and approval of revised labeling by filing a supplemental application. *Id.* § 314.70. A supplemental application must satisfy all regulatory requirements that apply to original applications. *See id.* § 314.71(b). Although some label changes require prior FDA approval—obtained through a "prior approval supplement," *id.* § 314.70(b)—other changes are brought to FDA's attention at the time the applicant makes the change through a "changes being

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http://www.gao.gov/assets/300/298135.pdf; *Drug Safety: Improvement Needed in FDA's Postmarket Decision-making and Oversight Process*, GAO (Mar. 2006), http://www.gao.gov/new.items/d06402.pdf; *see also A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, David A. Kessler & David C. Vladeck, 96 Geo. L.J. 461, 485 (2008) (noting that "[r]esource constraints have been especially acute with the agency's post-marketing surveillance efforts" and that two-thirds of FDA doctors and scientists "worry that the FDA is not adequately monitoring the safety of drugs once they are on the market").

effected" (CBE) supplement. *Id.* § 314.70(c). CBE supplements are authorized for, among other things, "[c]hanges in the labeling to reflect newly acquired information ... [t]o add or strengthen a contraindication, warning, precaution, or adverse reaction for which" there is reasonable evidence of a causal association. *Id.* § 314.70(c)(6)(iii)(A).

Generic manufacturers, however, have neither the power nor the responsibility for new safety updates. The United States Supreme Court, deferring to the FDA's interpretation of the existing regulation, has held that the CBE process is not available to generic manufacturers. *PLIVA, Inc. v. Mensing*, 564 U.S. at 614–15. Instead, in most cases, generic drug manufacturers can make safety updates only after approval of a CBE supplement submitted by the brand-name manufacturer for that product or when ordered to by the FDA.[15] This restriction follows from the general rule that the labeling of the generic product must generally be "the same as the labeling of" the corresponding brand-name drug. 21 C.F.R. § 314.94(a)(8)(iii); *see also id.* § 314.105(c). As a result, brand-name manufacturers—and only brand-name manufacturers—have the responsibility for updating labeling to provide adequate warnings, even after generic versions of the brand-name drug are on the market.

II. Brand-name manufacturers can easily foresee that physicians and patients will rely on the brand-name labeling, regardless of whether a patient's prescription is filled with a generic drug.

As explained above, current FDA regulations allow the brand-name company to make safety updates without prior FDA approval, but prohibit the generic company from making safety

[15] *Guidance for Industry, Revising ANDA Labeling Following Revision of the RLD Labeling*, FDA, p. 5 (May 2000), http://www.fda.gov/downloads/Drugs/GuidanceCompliance 2000062RegulatoryInformation/Guidances/ucm072891.pdf; *see also Draft Guidance, Updating ANDA Labeling After the Marketing Application for the Reference Listed Drug Has Been Withdrawn*, FDA (July 2016), http://www.fda.gov/downloads/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/UCM510240.pdf.

updates except to mimic the brand-name labeling revision or as instructed by the FDA. *See* 78 Fed. Reg. at 67988. Indeed, the brand-name manufacturer, *even after generics come on the market*, has an "ongoing obligation to ensure [its] labeling is accurate and up-to-date," *id.* at 67987, while the generic manufacturer's obligation is only to ensure that its labeling matches the brand-name labeling, *id.* at 67988. Amicus Public Citizen has advocated that this system should be changed to allow generic companies to initiate safety updates. However, as the regulatory scheme currently exists, the responsibility for safety labeling remains squarely with the brand-name manufacturer.

For this reason, a patient's (and physician's) reliance on the brand-name labeling is not only foreseeable—whether the patient takes the brand-name or the generic form of the drug—it is inevitable and expected. And in light of the brand-name manufacturer's responsibility for maintaining the adequacy of the drug's labeling, it is not surprising that patients who suffered injury after taking a generic drug that had inadequate safety warnings have sometimes sought to hold the brand-name manufacturer accountable. At least some such lawsuits do not merely seek to hold the brand-name company responsible under strict products liability theory; some cases, including this one, are also premised on negligence. As the McNairs argue, holding defendants liable in negligence for physical harms foreseeably caused by their misrepresentations is consistent with West Virginia tort law. It is also consistent with the Restatements: The Restatement (Third) of Torts § 18(a) (2016), provides that a defendant may fail to exercise reasonable care by failing to warn if "(1) the defendant knows or has reason to know: (a) of that risk; and (b) that those encountering the risk will be unaware of it; and (2) a warning might be effective in reducing the risk of harm." And the Restatement (Second) of Torts § 311(1)(b), at 106 (1965), provides that "one who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm

results ... *to such third persons* as the actor should expect to be put in peril by the action taken." This traditional understanding of a negligent failure-to-warn claim provides strong support for the McNairs' position here.

As the district court recognized in this case, several federal appellate courts, predicting how the issue would be resolved under state laws of states *other than* West Virginia, have held to the contrary. Only two *state* Supreme Courts, however, have authoritatively addressed the issue under the laws of their states. In one, *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014), the state court held that such a claim was a products liability claim under Iowa law, not a negligent-misrepresentation claim, and under Iowa law a products liability claim can be brought only against the product seller or supplier. *Id.* at 369, 371. In the other, however, the Supreme Court of Alabama rejected the notion that a misrepresentation claim is a species of products liability claim. *Wyeth, Inc. v. Weeks*, 159 So. 3d 649, 675 (Ala. 2014). That court held that the brand-name manufacturer *could* be held liable in an action brought by a patient who was injured by the generic version of its drug. *Id.* at 670.[16] *See also Kellogg v. Wyeth*, 762 F. Supp. 2d 694, 708–09 (D. Vt. 2010) (holding that brand-name manufacturer can be held liable for injury caused by generic drug under Vermont law because manufacturer owes duty of care to patients who ingest generic equivalent); *Conte v. Wyeth, Inc.*, 168 Cal. App. 4th 89, 85 Cal. Rptr. 3d 299 (Cal. Ct. App. 2008) (holding that a negligence claim against a brand-name manufacturer for injury caused when the patient took the generic equivalent was proper under California law in light of the relationship between branded and generic drug labeling).[17]

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[16] After intense lobbying by the pharmaceutical industry, the State of Alabama later enacted a statute superseding that decision, *see* Ala. Code § 6-5-530 (2015).

[17] The California Supreme Court is currently considering this question in a case entitled *T.H. v. Novartis Pharms. Corp.*, No. S233898.

Moreover, courts that have rejected recognition of a state-law failure-to-warn or negligence claim in this context have failed to appreciate the unique elements of drug regulation—such as the requirement that generics use the brand-name labeling, the bar against generic manufacturers updating except in response to a brand-name update or FDA order (and, on the flip side, the brand-name manufacturers' ability to update safety warnings promptly, without prior FDA approval), and state substitution laws, like West Virginia Code § 30-5-12b(b), requiring pharmacists to fill prescriptions with generic versions where available, unless the physician specifically indicates the need for the brand-name product. In addition, each of the federal court decisions look to the tort law of the state in which the claim arose, not to West Virginia law.

Here, the McNairs' failure-to-warn claims fit comfortably within the scope of West Virginia law: "The ultimate test of the existence of a duty to use care is found in the foreseeability that harm may result if it is not exercised." *Stevens v. MTR Gaming Grp., Inc.*, 237 W. Va. 531, 534, 788 S.E.2d 59, 62 (2016). Here, in light of the regulatory scheme, it is beyond dispute that "[a] brand-name manufacturer could reasonably foresee that a physician prescribing a brand-name drug (or a generic drug) to a patient would rely on the warning drafted by the brand-name manufacturer even if the patient ultimately consumed the generic version of the drug." *Weeks*, 159 So. 3d at 670. Accordingly, that manufacturer can be held liable for failure to warn under West Virginia law.

III. Defendants' position, if adopted, would put patients at risk.

This Court has recognized the strong public policy imperative that manufacturers provide patients with adequate warnings about potential harmful effects of pharmaceuticals. *See State ex rel. Johnson & Johnson v. Karl*, 220 W. Va. 463, 478, 647 S.E.2d 899, 914 (2007). Yet, as the FDA has recognized, generic drug manufacturers have little incentive to comply with current

requirements to conduct robust postmarketing surveillance, evaluation, and reporting, and even less ability to ensure that the labeling for their drugs is accurate and up-to-date. *See* 78 Fed. Reg. at 67988–89. Under the current regulatory scheme, only the brand-name manufacturer can ensure that adequate warnings are provided.

For this reason, if accepted, defendants' plea to be exempt from accountability for labeling for which it is solely responsible would exacerbate a dangerous safety gap. "[M]ost critical safety-related label changes" are made years after the drug's initial approval, "underscoring the importance of persistent and vigilant postmarket drug safety surveillance." *Evaluation of FDA safety-related drug label changes in 2010*, *supra* note 12, at 304. And the majority of labeling changes are initiated by the brand-name manufacturers, not the FDA. *Id.* at 303. Because critical safety information may come to light after entry of the generic onto the market, and because the generic manufacturer is limited to mimicking the brand-name labeling, if the brand-name manufacturer does not continue actively to monitor and propose safety updates, patients are at risk.

In its brief to the Fourth Circuit, defendants relied heavily on the Fourth Circuit's 1994 decision in *Foster v. American Home Products Corp.*, 29 F.3d 165 (4th Cir. 1994), which had rejected the argument that a brand-name manufacturer could be held liable for injuries to a patient who took the generic form of the manufacturer's product. *See* Defs. 4th Cir. Br. 6–7. In light of the Fourth Circuit's certification of the question to this Court, the company can no longer rely on that decision as authority. Rather, as the Fourth Circuit pointed out, *Foster* was based on the assumption that generic manufacturers could add or strengthen the warnings on drug labeling—an assumption that it recognizes "is no longer the case." Fourth Cir. Order at 11. Defendants also focused on *Meade v. Parsley*, an unreported decision of a district court bound by *Foster*. *See* No. 09-cv-00388, 2009 WL 3806716, at *3 (S.D. W. Va. 2009) ("Our court of appeals in *Foster* has

addressed this issue, making the negligent misrepresentation theory of liability unavailable to plaintiffs [in this circumstance]."). Notably, defendants did not rebut the fact that the brand-name manufacturer is the party responsible for the labeling that is alleged to have been inadequate and caused the McNairs' injuries, and that the McNairs' reliance on that labeling was entirely foreseeable.

As explained in *Wyeth*:

> 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.

129 S. Ct. at 1202. State-law remedies thus "further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id.* at 1200. The position of defendants here would leave no manufacturer accountable for failure to warn of hazards, thus eliminating a crucial bulwark against unsafe pharmaceuticals in the marketplace.

CONCLUSION

For the foregoing reasons and the reasons stated in the brief of appellants, the Court should answer the certified question in the affirmative.

Dated: October 30, 2017

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CERTIFICATE OF SERVICE

I, Anthony J. Majestro, certify that, on October 30, 2017, I caused a true and correct copy of the attached Brief of Amicus Curiae Public Citizen, Inc., to be served by first-class mail on each party and person required to be served, as follows:

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