IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

January 2018 Term

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No. 17-0519

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SUPREME COURT OF APPEALS
OF WEST VIRGINIA

KIMMY MCNAIR AND LARRY MCNAIR,
Petitioners

v.

JOHNSON & JOHNSON; JANSSEN PHARMACEUTICALS, INCORPORATED; AND ORTHO-MCNEIL PHARMACEUTICAL, INCORPORATED,
Respondents

CERTIFIED QUESTION ANSWERED

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Leslie A. Brueckner, Esq. (*pro hac vice*)
Public Justice, P.C.
Oakland, California
And
Richard D. Lindsay, Esq.
Tabor Lindsay & Associates
Charleston, West Virginia
Counsel for the Petitioners

Anthony J. Majestro, Esq.
Powell & Majestro, PLLC
Charleston, West Virginia
And
Allison M. Zieve, Esq. (*pro hac vice*)
Public Citizen Litigation Group
Washington, D.C.
Counsel for *Amicus Curiae*
Public Citizen, Inc.

Elbert Lin, Esq.
Hunton Andrews Kurth LLP
Richmond, Virginia
And
David B. Thomas, Esq.
Daniel R. Higginbotham, Esq.
Thomas Combs & Spann LLP
Charleston, West Virginia
And
John D. Winter, Esq. (*pro hac vice*)
Jonah M. Knobler, Esq. (*pro hac vice*)
Patterson Belknap Webb & Tyler LLP
New York, New York
Counsel for the Respondents

Anthony J. Majestro, Esq.
Powell & Majestro, PLLC
Charleston, West Virginia
Counsel for *Amici Curiae*
AARP and AARP Foundation

Forrest H. Roles, Esq.
Mark A. Carter, Esq.
Dinsmore & Shohl, LLP
Charleston, West Virginia
Counsel for *Amicus Curiae*
Washington Legal Foundation

Ancil G. Ramey, Esq.
Steptoe & Johnson PLLC
Huntington, West Virginia
And
Russell D. Jessee, Esq.
Steptoe & Johnson PLLC
Charleston, West Virginia
And
Michael X. Imbroscio, Esq. (*pro hac vice*)
Paul W. Schmidt, Esq. (*pro hac vice*)
Gregory L. Halperin, Esq. (*pro hac vice*)
Covington & Burling LLP
Washington, D.C.
Counsel for *Amicus Curiae*
Pharmaceutical Research and Manufacturers of America

Kannon K. Shanmugam, Esq. (*pro hac vice*)
Williams & Connolly LLP
Washington, D.C.
And
John M. Canfield, Esq.
West Virginia Chamber of Commerce
Charleston, West Virginia
Counsel for *Amici Curiae*
Chamber of Commerce of the United States of America
West Virginia Chamber of Commerce
American Tort Reform Association

JUSTICE LOUGHRY delivered the Opinion of the Court.

CHIEF JUSTICE WORKMAN dissents and reserves the right to file a dissenting opinion.

JUSTICE DAVIS dissents and reserves the right to file a dissenting opinion.

SYLLABUS BY THE COURT

1. "Product liability actions may be premised on three independent theories – strict liability, negligence, and warranty. Each theory contains different elements which plaintiffs must prove in order to recover." Syl. Pt. 6, in part, *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603 (1983).

2. "For the duty to warn to exist, the use of the product must be foreseeable to the manufacturer or seller." Syl. Pt. 3, *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603 (1983).

3. "In order to establish a *prima facie* case of negligence in West Virginia, it must be shown that the defendant has been guilty of some act or omission in violation of a duty owed to the plaintiff. No action for negligence will lie without a duty broken." Syl. Pt. 1, *Parsley v. Gen. Motors Acceptance Corp.*, 167 W.Va. 866, 280 S.E.2d 703 (1981).

4. There is no cause of action in West Virginia for failure to warn and negligent misrepresentation against a brand-name drug manufacturer when the drug ingested was produced by a generic drug manufacturer.

LOUGHRY, Justice:

This matter is before this Court upon a June 9, 2017, order of the United States Court of Appeals for the Fourth Circuit certifying the following question:

> Whether West Virginia law permits a claim of failure to warn and negligent misrepresentation against a branded drug manufacturer when the drug ingested was produced by a generic manufacturer.

By order dated August 30, 2017, this Court accepted the certified question and docketed the matter for resolution.[1] Upon review of the parties' briefs, arguments, the appendix record, and the pertinent law, we answer the certified question in the negative.[2]

I. Regulatory Background

We begin our analysis with a brief discussion of federal prescription drug regulations to provide the necessary background for addressing the question before us. A

[1]The petitioners, Kimmy and Larry McNair, ask this Court to reformulate the certified question to replace the term "negligent misrepresentation" with the term "negligence." In the McNairs' brief on appeal from the federal district court to the court of appeals, they framed the issue as "[w]hether West Virginia law permits a claim of failure to warn and negligent misrepresentation against a branded drug manufacturer when the drug ingested was produced by a generic manufacturer." Therefore, we decline to reformulate the question.

[2]This Court would like to acknowledge the participation of *amici curiae* in this case. Specifically, briefs were filed in support of the McNairs by the AARP, the AARP Foundation, and Public Citizen, Inc. Briefs were filed in support of Janssen Pharmaceuticals, Inc., the respondent, by the Washington Legal Foundation, The Chamber of Commerce of the United States of America, The West Virginia Chamber of Commerce, The American Tort Reform Association, and the Pharmaceutical Research and Manufacturers of America. This Court has considered the arguments presented by *amici curiae* in deciding this case.

manufacturer seeking federal approval to market a new drug in interstate commerce must prove that the drug is safe and effective and that the manufacturer's proposed label is accurate and adequate. *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 (2011) (citations and footnote omitted). The United States Supreme Court has explained the approval of a new prescription drug as follows:

> In the case of a new brand-name drug, FDA approval can be secured only by submitting a new-drug application (NDA). An NDA is a compilation of materials that must include full reports of all clinical investigations, relevant nonclinical studies, and any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source. The NDA must also include the labeling proposed to be used for such drug and a discussion of why the drug's benefits exceed the risks under the conditions stated in the labeling. The FDA may approve an NDA only if it determines that the drug in question is safe for use under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof. In order for the FDA to consider a drug safe, the drug's probable therapeutic benefits must outweigh its risk of harm.
>
> The process of submitting an NDA is both onerous and lengthy. A typical NDA spans thousands of pages and is based on clinical trials conducted over several years.

Mut. Pharm. Co. v. Bartlett, 570 U.S. 472, 476-77 (2013) (internal quotation marks, brackets, and citations omitted).

In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, which is commonly known as the Hatch-Waxman Act ("Hatch-Waxman" or "the Act"), in order to get prescription drugs to market in a speedier and less

expensive manner. *Abbott Labs. v. Young*, 920 F.2d 984, 985 (D.C. Cir. 1990). The Act was also intended to improve the affordability of prescription drugs while encouraging innovation of new drugs. *Id.* Under the Act, generic drugs can gain approval of the Federal Food and Drug Administration ("FDA") merely by showing equivalence to a brand-name drug that has already been approved by the FDA. *Mensing*, 564 U.S. at 612. Specifically, once the patent expires on a brand-name drug, a pharmaceutical company seeking to market a generic version of the drug can submit an "Abbreviated New Drug Application" ("ANDA") which requires the following:

> First, the proposed generic drug must be chemically equivalent to the approved brand-name drug. It must have the same active ingredient or active ingredients, route of administration, dosage form, and strength as its brand-name counterpart. Second, a proposed generic must be bioequivalent to an approved brand-name drug. That is, it must have the same rate and extent of absorption as the brand name drug. Third, the generic drug manufacturer must show that the labeling proposed for the new drug is the same as the labeling approved for the [approved brand-name] drug.

Bartlett, 570 U.S. at 479 (quotations marks and citations omitted). Further, generic manufacturers are prohibited from making any unilateral changes to their drug labels once those labels have been approved by the FDA, and they may alter a warning label only when necessary to duplicate a change in a brand-name label or to follow the FDA's instructions.[3] *See Mensing*, 564 U.S. at 613-615.[4] The Supreme Court has characterized

[3]Federal law requires generic manufacturers to propose labeling changes to the FDA if they believe stronger warnings are needed. *See Mensing*, 564 U.S. at 617 (noting that "federal law also required the [generic] Manufacturers to ask for FDA assistance in convincing the brand-name manufacturer to adopt a stronger label.").

the fact that generic drug labels must match brand-name drug labels as an "ongoing federal duty of 'sameness.'" *Mensing*, 564 U.S. at 613 (citations omitted). In return for granting generic drugs an expedited path to approval, Hatch-Waxman authorized the FDA to extend the length of brand-name manufacturers' patents for a period of up to five years, depending on the length of the review period, so that brand-name manufacturers have a monopoly over their newly-developed drugs for a longer period of time. *Sergeants Benevolent Assoc. Health and Welfare Fund*, Nos. 15-cv-6549, 15-cv-7488, 2016 WL 4992690, at *3 (S.D.N.Y. Sept. 13, 2016).

In 2009, the United States Supreme Court held in *Wyeth v. Levine*, 555 U.S. 555 (2009), that, generally, plaintiffs may bring state failure-to-warn claims against manufacturers of brand-name drugs. The Supreme Court reasoned that such a claim was not preempted by federal law because it is possible for a brand-name manufacturer to comply with both state and federal law under the FDA's regulations. *Id.* at 573. However, two years later in *Mensing*, the Supreme Court determined that federal labeling law for generic drugs generally preempts state failure-to-warn claims brought by plaintiffs alleging that manufacturers of generic drugs failed to warn of the risks of taking its drug. *Mensing*, 564 U.S. at 624. The Supreme Court reasoned that if the generic drug manufacturers had independently changed their labels to meet state law requirements to

[4]In contrast, a brand-name manufacturer may change the contents of its label without FDA approval. Specifically, it may "add or strengthen" a warning on its label by filing a simultaneous application with the FDA, without waiting for the FDA's approval. *Wyeth v. Levine*, 555 U.S. 555, 568 (2009).

attach a safer label to the drug, the generic manufacturers would have violated the federal requirement that generic drug labels must correspond verbatim to brand-name drug labels. 564 U.S. at 618. Thus, concluded the Supreme Court, it is impossible for the generic drug manufacturers to comply with both state and federal law. *Id.* at 624.

This preemption of state failure-to-warn claims against generic drug manufacturers has, in the words of the federal district court in the case at bar,

> [c]reated what the Supreme Court has acknowledged as an "unfortunate" quirk: plaintiffs who ingest a brand-name drug may well have a cause of action against the brand-name manufacturer, but those who ingest a generic drug with the same composition and same label as the brand-name drug have no similar recourse against the generic manufacturer.

McNair v. Johnson & Johnson, No. 2:14-17463, 2015 WL 3935787, at *4 (S.D.W.Va. June 26, 2015) (citing *Mensing*, 564 U.S. at 625) (indicating that "[h]ad [plaintiffs] taken Reglan, the brand-name drug prescribed by their doctors . . . their lawsuits would not be preempted. But because pharmacists, acting in full accord with state law, substituted generic metoclopramide instead, federal law pre-empts these lawsuits." (additional citation omitted)). We now turn to the specific facts of this case.

II. Facts and Procedural Background

The petitioners, the McNairs, filed an action in the Circuit Court of Kanawha County against the respondent, Janssen Pharmaceuticals ("Janssen"), alleging that in March 2012, Mrs. McNair developed acute respiratory distress ("ARDS") after

ingesting the generic drug levofloxacin[5] that was manufactured by Dr. Reddy's Laboratories Limited ("Dr. Reddy's"). Janssen originally trademarked and sold levofloxacin under the brand Levaquin®. Thus, Janssen produced the warnings on the label that accompanied the distribution of Levaquin, which were subsequently used by generic manufacturers of levofloxacin. The McNairs alleged in their complaint that Janssen was aware that ARDS had been linked to the use of levofloxacin but negligently failed to include a warning, knowing this omission would exist not only in its distribution of Levaquin, but also in the warnings accompanying generic versions of the drug. Asserting several products liability claims, the McNairs' general theory of liability is that even though Mrs. McNair took a generic version of the drug, Janssen had exclusive control of the content of the warnings that were published to the public and to health care providers for both the brand-name and the generic forms of the drug. Therefore, the McNairs conclude that Janssen is liable for their alleged injuries.

Janssen removed the action to federal court on diversity grounds. Janssen then moved for summary judgment, arguing that it could not be liable for a drug it did not manufacture or distribute because, under West Virginia law, a manufacturer's culpability in a products liability case is tied to conduct associated with designing, manufacturing or

[5]As explained in the federal district court's order granting summary judgment to Janssen, levofloxacin's inventor obtained a patent for the drug which it exclusively licensed to the respondent, Ortho-McNeil Pharmaceutical, Inc. ("Ortho"). All of Ortho's assets were ultimately transferred to Janssen. The respondent, Johnson & Johnson, is Janssen's parent company. For convenience, this Court will refer to the respondents collectively as "Janssen."

selling a defective product. The McNairs conceded that Janssen did not manufacture or sell the generic drug that Mrs. McNair ingested, but nonetheless urged the federal district court to deny Janssen's motion, averring that Janssen alone made the decision not to warn about ARDS in its labeling. The McNairs also pointed out that federal law precluded an action against Dr. Reddy's based on a failure to warn because the generic manufacturer was prohibited from changing the warning on its label in any way from the warning label prepared by Janssen. Finally, the McNairs argued that granting Janssen's motion would mean no party is liable for the alleged misinformation that purportedly caused Mrs. McNair's injury.

The federal district court granted summary judgment to Janssen. The district court reasoned that every federal court of appeals to consider the issue, both before and after *Mensing*, has rejected the contention that a brand-name drug manufacturer's statements regarding its drug could serve as the basis of liability for injuries caused by another manufacturer's drug. The district court observed that in West Virginia, "[p]roduct liability law . . . allows for recovery when the plaintiff can prove that 'a product was defective when it left the manufacturer and the defective product was the proximate cause of the plaintiff's injuries.'" *McNair*, 2015 WL 3935787, at *6 (citing *Meade v. Parsley*, No. 09-388, 2009 WL 3806716, at *3 (S.D.W.Va. Nov. 13, 2009) (quoting *Dunn v. Kanawha Co. Bd. of Educ.*, 194 W.Va. 40, 46, 459 S.E.2d 151, 157 (1995)). The district court found that because Janssen did not manufacture the product that Mrs. McNair ingested, there is no proximate cause and no basis on which to hold

Janssen liable. The district court further ruled that the McNairs' breach of express and implied warranty claim failed because Janssen did not sell to the McNairs the product that allegedly injured Mrs. McNair and made no warranty of any kind regarding the specific product the McNairs purchased.[6]

The McNairs appealed the district court's ruling to the Fourth Circuit Court of Appeals. The Court of Appeals certified to this Court the question set forth above.

III. Standard of Review

We have consistently held that "[a] de novo standard is applied by this Court in addressing the legal issues presented by a certified question from a federal district or appellate court." Syl. Pt. 1, *Light v. Allstate Ins. Co.*, 203 W.Va. 27, 506 S.E.2d 64 (1998). With this standard to guide us, we proceed to consider the certified question.

IV. Discussion

We have recognized that "[p]roduct liability actions may be premised on three independent theories – strict liability, negligence, and warranty. Each theory contains different elements which plaintiffs must prove in order to recover." Syl. Pt. 6, in part, *Ilosky v. Michelin Tire Corp.*, 172 W.Va. 435, 307 S.E.2d 603 (1983). This Court has succinctly defined a products liability action as one that typically

[6]The district court's ruling on the breach of express and implied warranties is not part of the certified question and, therefore, is not before this Court.

> allege[s] that a manufacturer designed and/or produced a product and put the product into the stream of commerce, and that the product was unsafe or flawed in such a way so as to give rise to the liability of the manufacturer for injuries resulting from the use of the product. The alleged unsafefulness or flaw(s) may be as a result of the actual design or construction of the product, or in the adequacy of warnings provided to the user(s) of the product.

Morris v. Crown Equip. Corp., 219 W.Va. 347, 356, 633 S.E.2d 292, 301 (2006), citing *Morningstar v. Black and Decker Manufacturing Co.*, 162 W.Va. 857, 888, 253 S.E.2d 666, 682 (1979) (recognizing that "a defective product may fall into three broad . . . categories: design defectiveness; structural defectiveness; and use defectiveness arising out of the lack of, or the inadequacy of, warnings, instructions and labels."). The McNairs premise their products liability claim on strict liability and negligence for use defectiveness arising out of an allegedly inadequate warning label.

In products liability cases premised on strict liability, the plaintiff must bring his or her claim against the manufacturer or seller of the alleged injury-causing product. The basis of strict liability is "that one engaged in the business of selling a product impliedly represents that goods which it places in the stream of commerce are free of defects, that is, they are reasonably suitable, safe and fit for the purposes for which those goods have been sold." *Hill v. Ryerson*, 165 W.Va. 22, 32-33, 268 S.E.2d 296, 304 (1980), quoting *Suter v. San Angelo Foundry Machine Co.*, 406 A.2d 140, 149 (N.J. 1979). Another

> philosophical underpinning of strict liability is to insure that the costs of injuries resulting from defective products are

> borne by the manufacturer that put such products on the market rather than by the injured persons who are powerless to protect themselves. This rationale results from the belief that manufacturers may spread the cost of compensating such injuries to society by including the cost of insurance or judgments as part of the product's price tag. This theory is often referred to as the risk of distribution principle.

Star Furniture Co. v. Pulaski Furniture Co., 171 W.Va. 79, 82, 297 S.E.2d 854, 856 (1982) (internal quotation marks and citation omitted). Critically, in *Yost v. Fuscaldo*, 185 W.Va. 493, 499, 408 S.E.2d 72, 78 (1991), this Court observed that "strict liability has only been applied to a manufacturer, seller, or distributor of the product in question." (citation omitted).[7] In other words, a plaintiff cannot recover damages in a strict liability action against the defendant, in the absence of showing that the defendant either manufactured or sold the product that allegedly injured the plaintiff. *See Ashworth v. Albers Med., Inc.*, 410 F. Supp. 2d 471, 476 (S.D.W.Va. 2005) (finding that "[t]he basic prerequisite necessary to having standing for [a strict liability claim] is the purchase by a person or consumer of a product placed into the chain of distribution by the manufacturer.").

In *Morningstar*, our modern seminal case on products liability, this Court found that "[o]nce it can be shown that the product was defective when it left the manufacturer and that the defect proximately caused the plaintiff's injury, a recovery is warranted absent some conduct on the part of the plaintiff that may bar his recovery."

[7] West Virginia Code § 55-7-31 (2017), which became effective on July 6, 2017, limits the liability of innocent sellers in products liability actions.

162 W.Va. at 883, 253 S.E.2d at 680; *see also Dunn*, 194 W.Va. at 46, 459 S.E.2d at 157 ("Product liability law in this State permits a plaintiff to recover where the plaintiff can prove a product was defective when it left the manufacturer and the defective product was the proximate cause of the plaintiff's injuries." (citation omitted)). We also explained in *Morningstar* that products liability

> applies to both the manufacturer and the seller, who are engaged in the business of selling such product which is expected to and does reach the user without substantial change in the condition in which it was sold. Most courts recognize that a seller who does not contribute to the defect may have an implied indemnity remedy against the manufacturer, when the seller is sued by the user.

Id., 162 W.Va. at 888-89 n. 22, 253 S.E.2d at 683 n. 22 (citations omitted); *see also Hill*, 165 W.Va. at 22, 268 S.E.2d at 299, syl. pt. 1 (holding that "[a] seller who does not contribute to the defect in a product may have an implied indemnity remedy against the manufacturer of the product, when the seller is sued by the user."). Moreover, in syllabus point three, in part, of *State ex rel. Johnson & Johnson v. Karl*, 220 W.Va. 463, 464, 647 S.E.2d 899, 900 (2007), this Court held that "[u]nder West Virginia products liability law, manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of *their* products as other manufacturers." (emphasis added). Our products liability law is abundantly clear: liability is premised upon the defendant being the manufacturer or seller of the product in question.

Requiring the defendant in a products liability case to be either the manufacturer or the seller of the product is the majority rule in this country.

Commentators have explained that "all of the collected cases recognize, either expressly or by implication, the rule that it is essential in a products liability action against the alleged manufacturer or seller for the plaintiff to identify the defendant as either the manufacturer or seller of the product complained of." Annotation, *Products Liability: Necessity and Sufficiency of Identification of Defendant as Manufacturer or Seller of Product Alleged to have Caused Injury*, 51 A.L.R.3d 1344, 1351 (1973) citing, in part, *Thompson-Hayward Chemical Co. v. Childress*, 169 So.2d 305 (Ala. 1964); *Nigro v. Coca-Cola Bottling, Inc.*, 305 P.2d 426 (Wash. 1957); *Undeck v. Consumer's Discount Supermarket, Inc.*, 349 A.2d 635 (Md. 1975)); *see also Jeffers v. Wal-Mart Stores, Inc.*, 171 F. Supp. 2d 617, 625 (S.D.W.Va. 2001) (indicating that "plaintiff has no evidence that [defendant] contributed to the design of the packaging in this case"); *Roney v. Gencorp.*, 431 F. Supp. 2d 622, 633 (S.D.W.Va. 2006) (noting that "[p]laintiff admits that in order to prevail on the product liability claims, he must prove which Defendants supplied the product to which his decedent was exposed."); *White v. Dow Chemical Co.*, No. 2:05-cv-00247, 2007 WL 6948824, *2-3 (S.D.W.Va. 2007) (ruling that "[i]n products liability cases, the plaintiff must establish a causal link between an injury or disease and a defect in a product which the defendant sold, and, in negligence cases, to the defendant's negligence." (footnote omitted)). Where the brand manufacturer neither manufactured nor sold the generic drug, it cannot impliedly represent that the generic drug is free of defects.

Under strict liability, "product unsafefulness arising from failure to warn 'is to be tested by what the reasonably prudent manufacturer would accomplish in regard to the safety of the product, having in mind the general state of the art of the manufacturing process, including design, labels and warnings, as it relates to the economic costs, at the time the product was made.'" *Ilosky*, 172 W.Va. at 443, 307 S.E.2d at 611 (quoting *Morningstar*, 162 W.Va. at 888, 253 S.E.2d at 682-83). This Court held in syllabus point three of *Ilosky*, 172 W.Va. at 436, 307 S.E.2d at 605, that "[f]or the duty to warn to exist, the use of the product must be foreseeable to the manufacturer or seller." Thus, while our law states that manufacturers are subject to the duty to warn about the risks of *their* products, the generic drug in this case is not a product of the brand manufacturer. Consequently, brand manufacturers cannot be held strictly liable for failure to warn of another's manufacturer's product.

Recognizing the fundamental problem in their products liability claims, the McNairs urge this Court to answer the certified question by deviating from our long-standing law that the defendant in a products liability case must be either the manufacturer or the seller of the allegedly injury-causing product. The McNairs assert that the product in this case is the warning label drafted by Janssen and not the generic drug ingested by Mrs. McNair. Janssen responds that "[w]here necessary safety information is missing from a label, that makes the *drug* defective, not *the label*." In *Morningstar*, 162 W.Va. at 888, 253 S.E.2d at 682, we explained that "a defective *product* may fall into three broad categories including use defectiveness arising out of the

lack of, or the inadequacy of, warnings, instructions and labels." *Id.* (emphasis added). Similarly, in *Cardinal v. Elsevier Inc.*, No. MICV201104442, 2014 WL 10937406, at *3 (Mass.Super. Aug. 11, 2014) the court explained that "the label . . . is not the product, but a way in which a plaintiff can claim that the product is defective." (citations omitted). We agree with this reasoning, which is consistent with our own products liability law. Here, the allegedly injury-causing product is the generic drug ingested by the consumer, not the warning label. Therefore, we find that a consumer allegedly injured by a generic drug cannot bring a strict liability failure to warn claim against the brand manufacturer who did not manufacture that drug.

We, likewise, find that a negligent misrepresentation claim against a brand manufacturer for injuries allegedly caused by a generic drug is not viable under our products liability law. "In order to establish a *prima facie* case of negligence in West Virginia, it must be shown that the defendant has been guilty of some act or omission in violation of a duty owed to the plaintiff. No action for negligence will lie without a duty broken." Syl. Pt. 1, *Parsley v. Gen. Motors Acceptance Corp.*, 167 W.Va. 866, 280 S.E.2d 703 (1981); *see also Robertson v. LeMaster,*171 W.Va. 607, 610, 301 S.E.2d 563, 566 (1983) ("[i]n order to establish . . . negligence in West Virginia, it must be shown that the defendant has . . . violat[ed] . . . a duty owed to the plaintiff" (citation omitted)). Whether a defendant owed a duty "is not a factual question for the jury," but rather, one that "must be rendered by the court as a matter of law." *Aikens v. Debow*, 208 W.Va. 486, 491, 541 S.E.2d 576, 581 (2000). Here, the McNairs assert that brand manufacturers have

a duty to consumers of generic drugs because brand manufacturers know that, under federal law, generic manufacturers must use brand manufacturers' warning labels. Therefore, say the McNairs, it is foreseeable that a defect in a warning label could cause injury to consumers of generic drugs, and, therefore, brand manufacturers have a duty to all consumers of the drug regardless of the manufacturer.

Although foreseeability of risk is an important consideration in establishing the element of duty in negligence cases, "broader policy considerations also enter the equation." *Robertson v. LeMaster*, 171 W.Va. at 612, 301 S.E.2d at 568; *see also Stevens v. MTR Gaming Group, Inc.*, 237 W.Va. 531, 535, 788 S.E.2d 59, 63 (2016) (rejecting plaintiff's "unadorned reasoning" that, as long as harm is foreseeable, there is a duty to prevent it); *Miller v. Whitworth*, 193 W.Va. 262, 267, 455 S.E.2d 821, 826 (1995) (providing that while "foreseeability of risk is an important consideration when defining the scope of duty . . . . it would be absurd to expect landlords to protect tenants against all crime since it is foreseeable anywhere in the United States."). In determining the limits of duty in cases like the present one, we find instructive the decision of the Sixth Circuit Court of Appeals in *In re Darvocet, Darvon, and Propoxyphene Products Liability*, 756 F.3d 917 (6th Cir. 2014).

In re Darvocet was a consolidated multidistrict products liability action in which residents of twenty-two states, including West Virginia, sought to recover damages for injuries allegedly sustained by the consumption of certain pharmaceutical drugs. One

issue before the Court of Appeals was whether the district court properly dismissed the negligent misrepresentation claims brought by consumers of generic drugs against brand manufacturers. After conducting a state-by-state *Erie* analysis,[8] the appeals court concluded that the highest courts in each of the twenty-two states would not recognize the plaintiffs' misrepresentation claims under their respective state laws. In addressing the issue of foreseeability, the Sixth Circuit reasoned:

> [T]he generic consumers' injuries are not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand manufacturers have no control. Congress made the public policy decisions to lower barriers of entry for generic drugs, as has the Illinois state legislature in enacting laws to require certain prescriptions be filled with available generics.[9] Using these laws as the basis of supplying the duty element for tort liability stretches foreseeability too far.

In re Darvocet, 756 F.3d at 944 (footnote added). With specific regard to West Virginia law, the Sixth Circuit observed that "West Virginia law requires that the defendants manufacture, sell, or distribute the product that injured the plaintiffs." *Id.* at 953. Further, the Court of Appeals correctly predicted that we would consider negligent misrepresentation in the instant context as a products liability claim that would fail

[8]"[F]ederal courts sitting in diversity apply state substantive law and federal procedural law." *Gasperini v. Center for Humanities, Inc.*, 518 U.S. 415, 427 (1996); *see also Erie R. Co. v. Tompkins*, 304 U.S. 64 (1938).

[9]*See* W.Va. Code § 30-5-12(b) (2016) ("A pharmacist who receives a prescription for a brand name drug or drug product shall substitute a less expensive equivalent generic name drug or drug product unless in the exercise of his or her professional judgment the pharmacist believes that the less expensive drug is not suitable for the particular patient: Provided, That no substitution may be made by the pharmacist where the prescribing practitioner indicates that, in his or her professional judgment, a specific brand name drug is medically necessary for a particular patient.").

because the brand manufacturer did not produce, sell, or distribute the generic drug. *Id.* at 954.

This Court also finds persuasive the reasoning of the Supreme Court of Iowa in *Huck v. Wyeth, Inc.*, 850 N.W.2d 353 (Iowa 2014). Rejecting the notion that brand manufacturers owe a duty to consumers of generic drugs, the Iowa court stated:

> We are unwilling to make brand manufacturers the de facto insurers for competing generic manufacturers. (Deep pocket jurisprudence is law without principle.) It may well be foreseeable that competitors will mimic a product design or label. But, we decline Huck's invitation to step onto the slippery slope of imposing a form of innovator liability on manufacturers for harm caused by a competitor's product. Where would such liability stop? If a car seat manufacturer recognized as the industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor's seat that copied the design? Why not, under Huck's theory, if it is foreseeable others will copy the design?
>
> In sum, we will not contort Iowa's tort law in order to create liability for brand manufacturers. The unfairness resulting from *Mensing* is best addressed by Congress or the FDA. . . .
>
> We will continue to apply the same long-standing causation rule . . . which required Huck to prove the defendant manufactured or supplied the product that caused her injury, and we decline to extend the duty of product manufacturers to those injured by use of a competitor's product. We will not impose liability on the brand defendants for injuries to those using only the competing generic formulation.

Huck, 850 N.W.2d at 380-81 (quotation marks and citations omitted). Accordingly, we decline to deviate from our traditional products liability law in order to extend the duty of

brand manufacturers to those allegedly injured by a competitor's product.[10] The vast majority of courts that have addressed this issue have also declined to extend liability to brand manufacturers.

Notably, all federal circuit courts that have considered the question have held, under the laws of different states, that a brand manufacturer does not owe a duty to a consumer who uses a generic drug. *See Eckhardt v. Qualitest Pharm., Inc.*, 751 F.3d 674, 681 (5th Cir. 2014) (observing that "[e]very circuit court has held (under the laws of several different states) that a brand-name manufacturer does not owe a duty to consumers who use a generic version of the drug." (citation omitted)); *Strayhorn v. Wyeth Pharm. Inc.*, 737 F.3d 378, 406 (6th Cir. 2013) (providing that "[a]lthough our decision is grounded in Tennessee law, we would note that every federal court of appeals to consider this issue has held that brand-name manufacturers are not liable to plaintiffs who are injured by a generic manufacturer's drug, whether under a state's product-liability act or under general principles of duty") (citations omitted); *Lashley v. Pfizer, Inc.*, 750 F.3d 470, 476 (5th Cir. 2014) (observing that Mississippi and Texas plaintiffs' claims against brand manufacturer were foreclosed by those states' product liability laws, and further noting that "because Appellants did not ingest the brand manufacturer's products, these [brand] defendants have no common-law duty to them"); *In re Darvocet,*

[10]In addition to absence of a duty, there is also an absence of proximate causation under the instant facts. Under traditional products liability law, where the manufacturer designed the product and the warning label, the consumer of a product can bring a claim for use defectiveness. However, in the case at bar, the brand manufacturer did not manufacture the drug that allegedly injured Mrs. McNair.

756 F.3d at 938 (noting that "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 statements regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug."(citation omitted)); *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1251 (11th Cir. 2013) (stating that "[e]very court in Florida to consider the question has concluded that the brand manufacturer of a prescription drug cannot be held liable for injuries suffered by consumers who ingested only the generic form of a drug"); *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1286 (10th Cir. 2013) (predicting, based on Oklahoma precedent and clear consensus of courts of other jurisdictions, "that the Oklahoma Supreme Court would not recognize brand-name drug manufacturer liability for injuries caused by a generic manufacturer's products."); *Demahy v. Schwarz Pharma, Inc.*, 702 F.3d 177, 183 n. 4 (5th Cir. 2012) (indicating that "even if the [Louisiana Products Liability Act] did not apply, [plaintiff's] tort claims would fail since [defendants] did not manufacturer the generic product giving rise to [plaintiff's] claims, and thus owed [plaintiff] no duty of care"); *Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1093 (8th Cir. 2013) (finding that "[e]ven if we were to ignore Arkansas' product identification requirement, [the plaintiff] has also failed to establish the brand defendants owed her a duty of care necessary to trigger liability under Arkansas law" (citation omitted)); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011) (explaining that "[a]s have the majority of courts to address this question, we reject the argument that

a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company").[11]

The McNairs argue that the foregoing federal authority is unpersuasive because it relies on the Fourth Circuit's flawed decision in *Foster v. American Home Products, Corp.*, 29 F.3d 165, 170 (4th Cir. 1994), which has since been discredited by *Mensing.* The McNairs maintain that *Foster* erroneously found that generic manufacturers can alter their labels without prior FDA approval and that this error was exposed by *Mensing.* While we agree that the Fourth Circuit erred in that regard, the core basis of Foster, rejecting the contention that a name brand manufacturer's statements regarding its drug can serve as the basis for injuries caused by another manufacturer's drug, was unaffected by *Mensing. Foster* was grounded on Maryland's law requiring a plaintiff seeking to recover for an injury by a product to demonstrate that the defendant manufactured the product at issue. *See Demahy*, 702 F.3d at 184 (explaining that "[w]e

[11]In addition, two of four state high courts to consider the issue have rejected making brand manufacturers liable in negligence for injuries allegedly caused by generic drugs. *See Huck*, 850 N.W.2d at 369 (finding brand manufacturer owed no duty to consumers of generic drug and observing that "[a]n overwhelming majority of courts adjudicating this issue have affirmed judgments or granted dispositive motions dismissing claims against the brand defendants when the plaintiff used only the generic formulation."(citations omitted)); *Rafferty v. Merck & Co., Inc.*, 92 N.E.3d 1205 (Mass. 2018) (concluding that plaintiff who took generic drug may not bring ordinary negligence claim against brand-name manufacturer for failure to warn.). A few courts have ruled to the contrary. *See T.H. v. Novartis Pharm. Corp.*, 407 P.3d 18 (Cal. 2017); *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705 (N.D. Ill. 2014); *Chatman v. Pfizer, Inc.*, 960 F. Supp. 2d 641 (S.D. Miss. 2013); *Kellogg v. Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010). A fifth case, *Wyeth, Inc. v. Weeks*, 159 So.3d 649 (Ala. 2014), cited by the the McNairs, was abrogated by statute at Alabama Code § 6-5-530(a). For the reasons provided in the body of this opinion, we do not find these cases persuasive.

do not view *Mensing* as overruling *Foster* because the court in *Foster* did not reach its holding by relying on the ability of a plaintiff to sue generic manufacturers. Instead, the court's holding was based on its interpretation of Maryland law and the conclusion that a name-brand manufacturer has no duty of care to consumers that are not using the manufacturer's product" (citation omitted)).

The McNairs also argue that most of the cases cited above are not applicable because they rely upon product identification statutes in the various states in which the actions arose. We disagree. Even though in several of the cases, state statutes were relied upon, in part, it is equally true that the courts considered products liability and general tort principles in reaching their decisions. For example, in *Smith*, the Sixth Circuit Court of Appeals reasoned that

> [a] threshold requirement of *any* products-liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury. The plaintiffs in this case concede that they had consumed only generic versions of metoclopramide and not Reglan. As the district court observed, adopting their theory of liability would require the court to attribute any deficiency in a name-brand manufacturer's labeling and marketing of its products to products manufactured by its generic competitors. Such a theory, however, fails to satisfy the threshold requirement of a products-liability action – that the *defendant's* product have injured the plaintiff. As the district court stated, "Just because a company is in the same business as a tortfeasor, the company is not automatically liable for the harm caused by the tortfeasor's product." The plaintiff's argument – that the name-brand defendants' liability stems from the fact that the regulatory structure governing the name-brand and generic drugs makes it foreseeable that patients and their physicians will rely upon the name-brand labels to use and prescribe

> generic drugs – has been rejected by all but one of the courts that have considered it.

Smith, 657 F.3d at 423-24 (citation omitted and emphasis added). Likewise, in *Schrock*, the Tenth Circuit Court of Appeals explained that

> [c]ourts that have concluded brand-name manufacturers are not liable to consumers of generic drugs relied on three principal rationales. First, they based their view on traditional common law tort principles under which a manufacturer is liable for injuries caused by its own product. Second, they reason that brand-name manufacturers' warnings and representations do not create a basis for liability to consumers of competitors' products because brand-name manufacturers only intend to communicate with their customers, not the customers of competitors. Finally, they conclude that public policy considerations weigh against holding name-brand competitors liable for injuries caused by their generic competitor's drug.

Schrock, 727 F.3d at 1285 (internal quotation marks and citations omitted). As these cases indicate, the rejection of brand manufacturer liability for injuries allegedly caused by generic drugs is based, in part, on traditional products liability and tort principles. In short, the reasoning employed by the many other courts addressing the issue supports rejecting the extension of liability to brand manufacturers.

We have also recognized limits to tort liability that are mandated by policy considerations. In this regard, we have observed,

> [t]ort law is essentially a recognition of limitations expressing finite boundaries of recovery. . . . [C]ourts and commentators have expressed disdain for limitless liability and have also cautioned against the potential injustices which might result. This Court's obligation is to draw a line beyond which the law will not extend its protection in tort, and to declare, as a

> matter of law, that no duty exists beyond that court-created line. It is not a matter of protection of a certain class of defendants; nor is it a matter of championing the causes of a certain class of plaintiffs. It is a question of public policy. Each segment of society will suffer injustice, whether situated as plaintiff or defendant, if there are no finite boundaries to liability and no confines within which the rights of plaintiffs and defendants can be determined.

Aikens v. Debow, 208 W.Va. 486, 502, 541 S.E.2d 576, 592 (2000). In our consideration of the certified question before us, this Court declines to acknowledge brand manufacturer liability for injuries allegedly caused by another manufacturer's product.

Our commitment to restricting products liability to the manufacturer or seller, regardless of the theory of liability, is consistent with the public policy of this State. "The sources determinative of public policy are, among others . . . our public statutes." *Cordle v. Gen. High Mercer Corp.*, 174 W.Va. 321, 325, 325 S.E.2d 111, 114 (1984) (quoting *Allen v. Commercial Cas. Ins. Co.*, 37 A.2d 37, 38-39 (N.J. 1944)). In 2016, the Legislature enacted West Virginia Code § 55-7-30 (2016), which provides, in part, that

> (a) A *manufacturer or seller* of a prescription drug or medical device may not be held liable in a product liability action for a claim based upon inadequate warning or instruction unless the claimant proves, among other elements, that:
>
> (1) The *manufacturer or seller* of a prescription drug or medical device acted unreasonably in failing to provide reasonable instructions or warnings regarding foreseeable risks of harm to prescribing or other health care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings; and

> (2) Failure to provide reasonable instructions or warnings was a proximate cause of harm.

Id. (emphasis added). Significantly, this statute incorporates this Court's long-standing restriction of products liability to the manufacturer and seller of the allegedly injury-causing product. The following year, the Legislature enacted West Virginia Code § 55-7-31 (2017), the purpose of which is to limit the liability of innocent sellers in products liability actions to specifically defined circumstances. These statutes, as well as our precedent, evince a clear public policy in West Virginia to limit the scope of products liability actions to manufacturers and, while now statutorily limited, to sellers. Any recognition of an outlier theory of liability permitting a generic drug consumer to bring an action against the brand manufacturer for an injury allegedly arising from the use of the generic drug would be plainly at odds with this public policy.

Moreover, this Court, as well as other courts, adopted "products liability to place responsibility for the harm caused by a product on the party who profits from its manufacture and sale." *Huck*, 850 N.W.2d at 378 (citation omitted). Because the brand manufacturer did not place the generic product on the market, it cannot spread the cost of compensating generic consumers "by including the cost of insurance or judgments as part of the product's price tag." *Star Furniture*, 171 W.Va. at 82, 297 S.E.2d at 856. Finding the brand manufacturer liable for the ingestion of a generic drug "would sever the connection between risk and reward," as Janssen argues, that forms the basis of products liability law. Indeed, the process of developing and securing FDA approval of a new drug

takes more than a decade and costs well over a billion dollars. Victor E. Schwartz, et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm Was Allegedly Caused by Generic Drugs Has Severe Side Effects*, 81 Fordham L. Rev. 1835, 1842 (2013). If brand manufacturers become liable for injuries allegedly caused by generic drugs, significant litigation costs would be added to the price of new drugs to the disadvantage of consumers. Further, the increase in litigation against brand manufacturers could stifle the development of new drugs, which would have negative health consequences for society. *Id.* at 1843.

The McNairs remind us that "[f]or every wrong there is supposed to be a remedy somewhere." *Sanders v. Meredith*, 78 W.Va. 564, 572, 89 S.E. 733, 736 (1916) (Lynch, J. dissenting). As indicated above, "[a] line must be drawn between competing policy considerations of providing a remedy for everyone who is injured and of extending exposure to tort liability almost without limits." *Aikens*, 208 W.Va. at 493, 541 S.E.2d at 583 (quoting *Harris v. R.A. Martin, Inc.*, 204 W.Va. 397, 403, 513 S.E.2d 170, 176 (Maynard, J., dissenting), abrogated by *Aikens*, 208 W.Va. 486, 541 S.E.2d 576). In this instance, the remedy for persons allegedly harmed by the use of a generic drug must rest with Congress or the FDA. Significantly, a brand manufacturer does not choose for its warning label to accompany the drugs marketed by its competitors. Instead, federal law mandates such a result. Relative to the case at bar, prescription drugs are unique because of the extensive federal regulation of that product by the FDA. Courts have characterized the Hatch-Waxman Act as a complicated statutory scheme which is intended "to balance

the two competing interests in the pharmaceutical industry: '(1) inducing pioneering research and development of new drugs and (2) enabling competitors to bring low-cost, generic copies of those drugs to market.'" *Janssen Pharm. N.V. v. Apotex, Inc.*, 540 F.3d 1353 (Fed.Cir. 2008) (quoting *Andrx Pharms., Inc. v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed.Cir. 2002)). We refuse to interfere in the delicate calculus of Congress in crafting the Hatch-Waxman Act, which is consistent with our traditional reluctance to impose liability on a party in a heavily regulated industry. *See Stevens*, 237 W.Va. 531, 788 S.E.2d 59 (finding that casino and manufacturer of video lottery terminals has no duty to protect customers from compulsive gambling because gambling industry is heavily regulated in this State).

Significantly, the United States Supreme Court recognized that the result of its decision in *Mensing* was that consumers of brand-name drugs could sue the manufacturers of those drugs for failure to warn, while consumers of generic drugs were generally precluded from bringing such actions against generic manufacturers. Nevertheless, this result did not alter the Supreme Court's analysis of the applicable law:

> It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the 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. But different federal statutes and regulations may, as here, lead to different pre-emption results. We will not distort the Supremacy Clause in order to create similar pre-emption across a dissimilar statutory scheme. As

> always, Congress and the FDA retain the authority to change the law and regulations if they so desire.

Mensing, 564 U.S. at 626. Just as the Supreme Court refused to distort the Supremacy Clause in *Mensing* to prevent the undesirable result of providing immunity to generic manufacturers in failure to warn cases, we decline to distort our products liability law to hold a brand manufacturer liable for injuries allegedly caused by a generic drug that the brand manufacturer neither manufactured nor sold. Like the Supreme Court, we find that the proper remedy for consumers harmed by generic drugs rests with Congress or the FDA.

V. CONCLUSION

Accordingly, for the reasons set forth above, this Court declines to expand our products liability law. Therefore, we now hold that there is no cause of action in West Virginia for failure to warn and negligent misrepresentation against a brand-name drug manufacturer when the drug ingested was produced by a generic drug manufacturer.

Certified Question Answered.