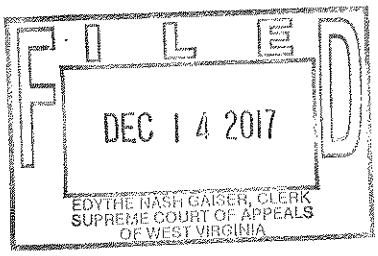
WEST VIRGINIA CHAMBER

December 14, 2017



VIA HAND DELIVERY
Edythe Nash Gaiser, Clerk
West Virginia Supreme Court of Appeals
WV State Capitol
1900 Kanawha Boulevard East
Charleston WV 25305

RE: ***Kimmy and Larry McNair, Plaintiffs - Appellants v. Johnson & Johnson, Janssen Pharmaceuticals, and Ortho-McNeil Pharmaceutical, Defendants - Appellees Docket Number 17-0519***

Dear Ms. Gaiser:

Please find enclosed for filing in the above-referenced case the following documents:

Original and ten (10) copies of the Brief of the *Amici Curiae,* the Chamber of Commerce of the United States, the West Virginia Chamber of Commerce, and the American Tort Reform Association in Support of the Defendants - Appellees.

I would note that consent to file this *Amicus* Brief has been obtained from all parties. Accordingly, we have not included a Motion for Leave to File this *Amicus* Brief.

Feel free to contact me if you have any questions or need additional information.

Thank you for your attention to this matter.

Sincerely,

John M. Canfield
Vice President and Counsel
West Virginia Chamber of Commerce

cc: w/ enclosure (sent via US Mail)

Leslie A. Brueckner, Esq.
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John Winter, Esq.

No. 17-0519

IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

KIMMY MCNAIR and LARRY MCNAIR,
Plaintiffs-Appellants,

v.

JOHNSON & JOHNSON, a foreign corporation; JANSSEN PHARMACEUTICALS, INCORPORATED, a foreign corporation; and ORTHO-MCNEIL PHARMACEUTICAL, INCORPORATED, a foreign corporation,
Defendants-Appellees,

ON CERTIFIED QUESTION FROM THE UNITED STATES COURT OF APPEAL FOR THE FOURTH CIRCUIT

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, THE WEST VIRGINIA CHAMBER OF COMMERCE, AND THE AMERICAN TORT REFORM ASSOCIATION AS AMICI CURIAE IN SUPPORT OF DEFENDANTS-APPELLEES

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December 14, 2017

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

Page

Cases—continued:

STATUTES, REGULATIONS, AND RULE

Page

Statutes, regulations, and rule—continued:

OTHER AUTHORITIES

Page

Other authorities—continued:

STATEMENT OF AMICI CURIAE[1]

The Chamber of Commerce of the United States of America ("the Chamber") is the largest organization of businesses in the world. It represents 300,000 direct members and represents the interests of more than 3 million companies and professional organizations of all sizes, in every industry, and across all regions of the country. One of the Chamber's most important responsibilities is representing its members before the courts, legislatures, and executive branches of the States and the federal government. The Chamber regularly files briefs as amicus curiae in litigation that touches on issues of vital concern to the Nation's business community.

The American Tort Reform Association ("ATRA") is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For more than a decade, ATRA has filed amicus briefs in cases involving important liability issues.

The West Virginia Chamber of Commerce ("the WV Chamber") is a nonpartisan advocacy association of employers that seeks to facilitate the continued operation and expansion of business in the State of West Virginia. The WV Chamber's member businesses come from every county in the state and employ more than half of West Virginia's workforce. Collectively, the WV Chamber's members constitute a major portion of the engine that drives West Virginia's economy. In facilitating the continued operation and expansion of existing businesses, and while also pursing new businesses to locate in West Virginia, the Chamber consistently advocates for public policies

[1] Pursuant to West Virginia Rule of Appellate Procedure 30(e)(5), amici state that no party or counsel for a party other than amici, their members, or their counsel authored this brief in whole or in part or made a monetary contribution intended to fund the preparation or submission of this brief. Counsel for all parties have consented to the filing of this brief.

that improve West Virginia's economic environment. The WV Chamber's objective is to build a business climate that promotes development that is sufficient to sustain employment in West Virginia, while simultaneously allowing certainty for employers.

The WV Chamber's interest has always been to foster a stable legal environment in which our state laws and regulations are applied in a uniform and predictable manner. The WV Chamber recognizes that a legal system that is predictable in its outcomes and functions within the mainstream of American jurisprudence is critical. Without it, businesses in West Virginia are deprived of the stable legal climate upon which other businesses operating in other states can and do rely. The absence of a predictable and stable legal climate serves to discourage the growth of existing businesses within, and the location of new businesses into, West Virginia.

The Chamber, ATRA, the WV Chamber, and their members have a strong interest in this case. This proceeding may have a widespread, serious impact on product developers in all fields that have until now relied on their understanding of long-settled principles of tort liability. The Chamber, ATRA, and the WV Chamber are uniquely positioned to explain the prevailing rule nationwide for imposing liability on a manufacturer only for harm traceable to the manufacturer's own product, and to address the significant policy consequences that might arise from expanding that rule by holding a manufacturer responsible for harms inflicted by its competitors' products.

INTRODUCTION

It is a fundamental and well-settled principle of tort law, both in West Virginia and across the Nation, that liability for harm caused by products is limited to the persons who actually made or sold the injurious products. That principle applies regardless of the theory of liability upon which a plaintiff proceeds. A manufacturer thus has no duty to warn consumers about products made and sold by a competitor, and it cannot be held liable for injuries caused by its competitor's

products when the manufacturer does not control the manufacture of the products and has made no representations about those products.

That longstanding principle of tort liability applies with equal force in the pharmaceutical industry, as courts around the country have confirmed. More than a hundred state and federal courts to have considered the question presented have concluded that pharmaceutical manufacturers, like all other manufacturers, may be held liable only for harm caused by their own products. There is no reason to carve out an exception for the pharmaceutical industry and send West Virginia down the path toward eroding basic tort doctrines and disturbing settled expectations about the scope of tort liability.

Creating an exception to ordinarily applicable tort principles in the pharmaceutical context would lead to undesirable policy outcomes. The cost of innovation would inevitably increase, and investment in developing and marketing innovative products would inevitably decrease—harming the economy and, uniquely in this field, public health. The Court should not tamper with prevailing tort principles and risk such profound problems for industrial and pharmaceutical innovation.

ARGUMENT

I. FUNDAMENTAL PRINCIPLES OF TORT LAW PRECLUDE THE IMPOSITION OF LIABILITY ON A MANUFACTURER FOR HARM CAUSED BY PRODUCTS MANUFACTURED BY ANOTHER

The American business community organizes its activities across the country in reliance on certain universally applicable rules of tort law. One of those rules is the venerable principle that a manufacturer can be held liable only for harms caused by products it actually made or sold. That principle, and others like it, provide a backstop on which manufacturers and other businesses depend. No matter the theory of liability, under any set of facts, liability does not exist unless a specific product links the allegedly culpable manufacturer to a particular injury. No such link

exists when a plaintiff is injured by a product the defendant manufacturer did not make and about which it has not made any representations. To impose liability without such a link would upend the settled expectations of businesses throughout the country and introduce serious uncertainty and instability into tort law.

A. As this Court explained in its landmark decision, *Morningstar* v. *Black & Decker Manufacturing Co.*, the "general tort product liability rule" in West Virginia for over a century has held manufacturers strictly liable when "*the thing used* or the negligent act is very dangerous to human life and injury may reasonably be expected to happen to others therefrom." 162 W. Va. 857, 879, 253 S.E.2d 666, 678 (1979) (quoting *Peters* v. *Johnson, Jackson & Co.*, 50 W. Va. 644, 651-652, 41 S.E. 190, 193 (1902)) (emphasis added); *see also Yost* v. *Fuscaldo*, 185 W. Va. 493, 499, 408 S.E.2d 72, 78 (1991) (holding that a defendant who did not "make, sell, or distribute" the injurious product cannot be subject to strict liability); *Meade* v. *Parsley*, Civ. No. 09-388, 2009 WL 3806716, at *3 (S.D. W. Va. Nov. 13, 2009) (noting that "[p]roduct liability law in West Virginia 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" (internal quotation marks omitted)).

The same is true when plaintiffs rely on negligence, as opposed to strict-liability, principles. This Court has held that "a duty to warn exists"—and, correspondingly, that a defendant can face negligence liability—only when "it [is] reasonably foreseeable to the manufacturer that *the product* would be unreasonably dangerous if distributed without a warning." *Church* v. *Wesson*, 182 W. Va. 37, 40, 385 S.E.2d 393, 396 (1989) (per curiam) (emphasis added). That duty—the duty of "[a] manufacturer" to warn of dangers arising from "all foreseeable uses of his product"—is well-established. *Ilosky* v. *Michelin Tire Corp.*, 172 W. Va. 435, 441-442, 307 S.E.2d 603, 610

(1983) (quoting *Smith* v. *United States Gypsum Co.*, 612 P.2d 251, 254 (Okla. 1980)). This Court has made clear that these universal rules of tort liability apply with equal force in the context of pharmaceutical manufacturing: "under 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." *State ex rel. Johnson & Johnson Corp.* v. *Karl*, 220 W. Va. 463, 478, 647 S.E.2d 899, 914 (2007). And that duty requires a "particular warning" if the absence of that warning would render "*the product* . . . unreasonably dangerous." *Wilkinson* v. *Duff*, 212 W. Va. 725, 730, 575 S.E.2d 335, 340 (2002) (per curiam) (emphasis added).

Faced with the consistent line of West Virginia decisions foreclosing their theory of liability, plaintiffs attempt to restate or narrow those decisions. For example, plaintiffs are correct that West Virginia imposes strict tort liability without regard to "privity of contract," meaning that a plaintiff injured by a product can sue the product's manufacturer whether he purchased the product from an intermediary or never purchased it at all. Br. 11, 16. But the fact that West Virginia, like many jurisdictions, has abolished the requirement of privity in product-liability suits says nothing about whether a defendant can be held liable regardless of whether it actually made or sold the product at issue. *See Morningstar*, 162 W. Va. at 888 & n.22, 253 S.E.2d at 683 & n.22 (holding that "strict liability in tort" applies "to both the manufacturer and the seller, who are engaged in the business of selling such product"). To the contrary, this Court had observed that "the identity of the manufacturer is *always* an issue in a products liability suit." *Hill* v. *Joseph T. Ryerson & Son, Inc.*, 165 W. Va. 22, 43, 268 S.E.2d 296, 309 (1980) (emphasis added). And this Court has explained that strict liability in tort allows plaintiffs to establish liability against "*the manufacturer*" by proving the defectiveness of "*the product*"—not some other product made by some other

actor. *Dunn* v. *Kanawha County Board of Education*, 194 W. Va. 40, 46, 459 S.E.2d 151, 157 (1995) (emphasis added).

The most plaintiffs can muster in support of their expansive view is a 1973 annotation from the American Law Reports that was among the several authorities this Court cited in *Hill* for the proposition that "the identity of the manufacturer is always an issue in a products liability suit." *Hill*, 165 W. Va. at 43, 268 S.E.2d at 309; *see* Br. 19-20. In that annotation, the West Publishing annotator summed up an overview of product-liability law with the general observation that a defendant can only be held liable on "proof that [it] produced, manufactured, sold, or was in some way responsible for the product" at issue. 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, 1349 (1973). But this Court did not even cite that particular passage, let alone endorse it. And there is no doubt about what it means to be "responsible for the product" in West Virginia: this Court has held that liability "is based solely upon [a defendant's] relationship to *the product*." *Dunn*, 194 W. Va. at 46, 459 S.E.2d at 157 (emphasis added). Based on that relationship, only the "product manufacturer" and "those in the product's chain of distribution" have an adequate relationship to the injurious product and can be held liable. *Id.* Those entities—the manufacturer and those who distribute and sell it—are the parties "responsible for the product" and therefore subject to liability. West Virginia law, like the law of other States, is unambiguous: liability follows the product that links the defendant to the plaintiff's injury and goes no further.

Nor can plaintiffs identify any basis in West Virginia law for their negligence claims. Whether a plaintiff frames his claim in terms of fraud, strict liability, or something in between, tort law does not permit liability unless the plaintiff can identify an instrumentality linking the defendant's acts or representations to the plaintiff's harm. No defendant can face negligence liability

without violating a duty it owes "to the plaintiff." *Robertson* v. *LeMaster*, 171 W. Va. 607, 610, 201 S.E.2d 563, 566 (1983). And a defendant has no duty to warn about the risks of products it did not make or sell. To the contrary, in West Virginia as elsewhere, a manufacturer has a duty to warn only as to the uses "a reasonably prudent person might make of the product" the manufacturer produced. *Ilosky*, 172 W. Va. at 442, 307 S.E.2d at 610.

Plaintiffs provide only one citation to West Virginia cases in support of their novel theory. Br. 23 (citing *Bragg* v. *United States*, 230 W. Va. 532, 539, 741 S.E.2d 90, 97 (2013), and cases cited therein). But those cases do not support plaintiffs' theory. In each case, this Court recognized liability when a common instrumentality linked the defendant's act or representation to the injury of which the plaintiff complained. In *Bragg* itself, a mine inspector's negligent inspection caused a miner's death. *Id.* at 542, 100. When the inspector's faulty representation that the mine was safe led the plaintiff into the danger that killed him, it is no surprise that the inspector faced liability for his misrepresentation. And the cases this Court relied on in *Bragg* are to the same effect. In *Sewell* v. *Gregory*, 179 W. Va. 585, 371 S.E.2d 82 (1988), this Court allowed homeowners who purchased a home from other, intervening owners to sue the builder for its negligent construction. *See id.* at 588, 371 S.E.2d at 85. In *Louk* v. *Isuzu Motors, Inc.*, 198 W. Va. 250, 479 S.E.2d 911 (1996), this Court found that an independent construction contractor who built an access road to a public highway for a retail store had a duty of care to those who used the access road. *See id.* at 260, 479 S.E.2d at 921. In *Kizer* v. *Harper*, 211 W. Va. 47, 561 S.E.2d 368 (2001) (per curiam), this Court upheld a verdict against property owners for negligently hiring an unlicensed electrician whose negligent wiring caused the plaintiff to fall and injure himself. *See id.* at 50, 561 S.E.2d at 371. And in *Eastern Steel Constructors, Inc.* v. *City of Salem*, 209 W. Va. 392, 549 S.E.2d 266 (2001), this Court permitted a contractor to sue a design engineer whose negligently prepared plans caused

construction delays. *See id.* at 401, 549 S.E.2d at 275. In each of those cases, this Court identified the instrumentality—the house; the access road; the electrical wiring; the plans—that linked the defendant to the plaintiff, even when the parties did not conduct a direct transaction. But here, that instrumentality is absent. And West Virginia does not recognize liability when the plaintiff and the defendant have nothing in common.

B. The law of West Virginia is no outlier in this regard. To the contrary, the vast majority of States agree that a manufacturer is responsible to warn only those who use its own products, not those who use products made and sold by its competitors. As the Tenth Circuit put it, "general tort principles" do not "impose liability with respect to a defendant that did not sell, distribute, manufacture, or otherwise have contact with the allegedly harmful product." *Schrock* v. *Wyeth, Inc.*, 727 F.3d 1273, 1284 (2013). Absent the link of a common instrumentality connecting the defendant to the plaintiff, defendants would pay for harms they did not cause, severing the essential connection that justifies imposing liability in the first place.

The rule that a manufacturer is responsible to warn only those who use its own products is also codified in Section 388 of the Second Restatement of Torts and its comments, on which this Court has relied to delineate the scope of the duty to warn. *See Ilosky*, 172 W. Va. at 442, 307 S.E.2d at 610 (citing Restatement (Second) of Torts § 388 (1977)). Section 388 provides that "those who supply chattels have a duty to warn those whom the supplier expects to use the chattel . . . or to be endangered by its probable use." Restatement (Second) of Torts § 388. And comment (e) to that section adds that liability "exists only if physical harm is caused by the use of the chattel by those for whose use the chattel is supplied." *Id.* cmt. e.

Plaintiffs insist otherwise, arguing that this case is different because their alleged harm arose not from Janssen's product but from its representations *about* the product. Br. 25. But they

ignore the principle that, in West Virginia as in other States, a manufacturer has a duty to warn only as to the uses "a reasonably prudent person might make of *the product*" the manufacturer produced. *Ilosky*, 172 W. Va. at 441, 307 S.E.2d at 609. Here, Janssen never made any representations to plaintiffs and had no duty to do so because plaintiffs did not use any product Janssen made. The warnings Janssen did issue were directed only at the users of its own product. In any case, plaintiffs elsewhere acknowledge that they are seeking to hold Janssen liable for "injuries caused by generic versions of its drugs," not injuries caused by its own representations to its own customers about its own products. Br. 28. And plaintiffs fail to identify even a single West Virginia case, applying any theory of liability, that holds a defendant responsible for harm caused by a product it did not make or sell and about which it made no representations.

Plaintiffs point to outlying decisions from other States that have created a new duty for manufacturers to warn consumers who were injured by the products of the manufacturers' competitors. But those cases merely illustrate that, in States that have adopted tort principles different from those in West Virginia, courts have followed those divergent principles to reach conclusions that West Virginia law forbids. For example, in *Conte* v. *Wyeth, Inc.*, 168 Cal. App. 4th 89 (Cal. Ct. App. 2008), a California intermediate court observed that, under California law, "misrepresentations that implicate a risk of physical harm to others" are governed by the rules set forth in Section 311 of the Second Restatement of Torts, governing negligent representation that creates the risk of physical harm. *Id.* at 103-104.[2] This Court has never cited Section 311 or adopted the tort Section 311 codifies. Plaintiffs therefore cannot rely on the duty *Conte* recognized. And while this

[2] The question presented in this case is currently before the Supreme Court of California. *See T.H.* v. *Novartis Pharmaceutical Co.*, No. 5233989, 371 P.3d 241 (Cal. 2016) (argued October 2, 2017).

Court has acknowledged that a cause of action for negligent misrepresentation exists in West Virginia, that tort arises only where a defendant "under a duty to give information to another . . . makes an erroneous statement . . . and thereby misleads the other to his injury." *Folio* v. *City of Clarksburg*, 221 W. Va. 397, 405, 655 S.E.2d 143, 151 (2007) (per curiam) (quoting *James* v. *Piggott*, 70 W. Va. 435, 74 S.E. 667 (1910)). Here, Janssen owed no duty to plaintiffs and made no statement to them.

Similarly, in *Kellogg* v. *Wyeth*, 762 F. Supp. 2d 694 (D. Vt. 2010), a federal district court in Vermont, relying on *Conte*, concluded that "the common law as it has developed in Vermont" extended a brand-name drug manufacturer's duty to warn to cover those injured by its competitor's products. *Id.* at 708. Even if that court got Vermont law right, however, the "common law as it has developed in" West Virginia requires a different conclusion here.

Where, as here, the plaintiff was injured by a product made by a competitor, no common instrumentality links the manufacturer's acts and statements with the plaintiff's injury. It would "stretch . . . foreseeability" far beyond that concept's capacity to create a new duty of brand-name drug manufacturers to warn consumers of harms even when the harm giving rise to liability was actually caused by a competing version of the manufacturer's product. *Foster* v. *American Home Products Corp.*, 29 F.3d 165, 171 (4th Cir. 1994).

In sum, it is immaterial whether a plaintiff, injured by a product, asserts a claim arising in fraud, negligence, or strict liability. If the defendant manufacturer did not produce that product or make representations about it, then the manufacturer cannot be liable. Nor does the outcome change if the plaintiff argues that he was harmed by the defendant's statements about its own product (a product the plaintiff never used), as opposed to statements about the product that actually inflicted the plaintiff's injury. Under fundamental rules governing tort disputes—rules that

West Virginia law incorporates and applies—only the producer or seller of a product, or one who makes representations about that product, should be held responsible for harm the product inflicts.

II. THERE IS NO VALID JUSTIFICATION TO CREATE AN EXCEPTION TO FUNDAMENTAL PRINCIPLES OF TORT LAW IN THE CONTEXT OF THE PHARMACEUTICAL INDUSTRY

The foregoing basic principles of tort law apply across all industries, and there is no reason to carve out an exception to those principles solely for pharmaceutical manufacturers. Courts across the Nation have overwhelmingly held that pharmaceutical manufacturers are not liable for injuries caused by their competitors' products. In the absence of an instrumentality linking a defendant's product or statements to the plaintiff's injuries, those courts—including every federal court of appeals to consider the question and state courts in more than a dozen jurisdictions—have concluded that the defendant cannot have caused the plaintiff's injuries or have a duty to warn against them.

Contrary to plaintiffs' contention (Br. 12, 20), there is nothing "unique" about this case or any of the other cases presenting the same question that have been decided over the last two decades. Instead, this case requires nothing more than application of the well-established principles that govern every tort case. Under those principles, the answer is clear: a manufacturer may be called to account only for the harms its own products inflict, regardless of the theory of liability on which a plaintiff's claim is based.

A. By way of background, a pharmaceutical manufacturer seeking regulatory approval from the Food and Drug Administration (FDA) for a new drug must submit a new drug application (NDA), showing that the drug is safe for use and effective for its indications and that the proposed label accurately and sufficiently describes the risks of its use. *See* 21 U.S.C. § 355(b)(1), (d). Once granted, an NDA brings with it certain responsibilities, including the obligation to submit annual

reports demonstrating the safety, effectiveness, and appropriate labeling of approved drugs. *See* 21 C.F.R. §§ 314.80, 314.81. Pharmaceutical manufacturers that hold NDAs may also submit supplemental applications to change the label and accompanying warnings of a drug; they are required to do so if they learn of a risk not already adequately identified. *See* 21 C.F.R. §§ 314.70, 314.71.

A pharmaceutical manufacturer may sell an NDA to another company, transferring ownership of the right to make the drug as well as the attendant regulatory obligations. *See* 21 C.F.R. § 314.72. Thereafter, the new NDA holder has exclusive authority to revise the label and submit supplemental applications regarding label changes, and it has the exclusive responsibility to monitor the market and submit annual reports and supplemental applications to FDA. *See* 21 C.F.R. §§ 314.70, 314.71.

Congress has also created a streamlined process for approval of generic versions of brand-name drugs once the patent exclusivity accorded to new pharmaceutical products expires. *See* Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (Hatch-Waxman Act) (codified as amended at 21 U.S.C. § 355(j)). A generic pharmaceutical manufacturer can submit an abbreviated new drug application (ANDA), which requires only that the manufacturer show that its product is "bioequivalent" to the brand-name drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv). That process allows the generic manufacturer to rely on the safety and effectiveness studies conducted by the original brand-name manufacturer at its own expense. *See id.* After ANDA approval, a generic manufacturer is required to maintain a label and accompanying warnings for its product that are "the same" as those used for the brand-name drug with which the generic version competes. *PLIVA, Inc.* v. *Mensing*, 564 U.S. 604, 613 (2011) (citing 21 U.S.C. § 355(j)(2)(A)(v), 355(j)(4)(G), and 21 C.F.R. §§ 314.94(a)(8), 314.127(a)(7)).

While generic pharmaceutical manufacturers are not authorized independently to update the labels for their products, *Mensing*, 564 U.S. at 613, they otherwise have similar responsibilities to those of NDA holders: they are required to monitor the market and to submit annual reports and supplemental applications (when appropriate) to FDA. *See* 21 C.F.R. §§ 314.70, 314.71, 314.80, 314.81, 314.97, 314.98; 57 Fed. Reg. 17,950, 17,961 (Apr. 28, 1992).

B. Since 1996, at least 134 federal and state decisions have concluded that pharmaceutical manufacturers cannot be held liable for products made and sold by others. Those decisions rely on three basic lines of reasoning. *First*, general principles of tort law impose liability on manufacturers only for injuries caused by their own products and do not impose a duty on manufacturers to warn consumers about the risks associated with other manufacturers' products. *Second*, the labels and warnings issued by brand-name manufacturers are representations only about the safety of their own products, not about the safety of their competitors' products. *Third*, policy considerations—and in particular the need to promote innovation—strongly counsel against creating a special rule for pharmaceutical manufacturers for injuries resulting from their competitors' products.

The first federal court of appeals to confront this question was the Fourth Circuit, in a 1994 case that considered whether a plaintiff injured by the generic version of a drug could recover from the manufacturer of the drug's brand-name analogue. *See Foster*, 29 F.3d at 168-169. The Fourth Circuit held that the brand-name manufacturer could not be held liable. *See id.* at 169. The court reasoned that each manufacturer was responsible for preventing the consumers of its own products from being injured, and correspondingly liable only for its own products' harms; it "stretch[ed] the concept of foreseeability too far" to impose a duty on brand-name manufacturers to warn those

who never used their products of the risk of harm posed by products their competitors made and sold. *See id.* at 169-171.[3]

Since *Foster*, six other federal courts of appeals have likewise held that brand-name pharmaceutical manufacturers cannot face liability for injuries caused by their competitors' products. For example, the Eighth Circuit held, in an opinion reinstated after reversal on other grounds by the Supreme Court, that a plaintiff could not adequately show that the brand-name manufacturers "owed her a duty of care necessary to trigger liability" under Minnesota law, in part because their statements about their products were representations made to "*their* customers, not the customers of their competitors." *Mensing* v. *Wyeth, Inc.*, 588 F.3d 603, 613 n.9, 614 (2009), *rev'd*, 564 U.S. 604 (2011), *opinion reinstated in relevant part*, 658 F.3d 867 (8th Cir. 2011).

The Sixth Circuit followed suit, applying Kentucky law to "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." *Smith* v. *Wyeth, Inc.*, 657 F.3d 420, 424 (2011). Several years later, the Sixth Circuit revisited the issue in a multidistrict litigation, examining the law of some 22 States and concluding in each case either that a manufacturer owed no duty to a plaintiff injured by a drug produced by its competitor, or that the plaintiff's suit was otherwise barred under

[3] It is not correct, as plaintiffs argue repeatedly, that *Foster* is "no longer good law" after the Supreme Court's decision in *Mensing*. Br. 14. *Foster* remains good law because it rested on the conclusion that Maryland law did not impose liability when the plaintiff "was injured by a product that [the defendant] did not manufacture." 29 F.3d 165, 171. Many courts since *Mensing* have followed *Foster*'s conclusion that acknowledging the duty plaintiffs ask this Court to invent would "stretch the concept of foreseeability too far." *Id.* at 171; *see, e.g.*, *Demahy* v. *Schwartz Pharma, Inc.*, 702 F.3d 177, 184 (5th Cir. 2012) (per curiam); J.A. 5 (citing other cases). The Fourth Circuit's recognition in its certification order that this Court had not yet addressed this issue does not abrogate *Foster*'s holding or undermine its logic, and nothing in the Fourth Circuit's order says otherwise. *See* J.A. 5.

state-specific product-liability statutes or rules. *See In re Darvocet, Darvon & Propoxyphene Products Liability Litigation*, 756 F.3d 917, 937-939, 941-954 (2014).

The Fifth, Ninth, Tenth, and Eleventh Circuits have also held that a plaintiff has a claim only against the manufacturer of the pharmaceutical product that caused the injury, no matter the theory of liability. *See Lashley* v. *Pfizer, Inc.*, 750 F.3d 470, 476 (5th Cir. 2014) (per curiam) (concluding that, "because [a]ppellants did not ingest the brand manufacturers' products, these defendants have no common-law duty to them"); *Moretti* v. *Wyeth, Inc.*, 579 Fed. Appx. 563, 565 (9th Cir. 2014) (holding that "Nevada law [does not] recognize[] a claim against the [b]rand [d]efendants for misrepresentation"), *cert. denied*, 135 S. Ct. 1398 (2015); *Guarino* v. *Wyeth, LLC*, 719 F.3d 1245, 1253 (11th Cir. 2013) (concluding that "Florida law does not recognize a [misrepresentation] claim against the brand manufacturer of a prescription drug when the plaintiff is known to have consumed only the generic form"); *Schrock*, 727 F.3d at 1283-1286 (noting that "[n]o authority is cited to suggest that a manufacturer may be held liable under Oklahoma law for concealing a defect in a product that is never purchased or used by the plaintiff").

In all of these cases, the courts, while applying the law of different States, reached the same conclusion. Although there are certain variations in tort law from State to State, the law of each State grows out of and incorporates certain common principles. One of those principles is that a defendant can be held liable only for harm fairly traceable to its own acts or omissions. In the product-liability context, an individual manufacturer can thus be called to account only for harms caused by its own products. Courts have consistently concluded that manufacturers cannot be held

responsible for failing to warn against or prevent harm caused by products they did not make, from which they did not profit, and about which they made no statements at all.[4]

As in other similar cases, plaintiffs argue that, in the wake of *Mensing* and *Wyeth* v. *Levine*, 555 U.S. 555 (2009), the law anomalously treats brand-name and generic pharmaceutical manufacturers differently: under *Levine*, consumers injured by brand-name pharmaceutical drugs may sue brand-name manufacturers for their harms, while under *Mensing*, generic manufacturers are not liable for injuries their products inflict. Br. 26-29. But the mere fact of this inconsistency in *federal* preemption law does not justify reshaping the accepted principles of *state* tort liability and discarding principles that guide the decisionmaking of manufacturers in all industries. "As always, Congress and FDA retain the authority to change the law and regulations if they so desire," and resolving inconsistencies such as this one is the proper province of those federal actors. *Mensing*, 564 U.S. at 626.[5] That is particularly true in a case like this, where the choice of liability rule implicates "health care policy for the [entire] country." 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, 1875 (2013) (Schwartz).

It would create more problems than it would solve if longstanding principles of tort law were modified to address potentially temporary anomalies in federal preemption law. That is es-

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[4] Only *Wyeth* v. *Weeks*, 159 So. 3d 649, 670, 672 (Ala. 2014), threatened to reshape the settled understanding on the question presented here. But *Weeks* was promptly repudiated by the Alabama legislature, which enacted a statutory prohibition on holding a defendant liable for harms caused by any product it had not "designed, manufactured, sold, or leased." Ala. Code § 6-5-530(a) (2017).

[5] FDA has already twice issued proposed rules for public comment that could restore generic pharmaceutical manufacturer liability for harms caused by their own products. *See* 80 Fed. Reg. 8577-01 (Feb. 18, 2015); 78 Fed. Reg. 67985-02 (Nov. 13, 2013).

pecially true because the question of whether to expand tort liability to those that did not manufacture the injury-causing product "involves policy choices . . . more appropriately within the legislative domain." *Huck* v. *Wyeth, Inc.*, 850 N.W.2d 353, 376 (Iowa 2014) (internal quotation marks omitted), *cert. denied*, 135 S. Ct. 1699 (2015). And any exception this Court might carve into fundamental tort principles, even if intended to apply only to the pharmaceutical industry, would introduce uncertainty across all industries in the calculation of what tort liability an innovator should expect to face. The Court should not accept the invitation to create a far-reaching solution to a potentially temporary problem when that solution risks significant costs to the public and the economy by discouraging innovation.

III. CREATING AN EXCEPTION TO FUNDAMENTAL PRINCIPLES OF TORT LAW IN THE CONTEXT OF THE PHARMACEUTICAL INDUSTRY WOULD HAVE SERIOUS ADVERSE POLICY CONSEQUENCES

Courts across the Nation have recognized that public-policy considerations strongly support the conclusion that fundamental principles of tort law forbid imposing liability on a manufacturer for harm caused by its competitors' products. Shifting liability onto innovative manufacturers in any industry comes at too high a cost and risks too much. As this Court has explained:

> [a] line must be drawn between the competing policy considerations of providing a remedy to everyone who is injured and of extending exposure to tort liability almost without limit. It is always tempting to impose new duties and, concomitantly, liabilities, regardless of the economic and social burden. Thus, the courts have generally recognized that public policy and social considerations, as well as foreseeability, are important factors in determining whether a duty will be held to exist in a particular situation.

Mallet v. *Pickens*, 206 W. Va. 145, 156 n.15, 522 S.E.2d 436, 447 n.15 (1999) (quoting *Harris* v. *R.A. Martin, Inc.*, 204 W. Va. 397, 403, 513 S.E.2d 170, 176 (1998) (Maynard, J., dissenting)).

The original developer of a product incurs significant costs. And no matter how costly its development, a new product may never even be sold, much less prove successful, if regulatory or

marketplace obstacles prove insuperable. Even if the developer manages to steer a product to the marketplace and market it successfully, it has no guarantee that its profits will ever cover its investment. And of course, the developer must also consider, and price in, the potential cost of liability to consumers for the product. The challenges a developer faces are all the more significant given the competition of alternatives, which can crowd the original developer out of the market entirely—even more so when competitors can entirely forgo the cost of development, regulatory approval, and marketing.

As many courts have recognized, those challenges are uniquely acute for pharmaceutical manufacturers. Developing and obtaining approval for groundbreaking pharmaceutical products can require enormous investment over decades. And federal law and regulations are especially solicitous toward competing generic versions which, after the brand-name manufacturer's period of exclusivity expires, almost invariably capture most of the product's market. But similar problems "may arise with other types of consumer goods, ranging from nonprescription drugs and foods to household chemicals and appliances; in other words, crossover tort litigation could occur in any market served by brand-name companies that actively promote their wares but face competition from largely identical but lower-priced store brands" or other competing alternatives. Lars Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product*, 45 Tort Trial & Ins. Prac. L.J. 673, 694 (Spring-Summer 2010).

Whatever the challenges of developing new products, developers have always been able to rely on the settled understanding that their exposure to risk is limited to the products they manufacture or sell themselves. That settled understanding allows manufacturers to anticipate their potential liability based on their sales; to set the price of their products at a level adequate to cover those projected costs; and to negotiate with insurers to cover that projected liability. Developers

depend on that understanding when they make decisions about how to develop new products. And relying on that understanding, American industry has achieved dazzling success in innovation in all fields, with appropriate opportunity for those injured by innovative products to recover from those that produced them. *See Huck*, 850 N.W.2d at 379-380. At the same time, by placing liability solely on the actual manufacturer of a product, this rule sharpens manufacturers' incentives to ensure that their products are safe and bear adequate warnings, and underscores for consumers that a product's manufacturer is the authoritative source of warning information for that product.

Shifting the cost of harm to consumers onto manufacturers whose products the consumers did not even use risks permanently disrupting developers' ability to plan for the future and to project the size of their risk. Developers of new products would face liability arising from product sales made not by them but by their competitors, which took advantage of the innovators' initial investment in research, regulatory approval, and marketing. Such a shift would effectively force innovators in all industries to serve as insurers for the tort liability arising from all sales of their own and their competitors' products, increasing their cost but not the cost of competing alternatives—a particularly unjust result where the competitors were able to bring their products to market without paying for development, regulatory approval, or marketing. *See, e.g.*, Sarah C. Duncan, Note, *Allocating Liability for Deficient Warnings on Generic Drugs: A Prescription for Change*, 13 Vand. J. Ent. & Tech. L. 185, 215 (2010); Schwartz 1861.

What is more, the assignment of tort liability to manufacturers for products they do not make would expose product developers to risk based on sales activity and regulatory compliance they could neither control nor monitor, introducing lasting, unavoidable uncertainty into the calculus of product development. A manufacturer inevitably must, and should, consider tort liability to consumers of its products. But the new rule plaintiffs ask this Court to adopt would not merely

multiply the size of tort liability; it would also render it unpredictable. The loss of predictability in projecting risk is even costlier than the dollar value of tort judgments in favor of the class of consumers injured by competitors' products. *See* Schwartz 1870. And manufacturers would also face significant planning and compliance costs from the need to balance this new rule, applicable in West Virginia, with the long-settled rule that would still apply throughout the rest of the Nation.

As this Court has observed, the "economic and social burden" of increased tort liability is a critical factor to consider in weighing individual claims for creating new duties of care. *Mallet*, 206 W. Va. at 156 n.15, 522 S.E.2d at 447 n.15. There can be no doubt that imposing the liability plaintiffs argue for here would seriously affect the development and marketing of innovative products of all kinds, pharmaceutical and otherwise. *First*, the cost of innovative products would necessarily rise to fund the increased scope of liability that would follow once competing versions entered the market. That would have particularly grave consequences in the context of the pharmaceutical industry, where higher prices could have an effect on public health. *See, e.g., In re Darvocet*, 756 F.3d at 944, 945, 947, 948-949; Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 Tenn. L. Rev. 1357, 1360 & nn.17-18 (1994) (T. Schwartz).

Second, confronted with ballooning and unpredictable liability costs, manufacturers would necessarily devote fewer resources to innovation and release fewer innovative new products. *See, e.g., Darvocet*, 756 F.3d at 944, 945, 947, 948-949; T. Schwartz 1360 & nn.17-18. Manufacturers would have less incentive to launch new products because their profits from those products would be decreased (or wiped out altogether) by the murky and expanded scope of their tort exposure.

Innovative developers would now have to guess not merely at the size of their own liability, but also at the cost of insuring the sales of the product for an unknown period into the future. Any company contemplating investing in innovative research and development would have to weigh

the benefits of new products against enormous risks it could neither calculate nor control. This unpredictability would also affect the ability of manufacturers to arrive at meaningful valuations of their product lines and businesses as a whole, hampering their access to credit and their ability to sell, and license, their own products and product lines.

The results of a more expansive liability regime are highly unpredictable. Perhaps only blockbuster products, promising large and lasting profits, would prove worth the candle. Or perhaps manufacturers would eliminate development lines and product categories altogether, producing a smaller number of products in order to control their potential liability. No matter the specific strategy adopted by individual manufacturers, the aggregate consequence is clear and unavoidable: consumers would see fewer new products brought to market. *See* Schwartz 1871.

For most types of products, that decline might simply represent overall losses to the economy. For the pharmaceutical industry, however, the prospect is much more serious: the "economic and social burden" of this expansion of liability would include harm to public health as a whole. *Mallet*, 206 W. Va. at 156 n.15, 522 S.E.2d at 447 n.15; *see* H. William Smith III, Note, *Vaccinating AIDS Vaccine Manufacturers Against Product Liability*, 42 Case W. Res. L. Rev. 207, 218 & n.80 (1992) (discussing the efforts of courts in other States to shape the liability of pharmaceutical manufacturers to avoid the risk of "deter[ring] the marketing of new products for fear of large adverse monetary judgments").

The foregoing policy considerations have long informed the fundamental rule that tort liability can attach only where a common instrumentality links the injured person to the alleged wrongdoer. A more expansive liability regime would disturb the existing equilibrium between the undoubted obligation to redress injuries and the need to allocate liability in a way that maximizes

innovation and overall well-being. This Court should not disregard those policy considerations by creating an exception to well-settled tort principles for pharmaceutical manufacturers.

Nor is there any valid reason to believe that such an exception could remain cabined to the pharmaceutical industry. As another state court of last resort has noted, creating such an exception would leave courts on a "slippery slope." *Huck*, 850 N.W.2d at 380. "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?" *Id.*; *see also* Schwartz 1869-1870 (noting that "there is no principle limiting competitor liability to prescription drugs"). At a minimum, a new rule of tort liability for the pharmaceutical industry would destabilize the assumptions made by manufacturers in other industries about how far tort liability can run, and prudent manufacturers in all industries would have to consider the possibility that such a rule would be applied to their products as well.

The dramatic change to tort law plaintiffs seek in this case threatens serious and unmistakable consequences. This Court should not adopt a rule that would disrupt the process of developing new products in any industry, much less the development of life-saving pharmaceuticals.

CONCLUSION

This Court should answer the certified question in the negative.

S/ John M. Canfield

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December 14, 2017

DECLARATION OF SERVICE BY MAIL

I, John M. Canfield, counsel for amicus curiae, declare that I am over the age of eighteen years and not a party to or interested party in this action.

I further declare that, on December 14, 2017, I caused copies of the attached Brief of Amicus Curiae to be filed with the Clerk of the Court by hand-delivering one original and ten true copies.

I further declare that I caused copies of the attached Brief of Amicus Curiae to be served by placing one true copy thereof in a sealed envelope with postage fully paid, for shipment via first-class U.S. mail to the following:

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I further certify that all parties required to be served have been served.

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

s/ John M. Canfield
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DECEMBER 14, 2017