IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

No. 17-0519

KIMMY MCNAIR and LARRY MCNAIR,

Plaintiffs/Appellants,

v.

JOHNSON & JOHNSON, a foreign corporation; JANSSEN PHARMACEUTICALS, INC., a foreign corporation; ORTHO-MCNEIL PHARMACEUTICAL, INC., a foreign corporation,

Defendants/Appellees.

On Certified Question from the
United States Court of Appeals
For the Fourth Circuit, No. 15-1806

BRIEF OF *AMICUS CURIAE* WASHINGTON LEGAL FOUNDATION IN SUPPORT OF DEFENDANTS/APPELLEES

Cory L. Andrews
Richard A. Samp
WASHINGTON LEGAL FOUNDATION
2009 Massachusetts Avenue, NW
Washington, DC 20036
(202) 588-0302

Forrest H. Roles (WV Bar# 3162)
Mark A. Carter (WV Bar# 4316)
DINSMORE & SHOHL LLP
707 Virginia Street, East
Suite 1300
Charleston, WV 25301
(304) 357-0921
(304) 357-0919 (FAX)

Counsel for Amicus Curiae Washington Legal Foundation

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INTEREST OF *AMICUS CURIAE*[*]

Washington Legal Foundation (WLF) is a nonprofit, public-interest law firm and policy center with supporters in all 50 states, including West Virginia. WLF devotes a substantial portion of its resources to promoting free enterprise, individual rights, limited government, and the rule of law. To that end, WLF has appeared as *amicus curiae* before this and other state and federal courts in cases addressing the proper scope of liability for prescription drug manufacturers. *See, e.g., Sidney Hillman Health Ctr. of Rochester v. Abbott Laboratories*, 873 F.3d 574 (7th Cir. 2017); *In re: Zoloft Products Liab. Litig.*, 858 F.3d 787 (3d Cir. 2017); *In re Cipro Cases I & II*, 61 Cal. 4th 116 (2015).

In addition, WLF's Legal Studies Division, the publishing arm of WLF, regularly publishes articles concerning pharmaceutical liability, including the novel theory of "innovator liability" at issue in this case. *See, e.g.*, John J. Park, Jr., *Law Rejecting "Innovator Liability" Theory Restores Civil Justice Sanity to Alabama*, WLF LEGAL OPINION LETTER (June 19, 2015); Victor E. Schwartz & Phil Goldberg, *Iowa High Court Exposes Pharma "Innovator Liability" for What it Is: Deep-Pocket Jurisprudence*, WLF LEGAL OPINION LETTER (Sept. 12, 2014).

WLF believes that individual freedom and the American economy both suffer when state law, including state tort law, imposes upon industry a new basis for massive liability that frustrates the objective or operation of specific regulatory regimes, such as (in this case) the

[*]Pursuant to W.V. R. App. P. 30(e)(5), WLF states that no counsel for any party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation or submission of this brief. Pursuant to W.V. R. App. P. 30(b), at least five days prior to the due date, counsel for WLF notified counsel of record for all parties of WLF's intention to file its *amicus curiae* brief. All parties have consented to the filing of this brief.

Food, Drug, and Cosmetic Act (FDCA) administered by the Food and Drug Administration (FDA). The FDCA establishes a comprehensive scheme of safety and disclosure requirements as part of the approval process for all prescription drugs. WLF fears that permitting Plaintiffs to manipulate state-law tort duties as a means of second-guessing those federal regulatory requirements would undermine the very goals of public health and safety that Plaintiffs claim they want to further.

INTRODUCTION

Does West Virginia permit claims for failure to warn and negligent misrepresentation against a branded drug manufacturer when the drug ingested was manufactured and sold by its generic competitor? That certified question arises from a suit alleging that Mrs. McNair's acute respiratory distress syndrome was caused by ingesting levofloxacin, an antibiotic drug marketed by Janssen under the trade name Levaquin®. But discovery of the McNairs' pharmacy records revealed that Mrs. McNair *never* took Levaquin®; rather, she took a generic version of levofloxacin previously prescribed to her husband and manufactured by a multinational pharmaceutical company, Dr. Reddy's Laboratories, based in Hyderabad, India. Nonetheless, urging this Court to retroactively impose liability on Defendants for injuries allegedly caused by a drug they neither sold nor manufactured, Plaintiffs seek to put West Virginia squarely at odds with every other jurisdiction in the country.

The gravamen of Plaintiffs' theory is that "it is not just foreseeable to a brand-name manufacturer that misstatements on its labels will mislead consumers of generic drugs—it is a virtual certainty." Appellants' Br. at 22. But West Virginia does not impose a legal duty based on mere foreseeability, and Plaintiffs' unbounded theory of liability would stretch West Virginia tort law well beyond its basic moorings. Under West Virginia law, as everywhere else, a

manufacturer owes no duty of care to customers of its competitors. That is because this Court recognizes a duty of manufacturers to warn consumers of the dangerous propensities only of ***their*** products. Companies are not their competitors' keepers, nor are they insurers against harm from products they never manufactured or sold.

By conflating the existence of a legal duty with the "foreseeability" of injury, Plaintiffs' novel theory of liability also marks a sharp and unwarranted break from longstanding principles of tort law. Under those long settled precepts, foreseeability determines the *scope* of a duty; it does not determine whether a duty *exists*. The latter question is a quintessential question of public policy. If no duty exists in the first place, the need never arises to determine the scope of duty by considering whether the injury was foreseeable. Simply put, foreseeability cannot create a duty where none existed before. For these reasons, among others, Plaintiffs' "foreseeability-ergo-duty" approach to negligence has been rejected by virtually every other state and federal jurisdiction—including the U.S. Supreme Court.

In any event, this Court should reject Plaintiffs' call to alter the careful policy balance that Congress has watchfully maintained in the pharmaceutical market for decades. It is not for the judiciary to refashion a remedy for Plaintiffs by distorting existing law, particularly in the context of a comprehensive federal regulatory scheme. Only Congress has the institutional capacity to fully accommodate the myriad of competing interests that are implicated in regulating prescription drugs. Allowing non-expert judges and juries to second-guess that careful balance would severely undermine Congress's preferred policy aims. This Court should therefore decline to embrace Plaintiffs' novel legal theory, which would shift liability to branded drug manufacturers any time someone is injured by their generic competitor's drugs.

To the extent there is any "unfairness" in the present system to plaintiffs like the McNairs, the proper recourse is not a revolution in state product-liability law, but rather, a targeted legislative or regulatory fix by Congress or the FDA. Those deliberative policymaking bodies have the requisite expertise to consider and weigh all the economic, scientific, and public-health ramifications that their approach would have—in a way that a panel of state judges, acting on a limited record, does not. Congress and FDA also have the ability to narrowly target any fix to the specific "unfairness" at hand—the inability for those injured by generic drugs to sue generic drug manufacturers—whereas judicial imposition of innovator liability in the pharmaceutical context would open the door to imposition of the same legal duty on manufacturers in other industries far afield from pharmaceuticals.

Notwithstanding Plaintiffs' bare assertion, a negative answer to the certified question would not leave consumers injured by a drug manufacturer's negligence entirely without legal recourse. To the contrary, injured plaintiffs may continue to assert failure-to-warn claims against branded drug manufacturers *whose products actually caused their injuries*. Likewise, if a plaintiff can demonstrate that he or she was injured by a branded or generic drug that was negligently manufactured, nothing would prevent a state-law tort suit against that drug's manufacturer from proceeding. Moreover, consumers may still sue generic manufacturers if they are injured by that manufacturer's failure to timely update its generic labeling to match that of the innovator drug. And finally, where the prescribing physician fails to consult the product label before prescribing the drug in question, the injured patient can always sue that physician for negligence. In sum, nothing supports Plaintiffs' exaggerated claim that, were the Court to agree with Defendants in this case, injured consumers of prescription drugs would be left without any legal recourse.

ARGUMENT

I. MERE "FORESEEABILITY" IS A LEGALLY INSUFFICIENT BASIS FOR ESTABLISHING A DUTY OF CARE

Plaintiffs contend that the answer to the certified question should turn solely on what they call the "absolute foreseeability" that an inadequacy in the labeling of a brand-name drug will ultimately result in injury to consumers of the generic version of that drug. *See* Appellants' Br. at 3. But that is not the law. By conflating the existence of a preexisting legal duty with the "foreseeability" of a potential injury, Plaintiffs' *sui generis* approach to negligence—if adopted by this Court—would not only upend long-settled West Virginia negligence law, but it would run roughshod over universally held bedrock principles of tort law. As explained below, this Court should reject Plaintiffs' extraordinary invitation to make "foreseeability" the first and last word when imposing a duty under West Virginia law.

A. Plaintiffs' "Foreseeability" Test for Establishing Duty Distorts West Virginia Negligence Law

It is axiomatic that to prevail on a negligence claim under West Virginia law, "the plaintiff must prove by a preponderance of the evidence that the defendant owed a legal duty to the plaintiff and that by breaching that duty the defendant proximately caused the injuries of the plaintiff." *Strahin v. Cleavenger*, 216 W. Va. 175, 183, 603 S.E.2d 197, 205 (2004). Accordingly, "the threshold question in all actions in negligence is whether a duty was owed." *Id.* If the answer to this threshold question is no, the analysis ends because no tort has been committed.

Plaintiffs nonetheless invite the Court to jettison this longstanding and straightforward approach to negligence on the basis that "it is not just foreseeable to a brand-name manufacturer that misstatements on its labels will mislead consumers of generic drugs—it is a virtual

certainty." Appellants' Br. at 22. But this Court has previously refused to adopt such "unadorned reasoning" to invent new tort duties on the basis of foreseeability. *See Stevens v. MTR Gaming Grp.*, 237 W. Va. 531, 535, 788 S.E.2d 59, 63 (2016). WLF submits that the Court should refuse to do so again here.

Whether a legal duty extends from a defendant to the plaintiff in any given case "is a question of law and not a question of fact for the jury." *Miller v. Whitworth*, 193 W. Va. 262, 265, 455 S.E.2d 821, 825 (1995); *see also Aikens v. Debow*, 208 W. Va. 486, 491, 541 S.E.2d 576, 581 (2000) (explaining that "the determination of whether a defendant in a particular case owes a duty to the plaintiff is not a factual question for the jury" but rather "must be rendered by the court as a matter of law"). By contrast, the jury "has the more specific job of considering the likelihood or foreseeability of the injury sustained under the particular facts of the case in order to decide whether the defendant was negligent in that his or her conduct fell within the scope of the duty defined by the court." *Strahin*, 216 W. Va. at 185, 603 S.E.2d at 207. In other words, the *legal* question of whether a duty exists at all is prior to and wholly distinct from the *factual* question of whether the plaintiff's injury was a foreseeable result of that duty's breach.

To form the basis for a valid negligence claim under West Virginia law, a "duty must be brought home to the particular plaintiff, for 'a duty owing to everybody can never become the foundation of an action until some individual is placed in position which gives him particular occasion to insist upon its performance.'" *Robertson v. LeMaster*, 171 W. Va. 607, 611, 301 S.E.2d 563, 567 (1983) (quoting Thomas Cooley, LAW OF TORTS § 478 (4th ed. 1932)). Simply put, if no duty to the plaintiff exists, there can be no negligence: "[n]o act of negligence will lie without a duty broken." *Jack v. Fritts*, 193 W. Va. 494, 495, 457 S.E.2d 431, 435 (1995); *see also Robertson*, 171 W. Va. at 610, 301 S.E.2d at 566; *Parsley v. Gen. Motors*, 167 W. Va. 866,

870, 280 S.E.2d 703, 706 (1981). Plaintiffs' dogged reliance on "foreseeability"—standing alone—does not change that threshold requirement.

Under West Virginia law, as everywhere else, a branded drug manufacturer owes no duty of care to customers of its generic competitor. That is because this Court recognizes only "a duty of manufacturers to warn consumers of the dangerous propensities of ***their*** products." *State ex rel. Johnson & Johnson Corp. v. Karl*, 220 W. Va. 463, 464-65, 647 S.E.2d 899, 901 (2007) (emphasis added). Here, Plaintiffs cannot prove—nor have they even alleged—that ***Defendants'*** "product was defective when it left the manufacturer and [that] the[ir] defective product was the proximate cause of [Plaintiffs'] injuries." *Dunn v. Kanawha Cty. Bd. of Educ.*, 194 W. Va. 40, 46, 459 S.E.2d 151, 157 (1995). And Defendants "are not responsible for the damage resulting from a product that they did not manufacture, distribute or sell." *Meade v. Parsley*, No. 2:09-cv-00388, 2009 WL 3806716, at *2 (S.D. W.Va. Nov. 13, 2009).

Plaintiffs rest their theory of duty on the regulatory requirement that generic manufacturers use the same drug label as branded manufacturers, but this would impose a duty based not on "the foreseeable result of the brand manufacturer's conduct, but [on] the laws over which the brand manufacturers have no control." *In re Darvocet, Darvon, and Propoxyphene Liability Litig.*, 756 F.3d 917, 944 (6th Cir. 2014). That is why "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 statement regarding its drug can serve as the basis for liability for injuries caused by another manufacturer's drug." *Id.* at 938 (internal citations and quotation marks omitted). Indeed, "the overwhelming national consensus … is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of [its generic counterpart]." *Guarino v. Wyeth, LLC*, 719 F.3d 1245, 1252 (11th Cir. 2013).

Even when relevant to determine the scope of a duty owed, this Court has emphasized that "foreseeability is not all that … must [be] consider[ed] when deciding if a given defendant owed a duty to a given plaintiff." *Mallet v. Pickens*, 206 W. Va. 145, 154, 522 S.E.2d 436, 446 (1999). Indeed, "[b]eyond the question of foreseeability," the recognition of a tort duty inherently involves multifaceted "policy considerations underlying the core issue of the scope of the legal system's protection." *Robertson*, 171 W. Va. at 612, 301 S.E.2d at 568. These include "the magnitude of the burden" that the putative duty would impose and "the consequences of placing that burden on the defendant." *Id.*

As Defendants have persuasively demonstrated, these policy considerations weigh strongly against imposing on branded drug manufacturers a new duty that runs to customers of their generic competitors. *See* Appellees' Br. at 15-24. Nor would it be fair to do so. *See, e.g., Huck v. Wyeth, Inc.*, 850 N.W. 2d 353, 376 (Iowa 2014) (explaining that "it would be 'especially unfair' to find brand manufacturers have a duty to those who take generic drugs 'when, as here, the generic manufacturer reaps the benefits of the name brand manufacturer's statements by copying its label and riding on the coattails of its advertising'") (quoting *Foster v. Am. Home Prods. Corp.*, 29 F.3d 165, 170 (4th Cir. 1994)).

Although federal law sometimes preempts the ***remedy*** that injured plaintiffs may seek under state law against generic manufacturers, such preemption does not alter the ***duty*** such manufacturers owe to consumers of their own products. Notwithstanding the federal preemption of certain remedies, then, generic manufacturers still have an independent duty to monitor drug safety and to seek labeling changes, when necessary. Indeed, if a generic manufacturer "believes that new safety information should be added" to its drug labeling, it must "provide adequate supporting information to FDA, and the FDA will determine whether the labeling for" that drug

should be revised. 57 Fed. Reg. 17,950, 17,951 (1992). Because that duty exists wholly distinct from the availability of any remedy for breaching it, shifting that duty to a branded manufacturer who did not manufacture the drug taken by the plaintiff makes no sense. Plaintiffs' response—that foreseeability of injury, standing alone, is an adequate basis for imposing a tort duty on branded manufacturers—simply "stretches foreseeability too far." *In re Darvocet*, 756 F.3d at 947.

B. Plaintiffs' Expansive "Foreseeability" Test Contravenes Universal Principles of Tort Law

"It needs no argument to show that duty does not always coincide with foreseeable risk." William Prosser, *Palsgraf Revisited*, 52 MICH. L. REV. 1, 16 (1953). Under long settled precepts of tort law applicable in every jurisdiction, "foreseeability should not be confused with duty. If there is no duty, the principle of foreseeability to determine the scope of duty is inapplicable. And foreseeability should not be employed as the sole means to create a duty where none existed before." 57A AM. JUR. 2D *Negligence* § 136, p. 198 (1989). Yet that is precisely the slapdash approach to tort liability Plaintiffs ask the Court to adopt here—despite the overwhelming weight of authority to the contrary.

Under Plaintiffs' untethered theory of liability, because nearly everything can be considered "foreseeable," almost everyone owes a duty of care to everyone else. Yet "however valuable the foreseeability formula may be in aiding a jury or judge to reach decision on the negligence issue, it is altogether inadequate for use by the judge as a basis of determining the duty issue." Leon Green, *Foreseeability in Negligence Law*, 61 COLUM. L. REV. 1401, 1417-18 (1961). Indeed, "[i]f the foreseeability formula were the only basis of determining both duty and its violation, such activities as some types of athletics, medical services, construction enterprises,

manufacture and use of chemicals and explosives, serving of intoxicating liquors, operation of automobiles and airplanes, and many others would be greatly restricted." *Id*. at 1418.

If adopted, Plaintiffs' novel theory of duty would far exceed the settled boundaries of tort liability established over many decades. While "[i]t is always tempting to impose new duties and, concomitantly, liabilities, regardless of the economic and social burden," a clear line must nonetheless "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." 57A AM. JUR. 2D *Negligence* § 87, p. 143 (1989); *see also Aikens*, 208 W. Va. at 493, 541 S.E.2d at 583 (same). Courts have long understood that "foreseeability" is a gossamer, flimsy basis upon which to impose tort liability. Contrary to Plaintiffs' unsupported view, it is the relationship between the parties that lies at the core of the legal concept of duty, which is primarily concerned with whether that relationship "imposes upon one a legal obligation for the benefit of the other." William Prosser, HANDBOOK OF THE LAW OF TORTS, § 53 at 324 (4th ed. 1971).

It should come as little surprise that Plaintiffs' "foreseeability-ergo-duty" approach to negligence has been rejected by virtually every other state and federal jurisdiction—including the U.S. Supreme Court. As the U.S. Supreme Court has cogently explained, "[c]onditioning liability on foreseeability … is hardly a condition at all," because "[i]f one takes a broad enough view, *all* consequences of a negligent act, no matter how removed in time or space, may be foreseen." *Conrail v. Gottshall*, 512 U.S. 532, 552-53 (1994). Other courts agree. *See, e.g*., *In re Darvocet*, 756 F.3d at 947 ("Using federal … laws designed to increase the availability of generic drugs as the basis of supplying the duty element for tort liability stretches foreseeability too far."); *Thing v. La Chusa*, 48 Cal. 3d 644, 668 (1989) ("Experience has shown that … there are clear judicial days on which a court can foresee forever and thus determine liability but none on which

foresight alone provides a socially and judicially acceptable limit on recovery of damages for that injury."); *D'Ambra v. United States*, 114 R.I. 643, 649-51 (1975) ("Given the wide disparity, however, between what courts have found to be 'foreseeable' …, any strong reliance on [foreseeability] … would seem to be misplaced."); *Lance v. Senior*, 36 Ill. 2d 516, 518 (1967) ("After the event, hindsight makes every occurrence foreseeable, but whether the law imposes a duty does not depend upon foreseeability alone.").

Even under the modern approach of the *Restatement (Third) of Torts*, the issue of foreseeability of harm is not a duty question at all, but a breach question. Placing isolated significance on foreseeability in determining whether a defendant owes a duty to an injured plaintiff, as Plaintiffs urge here, is flatly inconsistent with the approach urged by the American Law Institute (ALI). *See* RESTATEMENT (THIRD) OF TORTS: LIAB. FOR PHYSICAL & EMOTIONAL HARM § 7 (2010). As the drafters explained, the "extent of foreseeable risk depends on the specific facts of the case and cannot be usefully assessed for a category of cases; small changes in the facts may make a dramatic change in how much risk is foreseeable." *Id.*, § 7, cmt. j.

Accordingly, the ALI approach defers the foreseeability question to the second stage of the negligence analysis (*i.e.*, breach). At the first, threshold stage of the analysis (*i.e.*, the existence of a duty), the court makes a purely legal determination, based on the weighing of public policy factors. *Id.* Viewing the question of duty as wholly distinct from foreseeability of harm "also has the benefit of providing clearer rules of behavior for actors who may be subject to tort liability and who structure their behavior in response to that potential liability." *Id.*, § 7, cmt. i. The ALI intended its elimination of foreseeability from the duty analysis "to facilitate more transparent explanations of the reasons for a no-duty ruling and to protect the traditional function

of the jury as factfinder." *Id.*, § 7, cmt. j. Plaintiffs' theory of duty would "stretch the concept of foreseeability too far." *Foster*, 29 F.3d at 171.

In an effort to circumvent fundamental canons of tort law, Plaintiffs have sought to collapse duty, breach, and causation into a single factor: foreseeability. There is no principled basis for undertaking so seismic a shift in tort law. "While it may seem that there should be a remedy for every wrong, this is an ideal limited perforce by the realities of this world." *Tobin v. Grossman*, 24 N.Y. 2d 609, 619 (1969). If Plaintiffs' boundless view of foreseeability were to be adopted, the threshold concept of duty "would be so extended that many cases now disposed of on the duty issue would reach a jury on the fact issue of negligence." Green, *supra*, at 1418. Accordingly, this Court should reject Plaintiffs' deeply flawed "foreseeability" test and make clear that foreseeability alone is never an adequate basis for imposing a new legal duty.

II. THIS COURT SHOULD REJECT PLAINTIFFS' INVITATION TO SECOND GUESS CONGRESS'S CAREFULLY CRAFTED POLICY BALANCE BY IMPOSING AN UNPRECEDENTED TORT DUTY ON BRANDED MANUFACTURERS

Plaintiffs' opening brief reveals that a major impetus for their attempt to shift liability to Defendants, who neither manufactured nor sold the levofloxacin ingested by Mrs. McNair, is to counter the unfairness they perceive in the U.S. Supreme Court's holdings in *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), and *Mutual Pharmaceutical Co. v. Bartlett*, 133 S. Ct. 2466 (2013), which held some state-law tort claims against generic drug manufacturers are preempted under federal law. *See* Appellants' Br. at 8-11. Of course, because the Supremacy Clause commands that state law give way when federal policymakers have spoken, this Court must accept Congress's decision to preempt various tort claims against generic manufacturers. In doing so, however, this Court should resist the impulse to "turn somersaults to create," *Riegel v. Medtronic*, 552 U.S. 312, 325 (2008), a novel legal theory of liability for branded drug

manufacturers that would undermine the effectiveness of the comprehensive prescription drug regime Congress has implemented. It is for Congress, not this Court, to implement new policy in this complex and highly regulated area.

Congress enacted the Drug Price Competition and Patent Term Restoration Act of 1984 (the Hatch-Waxman Act) in an effort to strike a balance between two conflicting policy objectives: "to induce name-brand pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of those drugs to market." *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 230 (4th Cir. 2002) (internal quotation marks and citations omitted). On the one hand, Congress sought to facilitate generics to help ensure that prescription drugs remained affordable. On the other hand, Congress wanted to ensure that the patent system provided substantial financial rewards to those whose investments in research and development resulted in the development of new life-saving medications, thereby ensuring continued R&D expenditures.

As Congress's compromise solution, the Hatch-Waxman Act struck a careful balance among the competing interests of consumers, innovator drug manufacturers, and generic drug manufacturers. It granted certain patent rights to innovator drug manufacturers while simultaneously taking steps to control prescription drug prices by streamlining the approval process for generic drugs. In carefully crafting a balance among several competing interests, Congress sent an unmistakable message that the measures it adopted provided the appropriate level of incentives and constraints for both branded and generic drug manufacturers, while ensuring the safety and effectiveness of all prescription drugs.

Allowing non-expert judges and juries to second-guess that delicate policy balance would severely undermine Congress's carefully calibrated regulatory scheme. *See, e.g., United States v.*

Oakland Cannabis Buyers' Cooperative, 532 U.S. 483, 497 (2001) (explaining that courts can neither "override Congress's policy choice, articulated in a statute" nor "reject the balance that Congress has struck in a statute"). As this Court has repeatedly explained:

> With the wisdom or propriety of the [statute] we have nothing to do. Those are matters for the Legislature alone to consider; it determines the public policy. Our jurisdiction ends when we have determined the legislative power to exist. If the Legislature has made a mistake, it is a political one, ***and it alone can correct it***.

Stevens, 237 W. Va. at 538, 788 S.E.2d at 66 (quoting *Leonhart v. Bd. of Educ. of Charleston Ind. Sch. Dist.*, 114 W. Va. 9, 16, 170 S.E. 418, 421 (1933)) (emphasis added); *State ex rel. Key v. Bond*, 94 W. Va. 255, 270, 118 S.E. 276, 283 (1923) ("The Legislature declares public policy, not the courts."). Yet Plaintiffs urge the Court to disregard this venerable separation-of-powers principle all in the name of "fairness."

Contrary to Plaintiffs' view, "[t]his Court does not sit as a superlegislature, commissioned to pass upon the political, social, economic, or scientific merits of statutes pertaining to proper subjects of legislation." *Boyd v. Merritt*, 177 W. Va. 472, 474, 354 S.E.2d 106, 108 (1986); *New Orleans v. Dukes*, 427 U.S. 297, 303 (1976) ("[T]he judiciary may not sit as a superlegislature to judge the wisdom or desirability of legitimate policy determinations."). Only Congress has the institutional capacity to fully accommodate the myriad of competing interests that are implicated in regulating prescription drugs. Unlike Congress, West Virginia courts sitting in adversary proceedings are confined to rendering opinions on the basis of the parties' limited evidentiary record before them. Courts cannot commission independent studies, hire policy experts, or conduct public hearings to gather information from relevant constituencies. Nor can they balance the competing interests of stakeholders by making compromises with the benefit of comprehensive, legislative fact-finding.

In *Mensing*, the U.S. Supreme Court rejected a similar invitation to "distort" existing law by allowing generic drug consumers to seek common-law remedies under state law. *Mensing*, 564 U.S. at 623-626. In particular, *Mensing* observed that "'it is not this Court's task to decide whether the statutory scheme established by Congress is unusual or even bizarre.'" *Id.* at 625-626 (quoting *Cuomo v. Clearing House Ass'n, LLC*, 557 U.S. 519, 556 (2009) (Thomas, J., concurring)). Refusing to "distort the Supremacy Clause in order to" guarantee a legal remedy for every injured plaintiff, the Court in *Mensing* reiterated that "[a]s always, Congress and the FDA retain the authority to change the law and regulations if they so desire." *Id*. at 626.

Similarly, while acknowledging that "[r]espondent's situation is tragic and evokes deep sympathy," the Court in *Bartlett* nonetheless concluded that "a straightforward application of pre-emption law requires that the judgment below be reversed." *Bartlett*, 133 S. Ct. at 2480. Resisting the temptation to eviscerate settled law to achieve a particular policy outcome, the Court reaffirmed that "sympathy for [a party] does not relieve us of the responsibility of following the law." *Id*. at 2478. So too here.

The appropriate role of the judiciary is to interpret and apply the law, not to rewrite it. *See, e.g.*, *Boyd*, 177 W. Va. at 474, 354 S.E.2d at 109 (contrasting the duty of the legislature to "establish policy and embody that policy in legislation" with the duty of the courts "to enforce legislation unless it runs afoul of the State or Federal Constitutions"). Of course, the corollary to the rule that courts should not manipulate existing law to create remedies out of whole cloth is that the political branches can do so when necessary. The judiciary, however, is ill-suited to address complex regulatory concerns that are best left to the political branches. Absent this venerable constraint on judicial policy-making,

> Judges are nothing more than politicians in robes, free to tackle the social problems of the day based on avant-garde [tort] theory or, worse yet, their own

> personal preferences. While such jurists may often be well meaning, their approach is inconsistent with our government's history, structure, and framework, and it threatens the ideal of self-rule that we should so dearly cherish.

The Hon. Diarmuid F. O'Scannlain, *Politicians in Robes: The Separation of Powers and the Problem of Judicial Legislation*, 101 VA. L. REV. ONLINE 31, 33 (2015). Accordingly, any change in the law to address the "unfortunate hand that federal drug regulation has dealt" to Plaintiffs, *Mensing*, 564 U.S. at 625, must be undertaken by Congress, not this Court.

The principle that the judiciary should not distort existing law to engineer a remedy for a sympathetic plaintiff applies directly to this case. Rather than having to persuade a majority of both houses of the United States Congress, the President, and the public constituencies they represent to rewrite existing law, Plaintiffs and their counsel naturally would prefer to persuade only three out of five members of this Court. But because "courts are not institutionally qualified to balance the complex, interrelated, and divergent policy considerations in determining labeling and liability obligations of brand and generic pharmaceuticals," *Huck*, 850 N.W 2d at 377, this Court should resist any temptation to fashion a "fix" for Plaintiffs in this case but instead should direct them to Congress or the FDA.

III. A FINDING FOR DEFENDANTS HERE WOULD NOT LEAVE INJURED PHARMACEUTICAL CONSUMERS WITHOUT LEGAL RECOURSE

Plaintiffs contend that a failure to adopt innovator liability would "not only deprive plaintiffs [injured by prescription pharmaceuticals] of a 'sufficient remedy'—it would deprive them of *any* remedy." Appellants' Br. at 29. Not so.

Of course, this Court has never grounded its tort-law jurisprudence in a "sporting chance" rationale, whereby every allegedly injured plaintiff is entitled to have at least one shot at obtaining a monetary recovery for his or her alleged injuries. More fundamentally, a decision

favoring Defendants in this case would *not* leave most consumers injured by prescription pharmaceuticals without any legal recourse for their injuries.

To begin with, the U.S. Supreme Court has clarified that injured plaintiffs may always assert failure-to-warn claims against those branded drug companies *whose products* allegedly caused plaintiffs' injuries. *See Wyeth v. Levine*, 555 U.S. 555 (2009). And WLF is unaware of precedent from any court in any jurisdiction that holds that a *manufacturing*-defect claim (a claim for injuries caused by a pharmaceutical drug that was improperly made or somehow became tainted) is preempted by federal law or otherwise barred—whether the defendant is a branded or a generic drug manufacturer.

Even under *Mensing*, consumers may still sue generic manufacturers if they are injured by that manufacturer's failure to timely update its generic labeling to match that of the innovator drug. *See, e.g., In re Reglan Litig.*, 226 N.J. 315 (2016). And generic manufacturers are generally liable for any false or misleading statements they may make outside the drug's FDA-approved labeling regime.

In any event, nothing prevents an injured patient from bringing suit against the prescribing physician if that physician was negligent in writing the prescription. Indeed, in cases where a prescribing physician fails to consult levofloxacin's drug label, package insert, or the corresponding entry in the *Physician's Desk Reference* before writing a prescription, he or she may be a prime candidate for liability. *See, e.g., Wyeth*, 555 U.S. at 605 (Alito, J., dissenting) (observing that "it is unclear how a 'stronger' warning could have helped respondent" given that "the physician's assistant who treated [the plaintiff] disregarded at least six separate warnings that are already on Phenergan's labeling").

Plaintiffs' insistence that an answer of "no" to the certified question would somehow deprive injured consumers of generic drugs "of *any* remedy" strains credulity. Of course, even if Plaintiffs were actually left with no recourse, that fact alone would not provide a plausible legal basis for imposing liability on Janssen for injuries allegedly caused by a drug that it neither manufactured nor sold. Accordingly, the Court should reject the unprecedented expansion of tort liability sought by Plaintiffs and answer the certified question with a resounding "no."

CONCLUSION

For the foregoing reasons, the Court should refuse to drastically expand West Virginia law by extending a manufacturer's duty of care to warn of injuries sustained by a plaintiff's use of another manufacturer's product.

Respectfully submitted,

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Forrest H. Roles (WV Bar# 3162)
Mark A. Carter (WV Bar# 4316)
DINSMORE & SHOHL LLP
707 Virginia Street, East
Suite 1300
Charleston, WV 25301
(304) 357-0921
(304) 357-0919 (FAX)

Counsel for Amicus Curiae
Washington Legal Foundation

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CERTIFICATE OF SERVICE

I hereby certify that the foregoing document was served on this 14th day of December 2017 on all parties or their counsel of record via electronic and U.S. Mail at the address listed below.

Richard D. Lindsay, Esq.
TABOR LINDSAY & ASSOCIATES
PO Box 1269
Charleston, WV 25325
richlindsay@taborlindsay.com
Counsel for Plaintiffs/Appellants

Leslie A. Brueckner, Esq.
PUBLIC JUSTICE, PC
555 12th Street, Suite 1230
Oakland, CA 94607
lbrueckner@publicjustice.net
Counsel for Plaintiffs/Appellants

Daniel R. Higginbotham, Esq.
THOMAS COMBS & SMANN, PLLC
PO Box 3824
Charleston, WV 25338
DHigginbotham@tcspllc.com
Counsel for Defendants/Appellees

John D. Winter, Esq.
PATTERSON BELKNAP
1133 Avenue of the Americas
New York, NY 10036
jwinter@pbwt.com
Counsel for Defendants/Appellees

_____
Mark A. Carter