IN THE

SUPREME COURT OF WEST VIRGINIA

KIMMY MCNAIR AND LARRY MCNAIR

Plaintiffs and Appellants,

v.

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

Defendants and Appellees.

On Certified Question from the U.S. Court of Appeal,
For the Fourth Circuit,
Case No. 25-1806

Appellants' Reply Brief

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INTRODUCTION

As of this writing, the majority of state supreme courts to consider the issue agree that brand-name drug manufacturers have a duty of care that extends to consumers of mislabeled generic drugs. The California Supreme Court just reached this conclusion in a ruling that was unanimous on this point. *See T.H. v. Novartis Pharmaceuticals Corp.*, 2017 WL 6521684 (Dec. 21, 2017) ("*Novartis*").[1]

In *Novartis*, the brand-name drug company argued that it could not be held liable because, under California law, *as in this State*, manufacturers ordinarily cannot be sued for injuries caused by another manufacturer's product. *See id.* at *17. In rejecting this argument, the California Supreme Court held that an exception to this general rule was warranted because,

> although a product manufacturer ordinarily will have no control over the design and safety of another manufacturer's product..., *prescription drug markets are different.* They present the unusual situation where one entity's misrepresentations about its own product foreseeably and legally 'contributed substantially to the harm' caused by another entity's product (i.e., the generic drug bearing the warning label drafted by the brand name manufacturer." *Id.* (emphasis added; citation omitted.)

"That key circumstance," *Novartis* ruled, "distinguishes the situation here from those involving the general run of products." *Id.*

This ruling is correct. Janssen's argument that it cannot be held liable because it did not make the actual pills that injured Plaintiffs ignores that it *wrote the labeling information that failed to warn of the medication's adverse effects*–and, as a result, was directly responsible for Plaintiffs' injuries. As a matter of logic and fundamental fairness, it is the entity that causes the injury that should bear responsibility for the damages.

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[1] The California Supreme Court's ruling in *Novartis* is in accord with the ruling of the Alabama Supreme Court in *Wyeth v. Weeks*, 159 So.3d 649 (Ala. 2014), *superceded by statute*, Ala. Code § 6-5-530(a). *See* Appellants Br. at 23-24. The only other state supreme court to consider this question–the Iowa Supreme Court in *Huck v. Wyeth, Inc.*, 850 N.W.2d 359 (Iowa 2014)–ruled 4-to3 in favor of the drug industry based on factors unique to Iowa law. *See* Appellants' Br. at 32-33; *infra* at 16 n.12.

Just as was true in California, this Court has never before considered a circumstance where a company's warning label on its own product is required, *as a matter of federal law*, to be repeated on any and all generic versions of that product. *See PLIVA v. Mensing*, 564 U.S. 604, 613 (2011). That fact makes it 100% foreseeable to a brand-name drug manufacturer that its inadequate label on its *own* drugs poses a risk of injury to consumers of generic versions of that drug. Because foreseeability is *the* primary consideration bearing on whether to recognize a duty of care here in West Virginia, *see Robertson v. LeMaster*, 171 W. Va. 607, 612, 301 S.E.2d 563, 568 (1983), that fact militates powerfully in favor of allowing this lawsuit to proceed.

This lawsuit would also directly advance all the policy factors that this Court must consider in deciding whether to recognize a duty of care. *See id.* Among other things, a ruling in Plaintiffs' favor would not impose any additional burden on brand-name manufacturers, who are *already* subject to a federal duty to update their labels to warn of new risks. At the same time, a ruling for Janssen would render the entire drug industry completely immune from any liability for mislabeled generic drugs—a result that would deprive consumers of *any* ability to seek compensation for their injuries from generic drugs, which make up over 90 percent of all drugs consumed in America. *See* 78 Fed. Reg. 67,985, 67,988 (2013). This immunity, in turn, would strip brand-name manufacturers of much of their incentive to update their labels after their drugs "go generic"—a result that would directly threaten the health and safety of every West Virginian.

The citizens of this State deserve better. This Court should follow the majority of state supreme courts and rule that Plaintiffs have the right to pursue their claims.[2]

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[2] Janssen tries to derail this appeal by arguing that its label was adequate as a matter of fact because "Levaquin®'s labeling included a warning about 'acute respiratory distress'." *See* Appellee Br. at 3. This argument, which was raised for the first time here, has no relevance to the Certified Question and is not

ARGUMENT

I. Plaintiffs' Strict Liability Claim is Consistent with West Virginia Tort Law.

Janssen cites *Yost v. Fuscaldo*, 185 W. Va. 493, 408 S.E.2d 72 (1991), for the proposition that only manufacturers can be held strictly liable for product injuries. *See* Appellee Br. at 10. But *Yost* actually proves the opposite. There, this Court merely "refused to extend the theory of strict liability in tort to include an independent contractor *who does not have a specialized skill or competence* ...to modify a product to enhance its safety." *Yost*, 185 W. Va. at 499, 408 S.E.2d at 78 (emphasis added). As the italicized phrase reveals, strict liability *would* have been available against a defendant that *did* have "a specialized skill or competence..." with regard to the injurious product, *even though the defendant did not manufacture the injurious product*. If anyone possesses "special competence" with regard to the drug that injured Plaintiffs it is Janssen, given that Janssen designed the brand-name version and wrote the label for *all* versions of the drug, both brand and generic. *See Mensing*, 564 U.S. at 613.

Janssen also attacks Plaintiffs for supposedly arguing that Janssen's inadequate label was a "freestanding product." Appellee Br. at 11. But Plaintiffs never made any such argument. Rather, Plaintiffs argued that strict liability is available because Janssen was responsible for the inadequate

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properly before the Court. *See Preussag Intern. Steel Corp. v. March-Westin Co.*, 221 W. Va. 472, 476 n.6, 695 S.E.2d 494, 498 n.6 (2007) (holding that "this Court reviews issues of law de novo in certified question cases—not issues of fact. Therefore, ... facts and characterizations that were not presented to or ruled upon by the district court [ ] can be given no consideration by this Court."). The new argument also mischaracterizes Plaintiffs' claims. This suit alleges that the label was inadequate because it failed to warn that Levaquin® (and its generic equivalent levofloxacin) causes Acute Respiratory Distress Syndrome ("ARDS") (*see* J.A. 16), which is *not* the same thing as "acute respiratory distress." *See* https://www.nhlbi.nih.gov/health-topics/ards (ARDS is a separate condition and specific syndrome with a specific constellation of characteristics and onset as defined and identified by the National Heart Lung and Blood Institute). And, according to the chronology of Levaquin labels on FDA's website, the reference to ARDS on the Levaquin label was dropped sometime between 2003 to 2004—while Janssen was the only manufacturer of Levaquin. *See* http://bit.ly/2ivc1wm.

label on the drug that injured Plaintiff (Appellant Br. at 18-20)—a fact Janssen does not dispute, because it cannot.

Janssen fares no better in arguing that "the policies underlying strict liability confirms that manufacturers may not be liable for their competitors' products." Appellee Br. at 12. On this point, Janssen once again cites *Yost* (*see* Appellee Br. at 12), but (as just explained) *Yost* leaves ample room for strict liability claims against non-manufacturers. *See* 185 W. Va. at 499, 408 S.E.2d at 78. And holding Janssen strictly liable for its failure to update its label is entirely consistent with strict liability's ultimate goal: to rectify "the consumer's inability to protect himself adequately from defectively manufactured [and mislabeled] goods." *Hill v. Joseph T. Ryerson & Son, Inc.*, 165 W. Va. 22, 30, 268 S.E.2d 296, 303 (1980).

II. Plaintiffs' Negligence Claim is Consistent with West Virginia Tort Law.

Even if strict liability were limited to manufacturers and sellers (it is not), Janssen should still have to answer for its negligence. None of Janssen's contrary arguments withstands scrutiny.

A. Negligence Claims Involving Defective Products Are Not Limited to Manufacturers.

Janssen first argues that even *negligence* claims involving defective products may only be brought against the manufacturer or supplier of the product. *See* Appellee Br. at 14. That is not the law in this state. Although a number of state legislatures have limited claims involving defective products to the actual manufacturer, West Virginia's legislature has *not* adopted any such flat prohibition. *See* Appellants Br. at 37-38 & n.22.[3]

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[3] Ironically, Janssen's *amicus* accuses Plaintiffs of asking this Court to act as a "super-Legislator" (Washington Legal Foundation ("WLF") Br. at 14), but in reality this gets it backwards, because the West Virginia Legislature has never restricted tort claims involving mislabeled products to the product's manufacturer. *See* Victor E Schwartz *et al.*, *Warning: Shifting Liability to Manufacturers of Brand-Name Drugs When the Harm Allegedly Caused was from Generic Drugs Has Severe Side Effects*, 81 Fordham L. Rev. 1835, 1861-

Rather, in evaluating negligence claims in this state, this Court takes into account the foreseeability of the injuries and the policy consequences of recognizing a duty of care. *See Robertson v. LeMaster*, 171 W. Va. 607, 301 S.E.2d 563 (1983). And this Court has repeatedly recognized "a duty owed to a third party based primarily upon the foreseeability that harm may result if care is not exercised." *Bragg v. United States*, 230 W. Va. 532, 541, 741 S.E.2d 90, 99 (2013).[4]

The only case cited by Janssen on this point, *State ex rel Johnson & Johnson v. Karl*, 220 W. Va. 463, 464-65, 647 S.E.2d 899, 900 (2007) (Appellee Br. at 14), merely holds that "a manufacturer has a duty to warn of the dangerous propensities of its product." *Id.* *Karl* never said that tort claims may *only* be brought against the manufacturer of the injurious product; rather, it simply confirms that a manufacturer *can* be sued for failure to warn. Nothing in *Karl*—or in any other West Virginia case—suggests that a manufacturer cannot be sued for its negligent misrepresentations about the risks of its own product that foreseeably result in injuries to consumers of identical products.[5]

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62 (2013) ("*Shifting Liability*"). Janssen cites W. Va. Code § 55-7-30 as evidence of a legislative policy to the contrary (Appellee Br. at 23), but that statute *allows* tort remedies against drug companies that "acted unreasonably in failing to provide reasonable instructions or warnings..." to the prescribing doctor. W. Va. Code § 55-7-31, also cited by Janssen (Appellee Br. at 23), is just as unhelpful to its cause, because it affirmatively *preserves* liability as to sellers that "exercise[d] *substantial control over the aspect of the...warnings or instructions of the product that was the proximate cause of the harm...*"—language that describes Janssen's control over the label at issue in this case.

[4] Amicus the U.S. Chamber of Commerce *et al.* ("Chamber") tries to distinguish *Bragg* and progeny on the ground that "an instrumentality" under the defendant's control is needed to link a negligent act to a plaintiffs' injuries. *See* Chamber Br. at 7. But *Bragg* itself disproves this argument. *Bragg* held that a private mine inspector is subject to liability for its negligent failure to warn third-party mine employees of various "hazardous conditions in the mines." *Bragg*, 230 W. Va. at 542, 741 S.E.2d at 100. There, the hazardous "instrumentality" that killed the mine worker was the dangerous mine itself, which was constructed and operated by the Aracoma Coal Company. The mine inspector did not control this "instrumentality," yet this Court held that he could be liable to third parties for his negligent failure to warn of the mine's dangers.

[5] The only other authority cited by Janssen, the Restatement (Second) Torts § 388 (Am. Law. Inst. 1979) (Appellee Br. at 14), merely sets forth the circumstances under which the supplier of "chattel" may be subject to liability for injuries caused by that chattel. It does not address whether a manufacturer that

B. All the *Robinson* Factors Argue for Recognizing a Duty of Care in this Case.

Instead, this question must be decided by applying the factors set forth in *Robertson*, 171 W. Va. at 612, 301 S.E.2d at 568, to determine whether Janssen owes Plaintiffs a duty of care.

1. Foreseeability Weighs Heavily in Favor of Plaintiffs.

The first *Robinson* factor, foreseeability, is not seriously disputed. Janssen admits, as it must, that generic drug manufacturers are obligated to adopt the labels written by brand-name drug manufacturers. *See* Appellee Br. at 5-7. Janssen also does not dispute that a doctor's prescription for a brand-name drug will be filled with a generic equivalent unless the doctor or the pharmacist specifically dictates otherwise. *See* W. Va. Code § 30-5-122b(b). These facts present an iron-clad case for foreseeability.[6]

Not surprisingly, Janssen does not deny foreseeability as a factual matter. Instead, it argues that "foreseeability does not answer the duty question." Appellee Br. at 15-16. But Plaintiffs never argued that it did. To the contrary, Plaintiffs explained that, under *Robertson*, 171 W. Va. at 612, 301 S.E.2d

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misrepresents the dangers of its own "chattel" can be held liable for injuries to consumers of identical chattel that it knows must bear the identical warning. The cases cited by Janssen's amici are just as unhelpful. The Chamber of Commerce cites *Hill v. Joseph T. Ryerson & Son, Inc.*, 165 W.Va. 22, 43, 268 S.E.2d 296, 309 (1980) (Br. at 5), but *Hill* actually supports Plaintiffs, because the authority cited therein provides that "to hold a producer, manufacturer, or seller liable for injury caused by a particular product, there must first be proof that the defendant produced, manufactured, sold, *or was in some way responsible for the product.*" *Id.* (emphasis added). Even the Chamber does not deny that Janssen was "in some way responsible" for Plaintiffs' injuries. The Chamber also cites *Dunn v. Kanawha County Bd. of Education*, 194 W. Va. 40, 46, 459 S.E.2d 151, 157 (1995), for the proposition that "liability 'is based solely upon [a defendant's] relationship to *the product*" (Br. at 6), ignoring that Janssen *has* a direct and immediate relationship to "the product" in this case because it wrote the label that caused Plaintiffs' injuries.

[6] *See, e.g., Novartis*, 2017 WL 6521684 at *8-9; *Weeks*, 159 So.3d at 671 (holding that "an omission or defect in the labeling for the brand-name drug would necessarily be repeated in the generic labeling, *foreseeably* causing harm to a patient who ingested the generic product."). *See generally* Allen Rostron, *Prescription for Fairness, A New Approach to Tort Liability of Brand-Name and Generic Drug Manufacturers*, 60 Duke L.J. 1123, 1165-66 (2011).

at 568, foreseeability is only *one* of the factors bearing on whether to recognize a duty of care. *See* Appellants Br. at 21.

It is worth emphasizing, however, that foreseeability is the "*primary consideration* in establishing the duty of care in tort cases." *Robertson*, 171 W. Va. at 612, 301 S.E.2d at 568 (emphasis added). Just last year, this Court reaffirmed that "[t]he *ultimate* test of a duty to use care is found in the foreseeability that harm may result if not exercised." *Stevens v. MTR Gaming Group, Inc.*, 237 W. Va. 531, 534, 700 S.E.2d 59, 62 (2016) (emphasis added; citation omitted). Thus, although foreseeability is not the *only* factor, it is indisputably the most important one, and it weighs heavily in favor of Plaintiffs.

Janssen ignores the primacy of foreseeability in this Court's duty analysis. Instead, it merely recites the Sixth Circuit's conclusion that cases like this one "stretch foreseeability too far," because "'generic consumers' injuries are not the foreseeable result of the brand manufacturers' conduct, but of the laws over which the brand name manufacturers have no control.'" Appellee Br. at 15 (quoting *In re Darvocet, Darvon, and Propoxyphene Products Liability Litig.*, 656 F.3d 917, 944 (6th Cir. 2014)). This holding improperly conflates foreseeability with a *policy* conclusion that brand-name manufacturers should be immune because they "have no control" over the federal drug laws. *Id.* Whatever one thinks about the merits of that policy conclusion, it has no place in an analysis of foreseeability. *Accord Novartis*, 2017 WL 6521684 at *13.

2. All the Policy Factors Weigh Heavily in Favor of Plaintiffs.

And that policy conclusion—that brand-name manufacturers should be immune from liability because they lack control over the federal drug laws—is, in any event, quite wrong. In reality, *all* the *Robertson* factors strongly favor Plaintiffs.

a. **The Alleged Lack of a Direct "Nexus" Between Janssen and Plaintiffs is Irrelevant.**

As a threshold matter, Janssen's argument that there is insufficient "nexus" between Plaintiffs and Janssen (Appellee Br. at 17-18) fails on two counts. First, it fails as a legal matter because the *Robinson* factors do not include any "nexus" requirement. *See* 171 W. Va.at 612, 301 S.E.2d at 568. The only West Virginia case cited by Janssen on this point–*Aikens v. Debow*, 208 W. Va.486, 499, 541 S.E.2d 576, 589 (2000)–merely requires a "nexus" between a plaintiff and a defendant in tort cases involving "*purely economic loss*." *Id.* (emphasis added). That, obviously, is not this case.[7]

Second, Janssen's argument that "Plaintiffs and Janssen are strangers to one another in every sense" (Appellee Br. at 17) fails as a factual matter because it ignores the symbiotic relationship between brand-name and generic drug manufacturers–a relationship that has no parallel in any other commercial context. And, contrary to Janssen's contention that "Janssen never targeted Plaintiffs with its advertising" (*id.*), brand manufacturers know full well that their advertising will inevitably result in many patients consuming generic versions of their drugs. *See* W. Va. Code § 30-5-12b(b) (requiring pharmacists to substitute generic for brand-name drugs). That being so, Janssen's "nexus" argument fails as a matter of plain fact. *See also Novartis*, 2017 WL 6521684 at *9 (noting the "close connection between Novartis's alleged negligence and plaintiffs' injuries").

[7] The federal cases Janssen cites on this point–*Foster v. American Home Prods. Corp.*, 29 F.3d 165, 171 (4th Cir. 1994), and *Schrock v. Wyeth, Inc.*, 727 F.3d 1273, 1282-83 (10th Cir. 2013)–are distinguishable because, in each case, the state's substantive tort law required a direct nexus between the defendant and the allegedly injurious product. West Virginia's law contains no such requirement. *See* Appellants Br. at 34-36.

b. **The Magnitude of the Burden on the Defendant Weighs Heavily in Favor of Plaintiffs.**

Janssen's arguments regarding the first *Robinson* policy factor—the "magnitude of the burden on the defendant" from complying with the duty of care (Appellee Br. at 18-19)—are just as unconvincing. As the California Supreme Court just held, because the duty of care advocated by Plaintiffs is already imposed on brand-name drug manufacturers by federal law, the burden of complying with the duty of care in cases like this one is precisely "zero." *Novartis*, 2017 WL 6521684 at *11.

Janssen's related argument is that it would be "unfair" to hold it liable because it does not profit from the sale of generic drugs. See Appellants Br. at 24-26. Because this issue is addressed at length in Plaintiffs' opening brief (at 25-26), those arguments will not be repeated here. Suffice it to say that, as AARP argues, the fairness argument "misses the critically important point that the brand manufacturer's duty to warn is *already* mandated by federal law and that this duty extends to knowledge of risks associated with generic versions of the drug." AARP Br. at 7 (emphasis in original). Because brand-name drug manufacturers can only be held liable upon a finding that they breached a preexisting federal duty, it is hard to see how tort cases like this one are in any sense "unfair." Also, as stated in *Novartis*, the benefits granted brand-name manufacturers under the Hatch-Waxman Act "more than offset" the "zero" burden imposed on defendants by lawsuit like this one. 2017 WL 6521684 at *12.

c. **The Consequences of Placing a Duty of Care on Brand-Name Manufacturers Weighs Heavily in Favor of Plaintiffs.**

This factor also weighs heavily in favor of Plaintiffs for one simple, overpowering reason: cases like this one create a crucial incentive for brand-name manufacturers to update their labels to warn

of serious risks that emerge after their drugs "go generic"—an incentive that would not otherwise exist in the law. At the same time, none of the adverse policy consequences posited by Janssen and its *amici*—*e.g.* stifling of innovation and overwarning—has any serious basis in fact. *See generally* 2017 WL 6521684 at *13-14.

i. **Tort Liability Would Address a Dangerous Safety Gap by Incentivizing Brand-Name Drug Manufacturers to Update their Labels.**

Without the risk of tort liability, brand-name companies lack sufficient incentive to update their labels after their drugs go generic, putting the public at risk. *See Novartis*, 2017 WL 6521684 at *10-11. As Public Citizen states, Janssen's position would "exacerbate a dangerous safety gap" by "leav[ing] no manufacturer accountable for failure to warn hazards, thus eliminating a crucial bulwark against unsafe pharmaceuticals in the marketplace." *Id.* at 12. *Accord Novartis*, 2017 WL 6521684 at *10-11.

None of Janssen's answers withstands scrutiny. First, Janssen errs in arguing that there is no reason to worry about mislabeled generic drugs because most serious drug risks emerge *before* a drug goes generic. *See* Appellee Br. at 27. In reality, there are many real-world examples of serious drug risks becoming known only after the expiration of a drug's patent protection. *See* Public Citizen Br. at 5; AARP Br. at 5 (only one-half of drug risks are detected within seven years of FDA approval).

Janssen's second argument—that the FDA can adequately police generic drug labels by monitoring postmarketing safety data and, where needed, launching "civil or criminal enforcement actions" (Appellee Br. at 26)—is just as unrealistic. In truth, the FDA's inability to adequately to monitor postmarketing safety data has been a subject of intense concern for over a decade. *See* Public Citizen Br. at 5; AARP Br. at 6. And "the FDA has rarely, if ever, brought a misbranding action against the manufacturer of an approved drug being promoted only for approved uses." David

A. Kessler & David C. Vladeck, *A Critical Examination of the FDA's Efforts to Preempt Failure-to-Warn Claims*, 96 Geo. L. J. 461, 479 n.80 (2008) (emphasis added).[8]

Third, Janssen's suggestion that brand-name-manufacturer liability is not necessary because generic drug manufacturers have the means to effectuate a label change (*see* Appellee Br. at 7 n.4) is contrary to the federal labeling scheme. Unlike brand-name manufacturers, which can unilaterally add warnings under the FDA's "changes-being-effected" regulation (21 C.F.R. § 310.70(c)), the only thing a generic drug company can do is ask the FDA for permission to add or strengthen the warnings in its labeling. *See* 21 C.F.R. § 314.70. *See also* Public Citizen Br. at 7 ("Generic manufacturers...have neither the power nor the responsibility for new safety updates.")

Generic manufacturers have almost no incentive to seek such permission, however, because they are immune from tort liability for failure to warn under *Mensing*, 564 U.S. at 613. As the FDA recently observed, *Mensing* has greatly "alter[ed] the incentives for generic drug manufacturers to comply with current requirements to conduct robust postmarketing surveillance, evaluation, and reporting, *and to ensure that the labeling for their drugs is accurate and up to date*." 78 Fed. Reg. 67,985, 67,988–89 (2013) (emphasis added).

Nor is there any basis for Janssen's final argument that imposition of tort liability for injuries caused by generic drugs would not enhance public safety because "no rational manufacturer" would stay in the market after its drug goes generic. *See* Appellee Br. at 27. This argument, which was definitely rejected by the California Supreme Court in *Novartis* (*see* 2017 WL 6521684 at *12),

[8] "Misbranding" actions are typically brought against companies selling unapproved drugs or approved drugs being markets for unapproved uses. *See id.* Research has uncovered no misbranding actions by the FDA against brand-name drug companies based on a company's failure to update its label to disclose a postmarket risk.

ignores that market withdrawal would not relieve a manufacturer of liability for its *past* misconduct, if the label was inadequate at the time the manufacturer withdrew the NDA and the injured patient's reliance on the label was foreseeable. *See id.* And a brand manufacturer would not need to leave the market in order to avoid *future* liability because it could simply make sure that its labels were up-to-date and accurate on a going-forward basis. *Ibid.*

That aside, the possibility that some brand-name manufacturers *might* withdraw from the market when faced with tort liability for injuries caused by generic drugs is not a reason to categorically foreclose the imposition of such liability. Brand-name manufacturers' responsibility to update their labels while they still own the drug does patients little good if those manufacturers have no liability for failing to fulfill that duty. Tort liability helps ensure that they take this job seriously. Granting them the immunity they seek here would reward wrongdoing at the expense of public safety.

ii. Tort Liability Would Further Public Policy by Compensating Consumers Injured by Mislabeled Generic Drugs.

Tort liability also furthers public policy by giving the victims of generic drugs the right to seek compensation for their injuries. Under *Mensing*, generic manufacturers are immune from suit for failure to warn because they lack control over their labels—and thus suits against them are preempted by federal law. 564 U.S. at 613. As a result, suits like this one are the *only* way for victims of mislabeled drugs to seek any remedy for their injuries.

Janssen's response is that this problem is one for Congress or the FDA to remedy, not this Court. That argument would only make sense if brand-name manufacturers were innocent of any fault in the mislabeling of generic drugs. If that were true, then cases like this one could reasonably be characterized as seeking to make brand-name companies "the insurers" of the entire industry—and it would arguably be unfair to require them to compensate the victims of generic drugs, even if

such victims would go without any remedy. But, as the *Novartis* Court recognized, this characterization is inapt, because brand-name companies are directly at fault for mislabeled generic drugs: "[u]nder warning label liability, the brand-name drug manufacturer is liable *only* in a narrow circumstance—when deficiencies in its *own* label foreseeably and proximately caused injury." 2017 WL 6521684 at *11. In light of this fact, it is entirely appropriate for brand-name companies to compensate generic victims—particularly because such victims would otherwise go without any compensation at all. This "compensatory function," moreover, "may motivate injured persons to come forward with information" about drug hazards, which inures to the benefit of *all* consumers, not just those that recover damages in a court of law. *Wyeth v. Levine, Inc.*, 555 U.S. 555, 578-79 (2009).

iii. The Alleged "Adverse Public Health Consequences" of Tort Liability Are Chimerical.

Janssen's arguments about the "adverse public health consequences" of tort liability are just as unconvincing. *See* Appellee Br. at 20-21.[9]

First, the contention that tort liability will dramatically stifle innovation in the pharmaceutical industry is unfounded. As *Novartis* held, "[t]he logic buttressing this argument is far from self-evident." 2017 WL 6521684 at *13-14. While it is true that "[w]arnings about a product's efficacy or danger may indeed risk diminishing its value to the manufacturer[,] [l]ess obvious is the manufacturer's response to this predicament. One might just as easily assert that a drug company,

[9] All of Janssen's and its *amici*'s arguments on this point were considered and rejected by the California Supreme Court in *Novartis*. *See* 2017 WL 6521684 at *11-14. Janssen's main source for its arguments about "adverse public health consequences" is the Sixth Circuit's ruling in *In re Darvocet*, 756 F.3d at 946. *See* Appellee Br. at 20. *In re Darvocet* relies exclusively on a single law review article written by drug industry representatives. *Id.* at 944 (citing *Shifting Liability*, 81 Fordham L. Rev. at 1840-41).

after adding a new warning, will be incentivized to develop new and safer alternatives to the drug so that it can recapture the market for treatment of that disease." *Id.*

In addition, such liability would have no affect on the ability of brand-name companies to enjoy full profits during the entire market exclusivity period afforded by the Hatch-Waxman Act. It is hard to imagine that brand manufacturers would choose to forego all those profits simply in order to avoid potential future liability for mislabeled generic versions of their drugs. This argument, moreover, ignores that brand companies can always protect themselves by updating their labels once their drugs go generic.[10]

Second, the contention that tort liability may increase prices for brand-name drugs is also unpersuasive. There is no evidence that tort liability has caused any substantial increase in drug prices. Rather, as AARP explains, "high [brand-name] drug prices are the direct result of the 20 year patent protected monopoly in which brand-name manufacturers can raise the price of drugs without limitation and according to its demand." AARP Br. at 8 (citation omitted). It would be perverse indeed to allow brand manufacturers to evade liability for generic drugs based on a threat to raise brand-name prices even higher. This argument also assumes that consumers would rather "be penalized with toothless patient safety and tort laws" than pay more more for brand-name drugs—a result that AARP, a national nonprofit well known for efforts to restrict drug prices, resoundingly rejects. *See id.* at 9-10.

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[10] One of Janssen's *amici* argues that this protection is meaningless because "[i]nterested plaintiffs' lawyers have every incentive to craft arguments to undermine a medicine's labeling...," no matter how strong the warning accompanying a drug. Pharmaceutical Manufacturers' Br. at 8. But to support this argument, the *amicus* cites the United States' pro-preemption *amicus* brief in *Wyeth v. Levine*, 555 U.S. 555 (2009), which was resoundingly rejected by the U.S. Supreme Court in connection with its ruling that "state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Id.* at 578.

Third, the argument that imposition of tort liability on brand drug companies would harm consumers by stimulating "overwarning" (see Appellee Br. at 30-31) was definitively rejected in *Novartis*, 2017 WL 6521684 at *12, and in *Carlin v. Superior Court*, 920 P.2d 1347, 1353 (Cal. 1996), which observed that the FDA's own regulations preclude "overwarning." *Carlin*, notably, reached this conclusion in the context of allowing strict-liability failure to warn claims involving *brand-name* drugs, not just generic drugs. *See id.* If drug manufacturers would not "overwarn" to avoid the risk of liability for their brand-name drugs, then it implausible to assume that they would do so merely to avoid the added liability posed by generic drugs.

Nor is there any reason to fear that a ruling for Plaintiffs in this case would spill over into other product areas. See Appellee Br. at 24. This is the only sector where the law *requires* that one manufacturer's warnings be repeated, verbatim, on the labels of identical products made by another company. If (to use Janssen's example) a counterfeit product bearing a warning plagiarized from the original manufacturer were to injure a consumer, there would be no basis for holding the original manufacturer liable for failure to warn, because the "counterfeiter" was not obligated *by law* to adopt the insufficient warning. Generic drug manufacturers, in contrast, are required to adopt brand-name labels "verbatim." *Mensing*, 464 U.S. at 613. That's what makes this industry unique—and a ruling for Plaintiffs could easily be "cabined" to this context.[11]

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[11] Janssen's "proximate cause" argument (Appellee Br. at 28) ignores that "[t]he proximate cause of an injury is the *last negligent act* contributing to the injury and without which the injury would not have occurred." *Wilkinson v. Duff*, 212 W. Va. 725, 731, 575 S.E.2d 335, 341 (2002) (emphasis added; citation omitted). Janssen's failure to update its label to reflect the true risks of its drug *was* the "last negligent act" that resulted in Plaintiffs' injuries: If Janssen had updated its label to reflect the true risks of its drug, as the FDA regulations require, then the generic manufacturer (Dr. Reddy) would have been *obligated* to update its own label to mirror the new language. See Appellants' Br. at 9; 21 C.F.R. § 314.70(b)(2)(v). In that event, there would have been no need for Dr. Reddy to "approach the FDA and request permission to strengthen its warnings," as Janssen illogically claims it should have done, because the warnings would have already been strengthened to reflect the actual risks of the drug. *See also Robertson*, 171 W. Va. at 614, 301 S.E.2d at 570 (holding that,

III. Authorities from Other Jurisdictions Support Plaintiffs, Not Janssen.

Janssen insists that Plaintiffs' position cannot be reconciled with the "hundreds" of cases from other jurisdictions. Not so.

A. State Law Authorities Favor Plaintiffs.

First, the weight of state law favors Plaintiffs. Prior to the ruling in *Novartis*, the states were split down the middle on the issue of brand-name liability for generic drugs (*see* Appellant Br. at 34), but *Novartis* tipped the balance dramatically. And, in almost all pertinent respects, California tort law is markedly similar to West Virginia law.[12]

To begin, California, like West Virginia, has a general rule that manufacturers can "ordinarily" only be sued for injuries caused by their own products. *See O'Neil v. Crane Co.*, 266 P.3d 987 (Cal. 2012) (discussed in *Novartis*, 2017 WL 6521684 at *9-10). In *Novartis*, however, the California Supreme Court recognized that this general rule makes no sense in the unique context of prescription drugs, because brand-name manufacturers control the labels on *all* drugs, both brand-name and generic. *See* 2017 WL 6521684 at *10. There is nothing to stop this Court from reaching the same conclusion—and, as explained above, powerful policy reasons why it should so conclude.[13]

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if an "intervening cause is one which is to be reasonably anticipated, the defendant may be liable, for '[t]he risk created by the defendant may include the intervention of the foreseeable negligence of others.'") (citation omitted).

[12] The Iowa Supreme Court's ruling in *Huck v. Wyeth*, 850 N.W.2d at 376, is distinguishable because, as *Novartis* observed, it "categorically exclud[ed] from liability certain defendants" (2017 WL 6521684 at *17) and "discount[ed] the role of foreseeability." *Id.* at *16 n.5. Both aspects of *Huck* are at odds with West Virginia law as well. *See* Appellants' Br. at 32-33.

[13] Notably, this Court has a history of following California authority in the tort context. *See Morningstar v. Black & Decker Mfg. Co*, 162 W. Va. 857, 875 & 883, 263 S.E.2d 666 (1979) (following *Greenman v. Yuba Power Prods., Inc.*, 377 P.2d 837 (Cal. 1963), in removing "unreasonably dangerous" requirement for strict liability claims).

Second, just as in West Virginia, California courts consider a range of factors when deciding whether to recognize a duty of care. *See Rowland v. Christian*, 443 P.2d 561, 564 (Cal. 1968). The foremost of these factors is foreseeability—*just as in this State. See id.*; *accord Robertson*, 171 W. Va. at 611, 301 S.E.2d at 567 (stating that foreseeability is "the primary consideration..."). And the policy factors relevant to the California analysis under *Rowland* (*see Novartis*, 2017 WL 6521684 at *10-14) are similar to the *Robertson* factors, which also center on the burden to the defendant and the consequences to the community of imposition of a duty of care. *See Robertson*, 171 W. Va. at 611, 301 S.E.2d at 567. In fact, *Robertson* itself cites *Rowland* as an example of a similar policy test. *Id.* It is therefore no surprise that all the policy arguments made by Janssen and its *amici* in this case were *also* raised in *Novartis*—and every one of those arguments was squarely rejected by the California Supreme Court.

Third, although *Novartis* involved a claim for negligent misrepresentation under Section 311 of the Restatement (Second) of Torts, *see Novartis*, 2017 WL 6521684 at *6-7, the decision is broadly applicable because, in finding a duty of care, the Court looked to the standards governing *all* negligence claims in that state—which, as just explained, are on all fours with *Robertson*. *See id* at *7-8. Thus *Novartis* is directly relevant to this case, and strongly counsels in favor of a ruling in Plaintiffs' favor.[14]

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[14] The Chamber nonetheless argues that California tort rulings have no bearing here because "this Court has never cited Restatement § 311." Chamber Br. at 9. This argument fails because, as just explained, *Novartis*'s reasoning centered on foreseeability and policy factors that mirror this Court's own. In any event, Restatement § 311 is not incompatible with this State's tort law, and this Court has never rejected it (or even, it seems, had occasion to consider it)Section 311 provides that "one who negligently gives false information to another is subject to liability for physical harm caused by action taken by the other in reasonable reliance upon such information, where such harm results...to such third persons as the actor should expect to be put in peril by the action taken." Novartis, 2017 WL 6521684 at *6. This rule is in keeping with this Court's longstanding view that "one who engages in affirmative conduct, and thereafter realizes or should realize that such conduct has created an unreasonable risk of harm to another, is under a duty to exercise reasonable care

Finally, of course, Novartis' ruling is on all fours with the Alabama Supreme Court's ruling in *Wyeth v. Weeks*, the only other post-*Mensing* state high-court ruling on the issue presented in this case. *See* 159 So. 3d 649 (Ala. 2014).

B. Federal Law Authorities Do Not Favor Janssen.

Federal authority also does not help Janssen's cause. First, the majority of prior rulings relied on the Fourth Circuit's flawed decision in *Foster*, 29 F.3d 165, which has since been discredited by *Mensing*. See Appellants' Br. at 35-36; *Novartis*, 2017 WL 6521684 at *15-16 (explaining flaws in *Foster*). In holding that generic manufacturers are required by federal law to adopt, "verbatim," the labels written by corresponding brand name drug company (see 564 U.S. at 613), *Mensing* rendered foreseeability a non-issue in cases like this one—a huge and undisputable change in the law, and one of enormous importance here, given the primacy of foreseeability in the duty calculus under *Robertson*. Indeed, the Fourth Circuit itself recognized, *in this very case*, that *Mensing* overturned a key portion of its ruling in *Foster* and "leaves open the possibility that brand-name manufacturers may be liable for failure to warn when a plaintiff ingests the generic drug." J.A. 5.[15]

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to prevent the threatened harm." *Robertson*, 171 W. Va. at 611, 301 S.E.2d at 567 (quoting Restatement (Second) of Torts § 321 (1965)). And Section 311's imposition of liability on "such third persons as the actor should expect to be put in peril by the action taken" is fully consistent with this Court's prior rulings recognizing "a duty owed to a third party based primarily upon the foreseeability that harm may result if care is not exercised." *Bragg*, 230 W. Va. at 541, 741 S.E.2d at 99. It is worth noting, moreover, that none of the other decisions finding brand-name liability for injuries caused by a mislabeled generic drug involved a claim arising under Section 311 of the Restatement. *See Wyeth v. Weeks*, 159 So. 3d 649 (Ala. 2014); *Dolin v. SmithKline Beecham Corp.*, 62 F. Supp. 3d 705 (N.D. Ill. 2014); *Kellogg v. Wyeth, Inc.*, 762 F. Supp. 2d 694 (D. Vt. 2010).

[15] Janssen misstates the true import of *Mensing* by saying the decision "rejected a[n] invitation to 'distort' existing state law by allowing generic drug consumers to seek common-law remedies under state law." WLF Br. at 15 (citing *Mensing*, 564 U.S. at 623-26). In reality, what *Mensing* held was that federal law preempts generic-drug victims from suing *generic* drug companies for their injuries, because it is "impossible" for generic drug companies to update their labels under federal law. *Mensing*, 564 U.S. at 613. This holding helps *Plaintiffs*, because it confirms that brand manufacturers control the labels on generic drugs.

Janssen nonetheless insists that federal law is on its side because several federal courts rejected brand-name liability even in the wake of *Mensing*. As previously explained, however, all these decisions came from federal courts sitting in states that, *unlike West Virginia*, subject all tort claims to a "product identification" requirement. *See* Appellants Br. at 35-36. Indeed, *Foster* itself was one such case. *See* 29 F.3d at 168; *Novartis*, 2017 WL 6521684 at *15 (distinguishing *Foster* on that ground). There is no such "per se" requirement in the State of West Virginia; instead, as explained above, there is ample room under the laws of both strict liability and negligence to hold a manufacturer liable for injuries caused by a product it did not manufacturer, so long as it can be shown that the defendant's conduct was responsible for the plaintiff's injuries.

Moreover, as *Novartis* explained, all the contrary federal rulings in this area (including *Foster* itself) "arose in federal court under diversity jurisdiction." *Id.* at *16. "Federal courts sitting in diversity are 'extremely cautious' about recognizing innovative theories under state law." *Id.* (citation omitted). It is therefore not surprising that so many courts have rejected liability in cases like this one, particular given that the vast majority of these rulings pre-date *Mensing*. *Ibid.* That fact, however, should not give *this* Court pause when interpreting the case law of *this* state.

IV. This Lawsuit is Consistent With, and Directly Furthers, Federal Purposes.

Finally, there is no basis for the argument that this suit would "disrupt federal policy" by undermining the "delicate balance" embodied by the Hatch-Waxman Act. *See* WLF Br. at 12-13. First, this argument assumes that, in passing Hatch-Waxman, Congress intended to preempt all tort claims involving generic drugs. In reality, Hatch Waxman is subject to the federal Food Drug and Cosmetic Act's ("FDCA's") savings clause, which provides that state law may only be invalidated upon a "direct and positive conflict" with the FDCA. *See Wyeth*, 555 U.S. at 567 (citing 21 U.S.C.

§ 321). This provision, coupled with the absence of an express preemption clause in the FDCA and Congress' "certain awareness of the prevalence of state tort litigation" surrounding all prescription drugs, supplies powerful "evidence that Congress did *not* regard state tort litigation as an obstacle to" the Hatch-Waxman Act. *Id.* at 574–576 (emphasis added).

If anything, it is Janssen's argument that would "frustrate federal policy" by stripping consumers of their ability to seek any remedy for injuries caused by mislabeled generic drugs. In *Wyeth*, the U.S. Supreme Court held that failure-to-warn claims against brand-name drug manufacturers affirmatively *further* federal purposes, by incentivizing drug companies to "disclose safety risks promptly." 555 U.S. at 580. The same conclusion is applicable here.

But beyond that, disallowing tort claims in cases like this one would also disrupt the policies underlying Hatch-Waxman itself. As *Novartis* held, "if tort law [disallowed consumers of generic drugs] from obtaining...compensation for injuries attributable to the brand-name drug manufacturer's defective warning label, then consumers would insist on the brand-name drug over the cheaper bioequivalent, inflating health costs with no corresponding increase in safety and *in contradiction to the stated federal policy of making low-cost generic drugs more available.*" 2017 WL 6521684 at *11 (emphasis added). It is understandable why brand-name manufacturers might like that result, but it is directly contrary to everything that Hatch-Waxman was designed to achieve.

CONCLUSION

For the foregoing reasons, Plaintiffs pray this Court certify that they have claims under West Virginia law for strict liability and negligence against a brand-name manufacturer for injuries caused by a mislabeled generic drug.

Dated: January 3, 2018

CERTIFICATE OF SERVICE

I, Rich Lindsay, Esq., do hereby certifiy that the foregoing was served on this 3rd day of January, 2018 on all parties by their counsel of record via U.S. Mail at the address listed below:

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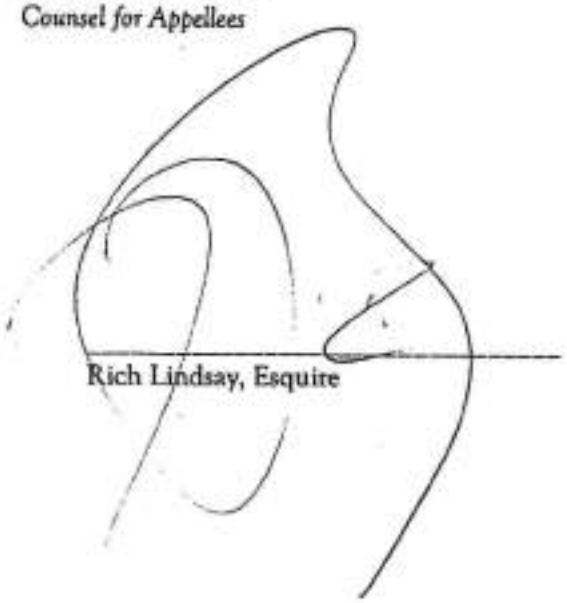

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