No. 17-0519 - *McNair v. Johnson & Johnson; Janssen Pharmaceuticals, Inc.; and Ortho-McNeil Pharmceutical, Inc.*

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Workman, Chief Justice, dissenting, joined by Justice Davis:

I respectfully dissent to the majority opinion in this extremely significant liability matter. This is, at its very essence, a reasonably straightforward failure to warn and negligence case. Although the facts are unique, the concepts certainly are not unfamiliar to the jurisprudence of this state. We have long held inviolate the rights of the citizens of this state to be protected from negligence of manufacturers.

The existing scenario presents an intriguing legal conundrum: (1) an injury occurs, allegedly caused by improper labeling of a prescription generic drug; (2) federal law requires generic drug manufacturers to adopt brand-name labeling verbatim and prohibits generic manufacturers from unilaterally altering drug labels; (3) an injured party is legally precluded from suing the generic drug manufacturer due to federal regulations; and (4) the entity who produced the warnings accompanying the distribution of the generic drug is the brand-name manufacturer. This Court is asked the deceptively simple question of whether, under these circumstances, our law permits a claim against the brand-name manufacturer. In my view, the question is whether the development and theoretical underpinnings of this

state's tort law support the advancement of such a claim. I think the answer is most assuredly yes.

The framework for analysis of tort recovery in this state is perfectly poised to recognize the cause of action forwarded by the plaintiffs.[1] In the seminal opinion of *Morningstar v. Black and Decker Co.*, 162 W.Va. 857, 253 S.E.2d 666 (1979), this Court explained that the *focus* in failure to warn cases "is not so much on a flawed physical condition of the product, as on its unsafeness arising out of failure to adequately *label, instruct or warn*." *Id.* at 888, 253 S.E.2d at 682 (emphasis supplied). We held that a third party, even though not in privity of contract with the manufacturer, has a strict liability claim against the manufacturer where its actions proximately caused the injury. *Id.* We unequivocally addressed the standard for recovery, explaining: "Once it can be shown that the product was defective when it left the manufacturer and that the defect proximately caused the plaintiff's injury, a recovery is warranted absent some conduct on the part of the plaintiff that may bar his recovery." *Id.* at 883, 253 S.E.2d at 680.

In *Dunn v. Kanawha County Board of Education*, 194 W.Va. 40, 459 S.E.2d 151 (1995), this Court reiterated the liability standard and again recognized that a

[1]Indeed, the United States Court of Appeals for the Fourth Circuit, in certifying this question to our Court, noted that the West Virginia "precedent leaves open the possibility that brand-name manufacturers may be liable for failure to warn when a plaintiff ingests the generic drug." *McNair v. Johnson & Johnson*, 694 F. App'x 115, 121 (4th Cir. 2017).

manufacturer can be liable for a product which was defective when it left the manufacturer. *Id*. at 46, 459 S.E.2d at 157. This Court held: "Product liability law in this State permits a plaintiff to recover where the plaintiff can prove a product was defective when it left the manufacturer and the defective product was the proximate cause of the plaintiff's injuries." *Id*. Moreover, we clarified that even an "innocent seller can be subject to liability that is entirely derivative simply by virtue of being present in the chain of distribution of the defective product." *Id.* at 46, 459 S.E.2d at 157.

With regard to general negligence claims asserted in the case sub judice, this Court has stated that foreseeability is a "primary consideration in establishing the duty of care in tort cases." *Robertson v. LeMaster*, 171 W.Va. 607, 612, 301 S.E.2d 563, 568 (1983). The *Robertson* analysis finds its genesis in fundamental tort concepts, reiterating that "[i]n order to establish a prima facie case of negligence in West Virginia, it must be shown that the defendant has been guilty of some act or omission in violation of a duty owed to the plaintiff. No action for negligence will lie without a duty broken." *Id.* at 610, 301 S.E.2d at 566 (citing *Parsley v. Gen. Motors Acceptance Corp.*, 167 W.Va. 866, 280 S.E.2d 703 (1981)); *see also Stevens v. MTR Gaming Grp., Inc.,* 237 W.Va. 531, 534, 788 S.E.2d 59, 62 (2016) (heralding foreseeability as the "ultimate test of the existence of a duty. . . ."); *Church v. Wesson*, 182 W.Va. 37, 40, 385 S.E.2d 393, 396 (1989) ("In ascertaining whether a duty

to warn exists, the basic inquiry is whether it was *reasonably foreseeable* to the manufacturer that the product would be unreasonably dangerous if distributed without a warning.").

We also cautioned in *Robertson* that, "[b]eyond the question of foreseeability, the existence of a duty also involves *policy considerations* underlying the core issue of the scope of the legal system's protection." 171 W.Va. at 612, 301 S.E.2d at 568 (emphasis supplied). Those considerations "include the likelihood of injury, the magnitude of the burden of guarding against it, and the consequences of placing that burden on the defendant." *Id.* (citations omitted).

Each of the factors identified in *Robertson* for the establishment of a cause of action in tort has been satisfied in this case. The policy considerations in this matter would involve an evaluation of the congressional schemes designed to ease the entry of generic manufacturers into the market place, as well as the "fiscal rewards [to the brand-name manufacturers] of name-brand recognition and the commensurate ability to charge a higher price . . . even after [their] exclusive marketing position expires." *Conte v. Wyeth*, *Inc.*, 85 Cal. Rptr.3d 299, 318 (Cal. Ct. App. 2008).

The burden of guarding against injury, as the Court characterized it in *Robertson,* is relatively minimal upon a brand-name manufacturer, particularly because it

already has an existing duty under federal law to update drug labels "as soon as there is reasonable evidence of an association of a serious hazard with a drug." *See* 21 C.F.R. § 201.80(e). As the plaintiffs aptly note, "plaintiffs merely seek to hold Janssen liable for the foreseeable consequence of Janssen's breach of that preexisting federal duty." Additionally, the consequences of placing the burden on the brand-name manufacturer militate in favor of the recognition of a duty, thus creating a significant incentive for it to scrupulously update its labels. As the United States Supreme Court observed in *Wyeth v. Levine,* 555 U.S. 555 (2009*),* tort litigation "uncover[s] unknown drug hazards and provide[s] incentives for drug manufacturers to disclose safety risks promptly." *Id*. at 559. That is particularly imperative where the state mandates substitution of a generic drug for a brand-name drug unless a pharmacist finds the generic unsuitable. *See* W. Va. Code § 30-5-12b(b) (2015). This Court clearly enunciated its strong public policy regarding the safety of prescription drugs in *State ex rel. Johnson & Johnson v. Karl*, 220 W.Va. 463, 647 S.E.2d 899 (2007), holding "manufacturers of prescription drugs are subject to the same duty to warn consumers about the risks of their products as other manufacturers." *Id*. at 468, 647 S.E.2d at 914. The injury in the present case was undeniably foreseeable; misrepresentations on prescription drug labels are obviously extremely likely to injure consumers.

The brand-name manufacturer herein contends that it should not be held liable for deficiencies in a warning label on a drug it did not manufacture or distribute. The

authority presented in support of that argument, however, is readily distinguishable and unpersuasive. Such authority can be divided into two broad categories: (1) court decisions in states, unlike West Virginia, utilizing a "product-identification" approach restricting injury claims involving products to suits against a manufacturer or supplier; and (2) court decisions based upon the previously assumed, but now precluded, theory that a plaintiff's most direct and available recourse would be to sue a *generic* manufacturer.

The most instructive example of the first category is found in the Alabama experience. The Alabama Supreme Court addressed the question now before this Court and ruled for the injured party, very clearly articulating its reasoning. *Wyeth v. Weeks*, 159 So.3d 649 (Ala. 2014). It found the brand-name manufacturer had a duty of care for injuries proximately caused by a mislabeled generic version of its drug. *Id.* at 670. The Alabama Supreme Court reasoned: "[A]n 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." *Id.; accord Conte,* 85 Cal. Rptr.3d at 318 (holding brand-name manufacturer liable for harm caused by generic drug); *Kellogg v. Wyeth*, 762 F.Supp.2d 694 (D. Vt. 2010) (holding brand-name manufacturer has duty to use reasonable care where consumers were provided generic bioequivalent of its drug).

In response to the Alabama Supreme Court decision in *Weeks*, the Alabama Legislature almost immediately enacted legislation prohibiting that type of suit and allowing only suits against product manufacturers.[2] Several other state legislatures have enacted such legislation; thus, courts in all those states obviously and unavoidably will have decisions reflecting the prohibitions established by their respective state statutes.

The rationale of the second category is best illustrated by the Fourth Circuit's decision in *Foster v. American Home Products Corp*., 29 F.3d 165 (4th Cir. 1994). In that case, the court found that a brand-name manufacturer's statements regarding its drug could not serve as a "basis for liability for injuries caused by another manufacturer's drug." *Id*. at 170. That conclusion, over two decades ago, was premised upon the false assumption that a generic manufacturer was "responsible for the accuracy of labels placed on its products[,]" and that generic manufacturers could "add or strengthen warnings and delete misleading statements on labels, even without prior FDA approval." *Id*. at 167. The flaw in the *Foster* reasoning concerning a generic manufacturer's ability to alter warning labels was exposed by the United States Supreme Court's decision in *PLIVA, Inc. v. Mensing*, 564 U.S. 604

[2]*See* Ala. Code 6-5-530(a) (2015) ("In any civil action for personal injury, death, or property damage caused by a product, regardless of the type of claims alleged or the theory of liability asserted, the plaintiff must prove, among other elements, that the defendant designed, manufactured, sold, or leased the particular product the use of which is alleged to have caused the injury on which the claim is based, and not a similar or equivalent product.").

(2011). The regulatory scheme makes it abundantly clear that there is "an ongoing federal duty of sameness" forcing generic manufacturers to utilize, verbatim, the warning labels created by the brand-name manufacturers. *Id.* at 624. The absence of ability to alter the labels renders generic manufacturers immune from state law claims,[3] and the Supreme Court in *Mensing* even "acknowledge[d] the unfortunate hand that federal drug regulation has dealt. . . ." *Id*.[4] Generic manufacturers are *not permitted* to make label additions or deletions, thus dismantling the essential premise of the *Foster* decision of 1994. Its reasoning can no longer serve as a legitimate rationale for any court's decision.[5]

Having examined the West Virginia precedent and the absence of convincing precedent favoring the defendant in this case, it is quite evident that the majority's holding is wrong. The majority's conclusion that a brand-name manufacturer can not be held liable

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[3]*See Mut. Pharm. Co., Inc. v. Bartlett*, 133 S.Ct. 2466, 2470-2471 (2013) (holding state law claims pre-empted by federal law).

[4]The Court in *Mensing* also observed:

> It is beyond dispute that the federal statutes and regulations that apply to brand-name drug manufacturers are meaningfully different than those that apply to generic drug manufacturers. Indeed, it is the special, and different, regulation of generic drugs that allowed the generic drug market to expand, bringing more drugs more quickly and cheaply to the public.

564 U.S. at 626.

[5]The United States Supreme Court in *Wyeth v. Levine*, however, made it clear that brand-name manufacturers can be held liable for failing to warn about known hazards of their drugs. 555 U.S. at 558. That ruling was not altered by the Court in *Mensing*.

where it did not manufacture or distribute the actual pill ingested by a plaintiff is imprudent. The crucial question is what entity is responsible for the omission of a warning on the drug's label about the potential for acute respiratory distress syndrome in this case. It was not the generic manufacturer, who was simply a conduit for the transmission of warning label information. The content of the label was exclusively within the control of the brand-name manufacturer. The right and obligation to include an appropriate warning label must be placed squarely at the feet of the entity responsible for the label's content. The injured party is simply attempting to hold the brand-name manufacturer liable for the foreseeable consequence of its own drafting of the warning label the generic manufacturer is forced to use. Whether this Court agrees with the policies of the federal regulations establishing such a construct or not, the entity responsible for the warning label is Janssen, as the brand-name manufacturer.

The reasoning of a very recent California case is quite persuasive and indicative of the concepts this Court should espouse. In *T.H. v. Novartis Pharmacuetical Corp.,* 407 P.3d 18 (Cal. 2017), a brand-name drug manufacturer argued that it could not be held liable for deficient labeling of its generic counterpart because manufacturers generally can not be sued for injuries caused by a different manufacturer's product. The California Supreme Court responded by chronicling the myriad decisions surrounding generic and brand-name pharmaceutical warning label liability, sifting through those decisions to discern

the better-reasoned authority, and ultimately concluding that an entity which promulgates and maintains exclusive authority over the content of warning labels is most certainly liable for flaws in such labels. *Id*. at 39. The court explained that the brand-name manufacturer essentially sought "an unequivocal declaration that California law relieves a manufacturer of any failure-to-warn liability relating to another manufacturer's products." *Id.* Evaluating the principle that "California's general duty of care is ordinarily applicable to *relieve* a manufacturer of the duty to warn consumers about a product's risks where the product is that of another manufacturer," the court articulated the fundamental reason for such a rule: "A product manufacturer *ordinarily* will have *no control* over the design or safety of another manufacturer's product, the other manufacturer's use of dangerous materials, or any warnings the other manufacturer might place on the product." *Id*. (emphasis supplied). Conversely, a very different circumstance exists in the relationship between a brand-name manufacturer and the manufacturer of its generic equivalent, particularly where the generic manufacturer is forced to use the warning label drafted by the brand-name manufacturer. As the court in *Novartis* observed:

> [P]rescription 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). . . . That key circumstance distinguishes the situation here from those involving the general run of products.

Id. (internal citations omitted). Based upon that critical distinction, the court held that the brand-name manufacturer could be sued "because of the allegedly deficient representations in Novartis's warning label." *Id.* "Novartis is not being sued for dangers inherent in the generic" *drug*; rather, liability civil action was premised upon the "allegedly deficient representations and omissions in Novartis's *warning label*. . . ." *Id.* (emphasis supplied)*; see also*, *Weeks*, 159 So.3d at 672 ("the [tort] claims are not based on the manufacturing of the product but instead allege that the label — drafted by the brand-name manufacturer and required by federal law to be replicated verbatim on the generic version of the medication — failed to warn.").

Adopting a nuanced approach to the issue of brand-name manufacturer liability, the Supreme Judicial Court of Massachusetts recently held that although it would not permit a plaintiff injured by a generic drug to bring an ordinary negligence action against the brand-name manufacturer for failure to warn, such plaintiff could advance a claim against the brand-name manufacturer where the failure to warn rises to the level of recklessness. *Rafferty v. Merck & Co., Inc.,* 92 N.E.3d 1205 (Mass. 2018). The court aptly observed: "If we were to shield brand-name manufacturers entirely from liability for the failure to warn generic drug consumers, we would leave those consumers with no chance of obtaining compensation for their injuries. . . ." *Id.* at 1218.

> In cases where, for instance, a brand-name manufacturer learns that its drug is repeatedly causing death or serious injury, or

> causes birth defects when used by pregnant mothers, and still fails to warn consumers of this danger, public policy does not dictate that these consumers be left with no remedy when those risks are realized, or that the manufacturer have little financial incentive to reveal these risks. We therefore hold that a brand-name manufacturer that controls the contents of the label on a generic drug owes a duty to consumers of that generic drug not to act in reckless disregard of an unreasonable risk of death or grave bodily injury.

Id. at 1219. Pursuant to the approach utilized in *Rafferty*, a brand-name manufacturer that "intentionally fails to update the label on its drug to warn of an unreasonable risk of death or grave bodily injury, where the manufacturer knows of this risk or knows of facts that would disclose this risk to any reasonable person, will be held responsible for the resulting harm." *Id*. at 1220.

The court also recognized in *Rafferty* "that, by imposing on brand-name manufacturers any duty to warn generic consumers, we find ourselves in the minority of courts that have decided this issue." *Id.* Yet, the court was adamant in its resolution of the matter, reasoning that if it prohibited "claims against brand-name manufacturers, [it] would only exacerbate the unfairness of [the federal] regulatory scheme. . . [and] countless consumers would be left without a remedy." *Id*. at 1218. The plaintiff was ultimately granted leave to amend his complaint to state facts sufficient to support a claim of recklessness. *Id.* at 1222.

Courts struggling with evaluation of this complex liability matter have consistently recognized the quandary created by the federal regulatory scheme of generic and brand-name pharmaceuticals. Of the vigorous arguments presented on all sides of the issue, the *Novartis* approach permitting brand-name manufacturer liability is the most legally sound, and the jurisprudence of this state certainly warrants the same conclusion. The majority's refusal to accept that reality is appalling and injurious to the public good. In determining which entity exercised control over the quality of the instrumentality of injury, it would be exceedingly astigmatic to conclude that the generic manufacturer is the *only* one potentially responsible for injury. In the instant case, the brand-name manufacturer did not have a merely peripheral role. It *drafted and maintained control over* the contents of the label providing guidance to the plaintiff; it controlled the degree to which such label could have been modified to provide accurate information regarding dangers of usage; and it should not be permitted to avoid liability under the failure to warn and negligence law of this state.

The failure to impose liability will necessarily invite inattention and neglectfulness by brand-name manufacturers, a transgression for which our citizens will have no legal recourse. The majority's decision is short-sighted and ill-advised. Consequently, I dissent and would have answered the certified question in the affirmative. I am authorized to state that Justice Davis joins me in this dissent.