
IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

WYETH, F/K/A AMERICAN HOME PRODUCTS,
D/B/A WYETH-AYERST LABORATORIES,
KETCHUM, INC., AND DANNEMILLER
MEMORIAL EDUCATIONAL FOUNDATION,

Petitioners,

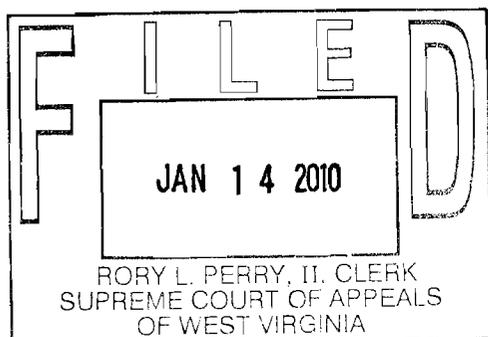
v.

SHIRLEY WHITE, CATHY DENNISON, AND JENNY L. TYLER,
ON BEHALF OF THEMSELVES AND A CLASS
OF OTHERS SIMILARLY SITUATED,

Respondents.

Question Certified by
The Circuit Court of Putnam County, West Virginia
Hon. O.C. Spaulding, Chief Judge

**BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL INC.
AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS**



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I. INTRODUCTION

The Circuit Court interpreted the West Virginia Consumer Credit and Protection Act (the “Act”) to permit a private plaintiff to pursue a claim for monetary damages on behalf of themselves and other patients who have suffered no personal injury of any kind and who are not alleged to have relied in any way (either directly or through their physicians) on the supposed deceptive acts of Wyeth violating the Act. For a claim alleging deception in marketing a prescription drug or medical device, the Act’s “as a result of” clause requires individual patients to show actual reliance on the defendant’s allegedly misleading statement in order to recover money damages. The Circuit Court’s rejection of a “reliance” requirement is unnecessary to achieve the purposes of the Act in such circumstances; and worse, it would create serious harmful consequences not intended by the Legislature when adopting the Act.

II. STATEMENT OF INTEREST

PLAC is a non-profit association with 101 corporate members representing a broad cross-section of American and international product manufacturers. These companies seek to improve and reform the law in the United States and elsewhere, with emphasis on the law governing the liability of product manufacturers. PLAC’s perspective is derived from experiences spanning a diverse group of industries in the manufacturing sector. In addition, several hundred of the leading product liability defense attorneys in the country are sustaining (non-voting) members. Since 1983, PLAC has filed over 800 briefs as *amicus curiae* in both state and federal courts, seeking balance, fairness, and reasonableness in the application of laws affecting product manufacturers. (A list of PLAC’s corporate members is attached as Appendix A.)

PLAC files this Brief in support of Petitioners Wyeth, et al., to underscore that the Circuit Court’s decision is an unnecessary and faulty interpretation of the remedial provisions of the Act

that has ramifications beyond consumer protection law. If, as the Circuit Court held, reliance resulting in actual injury is not required, this will have far-reaching negative effects on the development of product liability law and litigation in this State, as attorneys recast traditional product liability claims as consumer protection claims for which they seek class certification. This is a matter of great importance to the many members of PLAC whose products are sold within the State, and to the West Virginia residents who regularly purchase and use such products and whose interests will be harmed by such an interpretation of the Act.

This Brief will assist the Court by discussing the various well-enforced mechanisms by which deceptive marketing of drugs and medical devices have traditionally been prevented or remedied and the fundamental distinction between government enforcement and private actions addressing violations of the Act. It will discuss why every plaintiff, especially class representatives, should be required to plead and prove actual injury resulting from reliance on a defendant's allegedly deceptive conduct, lest the failure to enforce such requirements lead to widespread abuse of the consumer protection law, particularly in class actions.

III. RELEVANT FACTS

Three named plaintiffs filed a complaint in 2004 alleging that Defendants had violated the Act in the marketing and sale of Wyeth's hormone therapy ("HT") prescription drugs, FDA-approved prescription drugs used by women to treat serious menopausal symptoms. On behalf of a putative class of all purchasers of HT in West Virginia,¹ Plaintiffs seek to recoup the purchase price paid for the HT drugs or statutory damages under the Act.²

¹ Amended Complaint ¶ 6. The amended complaint in 2008 replaced two of the three class representatives.

² *Id.* ¶ 7.

Plaintiffs allege no personal injuries from their own HT use,³ nor that any putative class member has actually suffered such an injury. Rather, Plaintiffs claim that Wyeth promoted its product to doctors and patients through misleading statements in HT advertising, marketing, and labeling. However, Plaintiffs do not allege that they or their doctors had ever received or read – much less relied upon – the alleged misrepresentations.

The record resulting from depositions of Plaintiffs and their doctors shows that Plaintiffs neither received information about HT from Wyeth nor decided to use HT in reliance on anything they learned from Wyeth, and further that their doctors did not consider information from Wyeth in prescribing HT to them.⁴

IV. DISCUSSION

A. THE CERTIFIED QUESTION

Does the “as a result of” language in Section 46-6-106(a) of the West Virginia Consumer Credit and Protection Act require a plaintiff, in a private cause of action under the Act, to allege and prove that he or she purchased a product because of and in reliance upon an unlawful deceptive act?

B. RELEVANT STATUTES

Two provisions in the Act pertain most directly to the certified question. First, Section 106 provides for a private right of action to remedy a violation of the Act. It states that “[a]ny person who purchases ... goods ... and thereby suffers any ascertainable loss of money or property... *as a result of* the use or employment by another person of a method, act or practice ... declared to be unlawful by the provisions of this article may bring an action ...”⁵ Second, Section 102 defines the kind of seller wrongdoing which may be held unlawful: “Unfair methods of competition and unfair

³ *Id.* ¶ 7.

⁴ See Wyeth’s Memorandum in Support of Motion to Dismiss or, in the Alternative, for Summary Judgment Due to Lack of Standing, filed Oct. 27, 2008, at 8-14 [check page cites] and deposition transcripts attached as Exhibits 3, 4, 5, 7, 11, and 12 thereto.

⁵ W.VA. CODE § 46A-6-106(a) (2009) (emphasis added).

or deceptive acts or practices' means and includes ... (M) The act, use or employment by any person of any deception, fraud, false pretense, false promise or misrepresentation, or the concealment, suppression or omission of any material fact with intent that others rely upon such concealment, suppression or omission, in connection with the sale or advertisement of any goods..., *whether or not any person has in fact been misled, deceived or damaged thereby...*"⁶

C. THE "AS-A-RESULT-OF" CLAUSE IN SECTION 106 REQUIRES RELIANCE BY PLAINTIFFS.

Plaintiffs allege that they "suffered ascertainable loss as a result of the Defendants' unfair and deceptive acts." However, they do not plead, nor apparently can they prove, that Defendants made any specific deceptive statement upon which they relied, either directly or indirectly through their doctors, thereby causing injury to them. They argue that such reliance causing injury is unnecessary. While finding that the Act could reasonably be interpreted to require such reliance, the Circuit Court believed that to do so might be inconsistent with this Court's policy to give a liberal construction to remedial statutes. So it held that "the 'as a result of' language in W.Va. Code 46-6-106(a) does not require proof of reliance, but only proof of causation."⁷

The critical defect in the Circuit Court's decision may be simply stated: *one cannot be injured "as a result of" a deceptive act without actually being deceived.* The Court below erred because there can be no "proof of causation" in a case like this without "proof of reliance." There are several reasons for this conclusion.

⁶ W.VA. CODE § 46A-6-102(M) (2009) (emphasis added).

⁷ Amended Order at 33, 39-40. The Court's subsequent discussion is less than a model of clarity. First, it says that Plaintiffs need not prove "that they, in fact, relied on the statute." *Id.* at 41. This odd statement is followed by a classic logical fallacy: the Court's comment that Plaintiffs can prove causation by showing "only that they were harmed when Wyeth engaged in deceptive practices." *Id.* Of course, congruity in time is not the same as causation. Yet later, the Court concludes that Plaintiffs need not to plead or prove that they bought HT drugs "because of or in reliance upon a deceptive practice" of Wyeth. *Id.* at 45. While one can read such statements as rendering both "causation" and "reliance" meaningless, this brief will focus solely on the "reliance" element, which the Court clearly rejected.

First, the language and structure of the Act itself show that reliance is necessary. While it explicitly defines a “deceptive act” so as not to require proof that “any person has in fact been misled, deceived or damaged thereby,”⁸ when it creates the private cause of action, it with equal specificity requires proof that the plaintiff’s loss is “a result of” such a deceptive act.⁹ The distinction is obvious: a mandatory element of a private cause of action for money damages is proof that the plaintiff has in fact been misled or damaged by the deceptive act.

Second, such a reliance requirement is clearly needed in order to effectuate the “as a result of” language in Section 106. The Legislature provided for recovery of a plaintiff’s loss, *but only if* it is shown to be caused by a defendant’s deceptive conduct violating the Act. Rejecting reliance expands the private damages “remedy” by, in effect, reading the “as a result of” limiting language out of the Act. This case illustrates why such “causation” *must* include reliance. Plaintiffs here have not explained how there can be any causation without reliance. Although they vaguely allege a loss “caused” by Defendants, they nowhere spell out how this causation happens.

Third, this Court’s prior decision in *Orlando v. Finance One of West Virginia, Inc.*, 179 W.Va. 447, 369 S.E.2d 882 (1988), shows that an injury actually caused by the alleged violation is required. In that case, plaintiff borrowers alleged that their lender, unbeknownst to them, had inserted a clause into their loan papers purporting to waive certain of their rights. *Id.* at 448, 369 S.E.2d at 883. When the borrowers defaulted, the lender made no effort to enforce that clause. Nonetheless, the borrowers filed a class action seeking both an injunction and monetary penalties. Although this Court found that including the clause violated the Act, *id.* at 453, 369 S.E.2d at 888, it did not allow the borrowers to sue under Section 106 because they had sustained no ascertainable loss as a result of the unfair practice. *Id.* Rather, the proper remedy was injunctive relief. The

⁸ W.VA. CODE § 46A-6-102(M) (2009).

⁹ W.VA. CODE § 46A-6-106(a) (2009).

Court's opinion demonstrated quite clearly the difference between Sections 102 and 106. It was not enough that the lender had inserted an unenforceable clause into the loan documents; the plaintiffs were also required to show that they suffered a loss as a result of the inclusion of that clause.

Similarly, here, a loss compensable under the Act must be suffered as a result of the alleged deceptive act of the Defendants, whatever that may be in each individual plaintiff's case. Following the Court's holding in *Orlando*, it is not enough to allege that Plaintiffs purchased a product for which Defendants made deceptive marketing statements; Plaintiffs must also allege that they each suffered a loss as a result of a particular deceptive act. In the context of a patient taking a prescribed drug, this clearly requires a showing that the patient, either directly or indirectly via the treating physician, relied upon the alleged misrepresentation in deciding to use the drug. Without such reliance, there is no viable claim. This conclusion results from a simple reading of the statute as interpreted in the *Orlando* case.¹⁰

Fourth, a reliance requirement is supported by authorities construing similar language in other states' parallel consumer protection laws. They have recognized that in a misrepresentation case, causation and reliance are essentially the same thing – that is, if a defendant's statement did not influence the decision to purchase the product, then it did not cause a loss recoverable under the consumer protection statute. *See Group Health Plan, Inc. v. Philip Morris, Inc.*, 621 N.W.2d 2, 14 (Minn. 2001) (defendant's conduct must have had some impact on smokers' use of tobacco products that caused their damages); *Weinberg v. Sun Co.*, 777 A.2d 442, 446 (Pa. 2001) (interpreting "as a result of" to require proof that plaintiff heard and believed the false advertising); *In re Tobacco II*

¹⁰ Other prior decisions supporting the same reading of Section 106 include *State of West Virginia ex rel. Miller v. Secretary of Education*, No. 2:90-0590, 1993 WL 545730, at *12-13 (S.D.W.Va. Sept. 30, 1993) (refusing class certification in a consumer fraud case after rejecting plaintiffs' argument that there was no need for "an individualized ... investigation of what misrepresentation each member of the putative class relied upon"), and *In re Baycol Prod. Liab. Litig.*, No. 02-199, MDL-1431, at 3 (D. Minn. Dec. 9, 2008) (declining certification of a class of West Virginia prescription drug users after concluding that individual plaintiffs must prove losses "because of [defendant's] conduct in the marketing and sale of Baycol").

Cases, 207 P.3d 20, 40-41 (Cal. 2009) (named class plaintiffs must show reliance on advertising); *De Bouse v. Bayer, AG*, ___ N.E. 2d ___, 2009 WL 4843362 (Ill. 2009) (dismissing plaintiff's claim alleging deceptive statements advertising a prescription drug where she had "neither seen nor heard any such statement [and therefore] cannot have relied on the statement and, consequently, cannot prove proximate cause").

Finally, learned commentators have reached the same conclusion. *See, e.g.*, Sheila B. Scheuerman, *The Consumer Fraud Class Action: Reining in Abuse by Requiring Plaintiff(s) to Allege Reliance as an Essential Element*, 43 Harv. J. on Legis. 1 (2006) (in order to bring a private cause of action, the individual should be required to show reliance); Alan S. Brown & Larry E. Hepler, *Comparison of Consumer Fraud Statutes Across the Fifty States*, FDCC Quarterly, Spring 2005, at 308 (after conducting a review of all fifty states' consumer protection laws, interpreting the "as a result of" language in the West Virginia Act to require reliance).

D. IT IS NOT NECESSARY TO REJECT A RELIANCE REQUIREMENT TO PROTECT CONSUMERS.

The Circuit Court chose to reject a reliance requirement for private claims on the grounds that this was necessary to effectuate the purpose of the Act to protect consumers. In reaching this conclusion, the Court failed to take into account (1) the difference between public and private enforcement under the Act, and (2) the multiple levels of protection for patients buying prescription drugs or medical devices, and the remedies already available to consumers allegedly injured by such products. Such factors make it unnecessary to adopt the Circuit Court's expansive reading of the "as a result of" language in order to accomplish the Act's purpose.

1. **The public policy behind consumer protection acts and the distinction between public enforcement and private lawsuits are important in deciding how to construe the provisions of the Act's private cause of action.**

The Legislature passed the Act in 1974, relying on common law decisions that protect consumers, the Uniform Consumer Credit Code, and the National Consumer Act.¹¹ The Act developed in sync with consumer protection law in much of the rest of the country and was intended to complement the existing federal consumer protection law. West Virginia courts, following the Legislature's directive,¹² have recognized that precedent under the FTC Act may be more than ordinarily persuasive in construing the Act. *See e.g., State ex rel. McGraw v. Bear, Stearns & Co., Inc.*, 217 W.Va. 573, 577, 618 S.E.2d 582, 586 (2005) (noting Section 46A-6-101 and that "courts should be guided by applicable federal statutes such as the Federal Trade Commission Act in construing article 6."). For these reasons, PLAC believes that the Court may be assisted by a brief review of the development of federal consumer protection law, adoption of similar consumer protection laws in the states, and the creation of private rights of action to enforce such laws.

Before consumer protection statutes allowed private causes of action, consumers misled into purchasing a product had to rely on common law fraud and misrepresentation claims. Such claims were sometimes difficult to prove because, for example, plaintiffs had the burden of showing that the defendant *intended* to deceive them. In addition, those claims did not provide an effective means to stop deceptive conduct before it caused harm or when the injury was small.

In 1914, Congress established the Federal Trade Commission ("FTC") and in 1938 expanded its authority to regulate consumer transactions.¹³ When Congress first set up the FTC, it considered,

¹¹ Vincent P. Cardi, *The West Virginia Consumer Credit and Protection Act*, 77 W. Va. L. Rev. 401, 411-12 (1974).

¹² W. VA. CODE § 46A-6-101 (2009).

¹³ Wheeler-Lea Act of 1938, Pub. L. No. 75-447, § 3, 52 Stat. 111, 111(1938), codified as amended at 15 U.S.C. § 45(a) (2009).

but ultimately rejected, providing for private causes of action. Legislators expressed a general concern that the vagueness of the terms “unfair” and “deceptive” could lead to limitless lawsuits. One Senator warned, “a certain class of lawyers, especially in large communities, will arise to ply the vocation of hunting up and working up such suits.”¹⁴ Members feared that “[t]he number of these suits ... no man can estimate.”¹⁵ Members also expressed unease that, given the broad wording of the statute, firms would have no way of knowing whether a business practice was “illegal” until they were hit with a lawsuit.¹⁶ What makes this legislative history so interesting today is that many members of Congress foretold the very problems that would arise in various states when they adopted private causes of action in their consumer protection laws.

Congress specifically declined to provide a private right of action. It addressed the above concerns by providing for a five-person nonpartisan commission, whose membership would include expertise in business practicalities, that would determine whether conduct was unfair or deceptive.¹⁷ In addition, Congress decided that the FTC’s authority would be primarily injunctive in nature; after finding a deceptive practice, it would issue an order requiring the offender to stop that activity. If the offender disobeyed the order, then the Commission could impose hefty fines. In a bipartisan vote, Congress firmly rejected including a private right of action.¹⁸

Many states later adopted their own “mini-FTC acts.” The purpose of these laws, which were similar to the federal act, was to provide additional consumer protection, mostly by allowing state attorneys general or other government officials to protect their state’s consumers.¹⁹ Some also created private rights of action in order to supplement such enforcement by state officials. Here in

¹⁴ 51 Cong. Rec. 13,113, 13,120 (1914) (statement of Sen. Stone).

¹⁵ *Id.*

¹⁶ *See, e.g.*, 51 Cong. Rec. 11,084-109, 11,112-16 (1914).

¹⁷ *See* 51 Cong. Rec. at 11,108-09.

¹⁸ *Id.* at 13,149-50 (colloquy between Sens. Cummins and Clapp debating need for private remedy in addition to public enforcement).

¹⁹ *See* Victor E. Schwartz & Cary Silverman, *Common-Sense Construction of Consumer Protection Acts*, 54 Kan. L. Rev. 1, 15-16 (2006).

West Virginia, in addition to enacting the private right of action which is now at issue, the Legislature gave the state's Attorney General authority to enforce the Act.²⁰ In seeking to stop violations of the Act, the Attorney General (unlike private plaintiffs) has *not* been required to show that any individual is actually deceived or injured by a manufacturer's misleading advertising or other alleged unfair or deceptive act.

The AG's office has aggressively exercised its authority under the Act. Three attorneys are assigned full-time to the Consumer Protection Division to enforce the Act and to "protect West Virginia citizens from those that would harm them."²¹ As one federal court has said, the Attorney General's enforcement has been "motivated [and] effective in protecting the consumers of West Virginia." *Capital One Bank (USA), N.A., et al. v. Darrell V. McGraw, Jr.*, Civil Action No. 2:08-cv-00165 (S.D. W. Va. June 26, 2008).

In short, as with state consumer protection laws elsewhere, the Act places significant authority in the hands of an elected public official who has been successful in challenging wrongdoers. As a result, there is no need to read the Section 106's "as a result of" clause so as to create an expansive private right of action.

Comparing traditional tort lawsuits versus statutory public consumer protection enforcement is also instructive. Tort law is private – its intent being to redress a wrong between two parties – as opposed to public – intended to protect the populace from various ills. Thus, it is logical that the private cause of action in a consumer protection statute should require a plaintiff to demonstrate actual harm directly resulting from an unfair or deceptive practice, even though the Attorney General may be able to enjoin the exact same practice before any individual is actually harmed.

²⁰ See, e.g., W. VA. CODE § 46A-7-101 (1974) (creating a Division of Consumer Protection under the Attorney General's authority); W. VA. CODE § 46A-7-102 (1974) (granting the Attorney General investigatory, educational, and administrative authority).

²¹ W. Va. Attorney General, *2007 Annual Report: A Report on the Activities of the West Virginia Attorney General's Consumer Protection and Antitrust Divisions*, http://www.wvago.gov/pdf/annualreports/2007_report.pdf.

Unfortunately, including both public and private enforcement mechanisms in state consumer protection laws has sometimes blurred the line between them and led such fundamental differences in purposes and incentives to go unrecognized. For example, while government enforcement is primarily injunctive and designed to stop deceptive conduct before it causes harm, private lawsuits generally provide remedies for people who have already suffered monetary harm. And while government officials must consider broad public interest and policy issues, private lawsuits are personal and governed by very different incentives. Government enforcement is limited by public accountability as well as human and financial resources and priorities, but private lawsuits have very different boundaries that are set by, among other things, the financial motives of the suing parties, standing requirements, and need for plaintiffs to show a violation actually causing damages.

2. **Other public and private mechanisms for protecting patients are important in deciding how to construe the provisions of the Act's private cause of action on behalf of such patients.**

A major problem with the Circuit Court's decision is that it ignores the factual circumstances of this case. The Court below apparently believed that a "liberal" reading of the Section 106's "as a result of" clause is needed to prevent or remedy failures by manufacturers to make adequate disclosures of product risks. But this is not a routine consumer credit case, nor does it relate to a common commercial transaction. Rather, it involves the private health concerns and professional medical care of the numerous patients who are putative class members. PLAC believes that the Court may be assisted by a brief review of the myriad of regulatory and business realities that already protect such patients and thus undermine the rationale for the decision below.

a. **FDA regulation.**

The United States Food and Drug Administration ("FDA") is the primary agency concerned with regulation of drugs and medical devices. The FDA describes its role as follows:

“The mission of FDA is to enforce laws enacted by the U.S. Congress and regulations established by the Agency to protect the consumer’s health, safety, and pocketbook. *** The law is intended to assure the consumer ... that drugs and devices are safe and effective for their intended uses ... and that all labeling and packaging is truthful, informative, and not deceptive.”²²

To accomplish these responsibilities, the FDA regulates the labeling of prescription drugs and medical devices.²³ The FDA enforces stringent federal regulations which control the development, manufacture, and labeling of such products.²⁴

b. Professional obligations of health care providers.

In caring for their patients (such as *all* the putative class members here), treating physicians must meet the applicable standard of care in prescribing and administering drugs (or implanting medical devices), and in providing appropriate follow-up care.²⁵ Licensed pharmacists filling prescriptions must likewise meet the standard of care. In using drugs, such health care professionals must consider product risks pertinent to their patients’ specific medical conditions and needs.²⁶

c. FTC actions against deceptive advertising.

Under Section 5 of the Federal Trade Commission Act, 15 U.S.C. § 45 (2009), “unfair or deceptive acts or practices in or affecting commerce” are unlawful, and the FTC routinely reviews advertising claims in order to uncover and stop such conduct likely to harm consumers. It “protects consumers from unfair or deceptive advertising and marketing practices that raise health and safety concerns, as well as those that cause economic injury.”²⁷ The agency can act – even without proof of actual injury – to prevent deceptive acts that pose risks to consumers.²⁸ It has often used its

²² <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm090410.htm>.

²³ See 21 CFR 201.56(d) and 201.57 (2009).

²⁴ Frank C. Woodside, III, *Drug Product Liability* (2007), at § 1.02[1], citing 21 CFR § 310.3 *et seq.*

²⁵ See W. VA. CODE § 55-7B-3 (2009) (describing the elements of proof required in a medical professional liability claim).

²⁶ Frank C. Woodside, III, *Drug Product Liability* (2007), at §§ 1.05[2-3].

²⁷ <http://www.ftc.gov/bcp/bcpap.shtm>.

²⁸ See ABA Section of Antitrust Law, *Antitrust Law Developments* (5th ed. 2002), at 616-18.

authority in cases involving non-prescription drugs or supplements,²⁹ even requiring a manufacturer to add warnings about potential health risks to its advertising, labeling, and promotional materials.³⁰

d. State attorney general enforcement.

As previously noted, state attorneys general have significant power to enforce the consumer protection laws of their states, as exemplified by aggressive enforcement of the Act by the Attorney General of West Virginia. Most notably, the AG's office here has brought cases under the Act involving the following prescription drugs: Vytorin (regarding the release of negative test results),³¹ Risperdal and Duragesic (regarding language in advertising materials and resulting in an award of civil penalties totaling nearly \$4.5 million),³² and Oxycontin (regarding potential addiction and resulting in a settlement of \$10 million).³³ In these cases, the Attorney General has taken the position that the State is not required to demonstrate reliance.

e. Competition.

The Circuit Court also ignored the fact that competitors can, and often do, pursue various means for challenging false or deceptive marketing claims.

- They can seek to stop misleading advertising claims via industry self-regulation, such as through a complaint to the National Advertising Division of the Better Business Bureau.³⁴
- They can seek government intervention by:

²⁹ *Id.* at notes 182-83. *See, e.g., Bristol-Myers Co.*, 102 F.T.C. 21 (1983) (misrepresenting the safety and efficacy of non-prescription pain relievers).

³⁰ *See, e.g.,* consent decree in *FTC v. MET-Rx USA, Inc.*, No. 992-3180 (1999).

³¹ Press Release, *Attorney General McGraw Settles Unfair Marketing Charges Against Merck & Co., Inc., and Others Regarding Vytorin®* (July 15, 2009), <http://www.wvago.gov/press.cfm?ID=488&fx=more>.

³² Press Release, *Court Orders Johnson & Johnson to Pay Millions for Misleading WV Doctors; Attorney General McGraw States False Advertising* (March 2, 2009), <http://www.wvago.gov/press.cfm?ID=467&fx=more>.

³³ Press Release, *Deputy Attorney Generals [sic] Clear up Misconception About Oxycontin Suit* (Sept. 19, 2008), <http://www.wvago.gov/press.cfm?ID=448&fx=more>.

³⁴ *See Sanderson Farms, Inc. v. Tyson Foods, Inc.*, 549 F. Supp. 2d 708, 718, n. 7 (D. Md. 2008) (discussing the National Advertising Division's authority and enforcement power); *see also*, <https://www.nadreview.org> (summarizing case reports, including decisions rendered in disputes between prescription drug companies).

- the FDA,
 - the FTC, or
 - state Attorneys General.
- They can sue, both to stop the deception and to recover any money damages under the federal Lanham Act, when they are damaged by reason of a competitor's use of false statements in advertising.³⁵ While injunctive relief is available under the Lanham Act without demonstrating reliance, if money damages are sought, reliance must be proven. *L.S. Heath & Son, Inc. v. A.T.&T. Information Sys., Inc.*, 9 F.3d 561, 575 (7th Cir. 1993); *see also, Parkway Baking Co. v. Freihofer Baking Co.*, 255 F.2d 641, 648-49 (3d Cir. 1958) (same).

3. **Patients actually injured as a result of relying on a defendant's deceptive or misleading warnings already have remedies.**

Those consumers actually injured in their person or property as a result of relying on a manufacturer's deception already have remedies. For personal injuries, this is, of course, the primary purpose of state product liability laws. *See Morningstar v. Black & Decker Manuf. Co.*, 162 W. Va. 857, 253 S.E.2d 666 (1979) (discussing generally the evolution of strict liability in tort in the United States and West Virginia particularly). Also available for other monetary losses are common law and breach of warranty claims, which have been modified to provide additional relief to consumers.³⁶ In addition, the Act, by permitting recovery of attorney fees and expenses, enables plaintiffs with small monetary claims to sue where their losses actually result from reliance on a

³⁵ 15 U.S.C. § 1125(a)(1) (2009); *see also, Scotts v. United Indus. Corp.*, 315 F.3d 264 (4th Cir. 2002) (discussing generally the burden of proof for a claim brought by a competitor under the Lanham Act).

³⁶ For example, the CCPA provides that warranty claims cannot fail due to lack of privity between the consumer and the defendant, W. Va. Code § 46A-6-108 (2009), and warranties cannot be disclaimed in consumer transactions. W. Va. Code § 46A-6-107 (2009). As the Court is aware, other provisions of the CCPA also modify the holder in due course rules applicable to negotiable instruments to mitigate the harshness of those rules as applied to consumers and eliminate certain defenses by creditors in consumer sales. W. Va. Code § 46A-2-102 (2009); *State ex rel. McGraw v. Scott Runyan Pontiac-Buick, Inc.*, 194 W.Va. 770, 779, 461 S.E.2d 516, 525 (1995).

defendant's fraudulent acts. Thus, any widespread harm caused by failure to provide an adequate warning about the side effects of a drug or medical device is likely to give rise to multiple liability claims against the manufacturer. The ready availability of such remedies reinforces the "consumer protection" purposes of the Act and undermines the Circuit Court's notion that the "as a result of" language must be read in an overly expansive manner in order to protect consumers.

E. REJECTING A REQUIREMENT THAT PLAINTIFFS SHOW ACTUAL INJURY RESULTING FROM "RELIANCE" ON A DEFENDANT'S DECEPTIVE ACT COULD HAVE DIRE CONSEQUENCES.

The Circuit Court's decision to permit uninjured patients who did not rely upon the alleged deceptive acts of the defendant drug manufacturer to pursue money damages under the Act will have a negative impact on product liability litigation, and the likely consequences of allowing a case like this to go forward will be serious. Sound policy considerations counsel that such results could not have been intended by the Legislature.

As previously described, accepting Plaintiffs' answer to the certified question has the practical effect of emasculating the "as a result of" requirement, thus ignoring the intent of the Legislature. This path has, unfortunately, been trod before in a few other states (much to their later chagrin) where a consumer protection law did not unambiguously require private plaintiffs to show fundamental elements such as actual financial loss or reliance.³⁷ Loose construction makes such laws ripe for abuse, by creating a back door for evading the basic tenets of tort law – and, as one commentator has noted, especially susceptible to class-action abuse:

³⁷ See Victor E. Schwartz & Cary Silverman, *Common-Sense Construction of Consumer Protection Acts*, 54 Kan. L. Rev. 1, 18-21, 50-57 (2006).

“By themselves, these lawsuits are not troubling. But when the consumers themselves have never relied on a manufacturer’s misrepresentation, have never independently sought redress, and likely will never receive meaningful benefit from a suit (though their lawyers stand to make millions of dollars), these class actions become more akin to corporate blackmail than to consumer protection.”³⁸

Thus, some plaintiffs’ lawyers, who may be unable to prove the fundamental elements of another statutory action, a common tort claim, or a contract claim, are enticed to couch their lawsuits in consumer-protection terms. *See, e.g., Korea Supply Co. v. Lockheed Martin Corp.*, 29 Cal. 4th 1134, 1150-53 (2003) (the consumer protection claim “is not an all-purpose substitute for a tort or contract action”); *see also, Avery v. State Farm Mut. Ins. Co.*, 835 N.E.2d 801, 835-38 (Ill. 2004) (holding, in a case that began as a claim for breach of contract, was amended to add a consumer fraud claim that simply restated the contract claim, and was amended yet again in an effort to avoid dismissal, that “a plaintiff must prove that he or she was actually deceived by the misrepresentation”). This is a particular problem in product liability lawsuits where a plaintiff unable to show a defective design alternatively asserts liability under a consumer protection law based on alleged misrepresentation of a product’s design or level of safety or effectiveness, or a failure to disclose certain risks associated with it.³⁹ Even if the present case does not provide a clear example of such abuse, the Court should be cognizant of the impact of an expansive interpretation of the Act on future tort law cases.

One example of this trend is a group of lawsuits brought by fourteen residents and filed initially in eight states, seeking \$5 billion from DuPont stemming from its use of the popular nonstick coating Teflon. The claims, filed in July 2005, alleged that a chemical used in Teflon was dangerous and that DuPont failed to adequately warn consumers of the risk, despite no hard evidence

³⁸ Sheila B. Scheuerman, *The Consumer Fraud Class Action: Reining in Abuse by Requiring Plaintiff(s) to Allege Reliance as an Essential Element*, 43 Harv. J. on Legis. 1, 2 (2006)

³⁹ *See generally* Philip E. Karmel & Peter R. Paden, *Consumer Protection Law Claims in Toxic Torts Litigation*, 234 N.Y.L.J. 3 (2005) (commenting that consumer protection lawsuits are the latest in a “recurring motif in toxic torts litigation” where innovative plaintiffs’ attorneys seek to assert a product liability claim without the need to prove an actual injury by the product).

that the chemical was harmful to humans when used in cookware.⁴⁰ While this sounds like a typical product liability lawsuit, plaintiffs' lawyers quickly pointed out that, under consumer protection laws, they "don't have to prove that it causes cancer," but only that the company did not fully disclose information to the public.⁴¹ Such suits do not involve the everyday consumer transactions for which consumer protection claims were enacted. Rather, they are "repackaged" product liability claims where lawyers would have difficulty showing that the product is defective, caused an injury, or resulted in a loss to the plaintiff. Notably, the Dupont cases were dismissed after the Court denied class certification, noting that the plaintiffs could not meet the typicality requirement of Federal Rule 23 since the consumer fraud statutes in many states require plaintiffs to show reliance upon a defendant's alleged misstatements. *In re Teflon Products Liability Litigation*, 4:06-md-01733, (S.D. Iowa, Dec. 5, 2008).

Despite suits of this nature, courts thus far appear to have kept their collective finger in the dike. *Shreve v. Sears, Roebuck & Co.*, 166 F. Supp. 2d 378, 416-20 (D. Md. 2001), provides another good example. Plaintiffs brought a product liability action against the manufacturer of a snow thrower, alleging that Mr. Shreve was injured because of a defect in a safety device built into its design. *Id.* at 410-16. Plaintiffs also alleged that the defendants committed a deceptive trade practice when they failed to communicate to Mr. Shreve that the machine lacked an adequate guard and made other misrepresentations in the owner's manual. *Id.* at 417. The court granted summary judgment for the defendants after finding that the mere sale of a defectively designed product is not a violation of the consumer protection law. *Id.* at 418-20.

Yet another example is a lawsuit charging that OxyContin did not live up to its advertising claims as providing "smooth and sustained" relief. In *Williams v. Purdue Pharma Co.*, 297 F. Supp.

⁴⁰ See Amy Cortese, *Will Environmental Fear Stick to DuPont's Teflon?*, N.Y. Times, July 24, 2005, at 34.

⁴¹ John Heilprin, *DuPont Hit With \$5 Billion Suit Over Teflon Risks*, Assoc. Press (7/5/05), available at <http://www.law.com/jsp/article.jsp?id=1121763922530> (quoting plaintiffs' attorney Alan Kluger).

2d 171 (D.D.C. 2003), the dispute was essentially a product liability claim, yet the complaint alleged a violation of the District of Columbia’s consumer protection act. As the defendant observed, “[t]his is a product liability suit in which plaintiffs fail to allege any physical injury.” *Id.* at 175-76. Relying on a similar Texas case in which an uninjured plaintiff had sued a drug manufacturer for not warning of a potential risk, the court agreed and dismissed the claim. *Id.* at 177-78 (citing *Rivera v. Wyeth-Ayerst Labs.*, 283 F.3d 315 (5th Cir. 2002)).

West Virginia should adopt this same common-sense approach. When a claim sounds in product liability or contract law, its courts should not permit plaintiffs to assert claims under the Act. The courts need not give an overly expansive reading to the “as a result of” language in Section 106 in order to enforce the purposes of the Act when the real purpose of a lawsuit is to create a back-door escape from the fundamental requirements of tort law. Certainly, the Court need not interpret such language expansively when traditional tort or contract law will suffice.

Such an approach would also help to avoid the worst abuses of the consumer protection litigation – i.e., questionable class action lawsuits on behalf of large groups of *uninjured* product purchasers. Such lawsuits place tremendous pressure on defendants to settle regardless of the merits or whether class certification is appropriate, simply because an unfavorable ruling—however misguided—could result in millions (or billions) of dollars in liability. *See, e.g., In re Rhone-Poulenc Rorer, Inc.*, 51 F.3d 1293, 1298 (7th Cir. 1995) (stating that defendants in class action lawsuits “may not wish to roll these dice. That is putting it mildly. They will be under intense pressure to settle.”).

Affirming the Circuit Court’s answer to the certified question here would encourage just such lawsuit abuse. Consider the present case. Plaintiffs themselves (and, presumably, almost all those they purport to represent) have suffered no injury. They do not even allege an increased risk of harm

and a need for “medical monitoring.” To the contrary, most received what they hoped for – that is, the benefits of HT therapy. Yet they demand, collectively, millions of dollars based on wholly speculative risks which never materialized. Such a recovery would be a windfall for Plaintiffs and their lawyers. It would not help anyone alleging actual physical injuries from HT; indeed, class actions like this use up valuable resources that could be better devoted to resolving those claims.

Policy considerations also support the conclusion that the Legislature did not intend the Act to be misused in this manner. Endorsing Plaintiffs’ claims would ultimately harm most consumers. The Fifth Circuit discussed this reality years ago in *Willett v. Baxter International, Inc.*, 929 F.2d 1094 (5th Cir. 1991), where plaintiffs sought damages because they were allegedly at risk due to a “potentially fatal” defect in implanted heart valves. While there were about 19,000 patients, only seventeen actually had a problem. *Id.* at 1096. As the court explained, “[t]he damages of the seventeen are presumably incorporated into the price of the product and spread among the nineteen thousand who have purchased the valve.” *Id.* at 1100 n.20. The court concluded that it would be unwise to allow such a lawsuit to go forward:

“Because [under a regime rewarding plaintiffs having no actual injury] no loss-spreading occurs, the money flows in a circle, from each patient (in the form of a higher price) to the company back to the same patient (in the form of a fear recovery), with a substantial portion of the higher price skimmed off for attorneys’ fees. In addition, the higher price will place the product beyond the economic reach of at least some of the patients, forcing them to turn to the next best (affordable) alternative. We see little reason to adopt such a system.”

Id. The economic consequence of allowing consumers to recover even though their products have worked properly is what one court has labeled “excess compensation.” *In re Bridgestone/Firestone Tires Prods. Liab. Litig.*, 288 F.3d 1012, 1017 at n.1 (7th Cir. 2002) (explaining how allowing such recovery would unwisely both “overcompensate buyers as a class and induce manufacturers to spend inefficiently much to reduce the risks of defects”); *see also Lee v. General Motors Corp.*, 950 F. Supp. 170, 175 (S.D. Miss. 1996) (“If Courts were to allow cases such as this to go forward, the

costs of doing business would be so burdensome and so expensive that suppliers, manufacturers, and most consumers would suffer greatly.”).

Of course, in cases like this one, some plaintiffs may gain in the short run. But in the long run, *all* consumers will lose, as they bear the burden of higher prices to cover the manufacturers’ costs of routinely making (or just defending against) such windfall payments. Product manufacturers one way or another build such costs into the price of their products, and so the vast majority of consumers will simply have to pay more. And if enough expensive, time-consuming, and bankruptcy-threatening class-actions are filed, there may come a point where consumers who have real injuries receive less compensation.⁴² Given the increasing cost of health care in our country, not just consumers, but the general public cannot afford the additional, unnecessary costs that Plaintiffs’ answer to the certified question would impose.

Further, consumer product manufacturers perform an indispensable service by providing a broad array of beneficial products for use by the public. Directly to the point here, pharmaceutical manufacturers play a particularly important role by developing and selling products which prevent the onset of debilitating illnesses or (like HT) offer substantial relief from pain or other problems. Untold consumers will suffer from the loss of product innovation if manufacturers are forced to cut back on research and development spending or fear of litigation stifles design creativity.

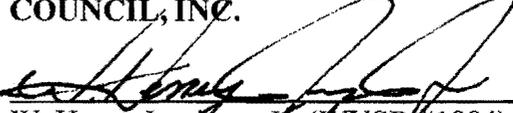
Finally, if complex, slow-moving class action lawsuits like this one are added to the line-up of cases that the state’s courts are expected to process in a timely fashion, they will clog the judicial system. The civil justice system should concentrate on the fair and efficient administration of cases filed by plaintiffs who are actually injured as a result of reliance on a defendant’s deceptive act.

⁴² See *Schweitzer v. Consol. Rail Corp.*, 758 F.2d 936, 942 (3d Cir. 1985) (“windfalls [will be awarded to] ... those who never take ill” and those who suffer may receive “insufficient compensation”), and numerous bankruptcies of product manufacturers.

V. CONCLUSION

The Circuit Court's reading of Section 106 of the Act to permit private money damage actions by uninjured patients who did not rely upon the alleged deceptive acts of Defendants is wrong, unnecessary, and likely to have perverse effects. Other mechanisms (including the Attorney General's enforcement of the Act) adequately prevent or remedy wrongful failures by drug or medical device firms to disclose product risks. Such government enforcement does not require reliance by individual patients, whereas reliance is a necessary element in cases brought by private plaintiffs, who must show actual harm tied directly to the alleged wrongdoing. Further, patients who have actual injuries caused by a manufacturer's failure to provide adequate warnings as to drugs or medical devices already have sufficient remedies under state product liability law. There is, in short, simply no good reason to emasculate the "as a result of" requirement for a private cause of action under the Act. The Product Liability Advisory Council respectfully requests that this Court reverse the Circuit Court's decision and clearly establish that it is mandatory for a private plaintiff seeking money damages under the West Virginia Consumer Credit and Protection Act to allege and prove actual injury caused by reliance upon a specific act of deception by the defendant.

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IN THE SUPREME COURT OF APPEALS OF WEST VIRGINIA

WYETH, F/K/A AMERICAN HOME PRODUCTS, D/B/A WYETH-
AYERST LABORATORIES, KETCHUM, INC., AND
DANNEMILLER MEMORIAL EDUCATIONAL FOUNDATION,

Petitioners,

v.

SHIRLEY WHITE, CATHY DENNISON, AND JENNY L. TYLER,
ON BEHALF OF THEMSELVES AND A CLASS
OF OTHERS SIMILARLY SITUATED,

Respondents.

CERTIFICATE OF SERVICE

I hereby certify that on this 14th day of January, 2010, a true and correct copy of the **BRIEF OF THE PRODUCT LIABILITY ADVISORY COUNCIL INC. AS *AMICUS CURIAE*** IN SUPPORT OF PETITIONERS has been served upon the following counsel by U.S. Mail, postage prepaid, addressed as follows:

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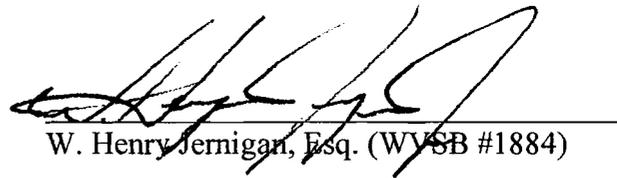
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