No. 1101397

SUPREME COURT OF ALABAMA

WYETH, INC., et al.,

Defendant-Appellants,

v.

DANNY WEEKS AND VICKI WEEKS,

Plaintiffs-Appellees.

# BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS AMICUS CURIAE IN SUPPORT OF THE APPLICATION FOR REHEARING OF APPELLANTS WYETH LLC, PFIZER INC., AND SCHWARZ PHARMA, INC.

FROM THE UNITED STATES DISTRICT COURT OF THE MIDDLE DISTRICT OF ALABAMA, SOUTHERN DIVISION
CASE NO.1:10-CV-00602-MEF-TFM

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February 18, 2013

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All members of the Court appeared to recognize that "the [certified] question's significance extends well beyond the Reglan® litigation – and for that matter, even beyond pharmaceutical litigation." Opinion, Ms. at 5 (quoting district court's certification order); Dissent, Ms. at 43. So too will the impact of the Court's answer to that question. The Court's answer threatens to unleash the plaintiff bar's most creative and damaging suits on all businesses in Alabama – particularly those in Alabama's burgeoning automotive, aerospace, and health-care industries. The decision's potential implications are already reverberating nationally. See, e.g., Katie Thomas, Man Taking Generic Drug Can Sue Branded Maker, N.Y. Times, Jan. 12, 2013, at B3; Victor Li, Alabama High Court Okays Suit Against Pfizer for Failure to Warn of Generic's Risks, The American Lawyer, Jan. 14, 2013.[1]

By holding that Appellant brand-name drug manufacturers may be held liable for physical injuries caused by their competitors' products, the Opinion rewrites decades of

[1] Available at http://www.americanlawyer.com/digestTAL.jsp?id=1202584462657&Alabama_High_Court_Okays_Suit_Against_Pfizer_for_Failure_to_Warn_of_Generics_Risks&slreturn=20130111180450.

settled tort law – law that has applied generally to all manufacturers. Although the Opinion attempts to tie its holding to federal law applicable specifically to the pharmaceutical industry, it may not be so easily cabined and certainly won't constrain the plaintiffs' bar from relying on the ruling to upend settled tort law in all areas of industry.

The fundamental problem is that the Opinion simply ignores foundational, generally applicable tort doctrines concerning duty and product-liability — doctrines that the Appellant drug manufacturers and their amici (including the Chamber) argued at length in their briefs on original submission. By disregarding these general tort principles, instead of addressing them, the Opinion encourages plaintiffs' bar will undoubtedly ask courts throughout Alabama to conclude that the Court has abandoned them entirely. Specifically, the Opinion discards the fundamental concept that claims based on a failure-to-warn theory require proof of a physical injury that can only be caused by a product, not a written label standing alone. Moreover, and separately, the Opinion abandons previous (and longstanding) Alabama law holding that a

"relationship" between the plaintiff and the manufacturer of the product that caused the harm is the focal point — and an indispensable element — of any duty analysis. Every business in Alabama must plan for and expect the plaintiffs' bar to attempt to capitalize on these novel legal steps to advance never before seen liability throughout Alabama.

## I. The Opinion Misapprehends the Nature of Warning-Based Claims and Appears to Abandon Traditional Limitations on the Duty Element of Torts.

Despite recognizing that the plaintiff here complains of — and the certified question involves — "physical injury," Opinion, Ms. at 2, the Opinion adopts the artificial view that any claim based on a failure-to-warn theory is totally separate from a product-liability claim, and indeed that the "manufacturing process" is "irrelevant" to any warning-based claim:

> [T]he Weekes's 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 the same as the label placed on the generic version of the medication – failed to warn.
>
> . . . .
>
> [I]t is not fundamentally unfair to hold the brand-name manufacturer liable for warnings on a product it did not produce because the

> manufacturing process is irrelevant to misrepresentation theories based, not on manufacturing defects in the product itself, but on information and warning deficiencies . . . .

Opinion, Ms. at 46, 52 (emphases added).

The Court cites no authority for that proposition, and with good reason: it cannot be correct. If the plaintiff experienced a physical injury, it was caused not simply by reading a label, but by reading the label in conjunction with using the accompanying product.[2] Artful pleading

[2] This Court and others have recognized that a claim based on a failure-to-warn theory requires identification of the product warned about and the manufacturer of the product that allegedly caused the injury. See, e.g., Yarbrough v. Sears, Roebuck & Co., 628 So. 2d 478, 481 (Ala. 1993) ("unreasonably dangerous" element in an AMELD action "may be obviated by adequate warning") (italics omitted, underline and emphasis added); Turner v. Azalea Box Co., 508 So. 2d 253, 254 (Ala. 1987) ("In an AEMLD action, the plaintiff must prove that the defendant manufactured and/or sold the allegedly defective product") (Emphasis added); Thompson-Hayward Chem. Co. v. Childress, 169 So. 2d 305, 309 (Ala. 1964) (reversing jury verdict in failure-to-warn case where the evidence did not show Thompson-Hayward manufactured the herbicide that killed plaintiffs' cattle: "Plaintiffs' claim against Thompson-Hayward rests on proof of the fact that this defendant had manufactured and placed on the market the particular dangerous substance which plaintiffs sprayed on the potatoes and which caused the death of the cattle. Thompson-Hayward is not shown to be liable unless it be shown that Thompson-Hayward manufactured and placed on the market the very substance complained of") (emphases added); Restatement (Second) of Torts § 402A cmt. J (1979) ("Directions or warning. In order to prevent the product from being unreasonably dangerous, the seller may be

aside, when a plaintiff alleges physical injury caused by a product or its constituent label, that is a product-liability claim, and the plaintiff must establish that the defendant manufactured the product that he used. See Pfizer, Inc. v. Farsian, 682 So. 2d 405, 407 (Ala. 1996) ("Regardless of how [plaintiff] pleads his claim, his claim is in substance a product liability/personal-injury claim. . . ."). Here, because Appellant brand-name drug manufacturers did not make the offending product, the plaintiffs' claim fails.

It simply is not the law that a product's label can be divorced from the product or that the label alone could provide the basis for liability. As Justice Murdock

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required to give directions or warning on the container as to its use.") (Second, third, and fourth emphases added); Sheffield v. Owens-Corning Fiberglass Corp., 595 So. 2d 443, 450 (Ala. 1992) (stating that the "threshold requirement of any products liability action is identification of the injury-causing product and its manufacturer") (internal quotation marks and citation omitted) (emphasis added); Yarbrough, 628 So. 2d at 482 (rejecting failure-to-warn claim regarding kerosene heater because "the evidence clearly establishe[d] that the damage to the Yarbroughs' house and personal belongings and the injuries to Mr. Yarbrough were caused by Mr. Yarbrough's misuse of the product") (emphases added); see generally Jefferson v. Lead Indus. Ass'n, 106 F.3d 1245, 1251 (5th Cir. 1997) (affirming dismissal of failure-to-warn claim "because nowhere in the complaint does plaintiff identify the manufacturer whose product caused her injury").

explained in his dissenting opinion, allegations of an inadequate warning are allegations of a product defect. See Dissent, Ms. at 24 n.11; see also Thompson-Hayward Chem. Co. v. Childress, 169 So. 2d 305, 309 (Ala. 1964) (stating that no manufacturer could be held liable in Alabama courts for a failure to warn "unless it be shown that [the defendant] manufactured and placed on the market the very substance complained of").

Having severed the label from the product — and thus the product's manufacturer — the Court concluded that the existence of a duty could be established based solely on the supposed "foreseeability" that brand-name drug manufacturers' warnings would make their way to generic-using consumers. This foreseeability-alone analysis abandons, without mention, the other traditional factors that have limited the duty element of all torts – including, most notably, the "relationship" between defendant and the plaintiff. Before this Court's Opinion, "[i]n addition to foreseeability, Alabama courts look[ed] to a number of factors to determine whether a duty exist[ed], including '(1) the nature of the defendant's activity; (2) the relationship between the parties; and (3)

the type of injury or harm threatened.'" DiBiasi v. Joe Wheeler Elec. Mbrshp. Corp., 988 So. 2d 454, 461 (Ala. 2008) (quoting Morgan v. South Cent. Bell Tel. Co., 466 So. 2d 107, 114 (Ala. 1985)) (citation omitted). Indeed, without a relationship between plaintiff and defendant, Alabama courts have never found a corresponding duty. See Dissent, Ms. at 5-10, 24 n.11, 27, 43-44; Thompson-Hayward, 169 So. 2d 305, 312 (holding that a manufacturer and seller of a herbicide owed no duty to a farmer whose cattle were killed by a herbicide that they neither made nor sold).

This Court's Opinion discards the relationship element in favor of a factor (i.e., simple foreseeability) that, standing alone, has never been sufficient to establish a duty — and that some courts have reasoned should not even be part of the duty analysis. See DiBiasi, 988 So. 2d at 464 ("Even assuming that [the decedent's] injuries were foreseeable, we conclude that none of the other Morgan factors support the existence of a legal duty [owed by defendant] sufficient to support an action for negligence.") (Internal quotation marks and citation omitted.); see also Dissent, Ms. at 10 n.7.

This Court's Opinion will unleash the plaintiffs' bar to call into serious question the continuing viability of these traditional duty-limiting principles – for all manner of torts and all manner of manufacturers.

## II. The Opinion Threatens To Unleash the Plaintiffs' Bar on All Manufacturers Doing Business in Alabama.

All members of the Court appeared to recognize that the Opinion's "significance extends . . . even beyond pharmaceutical litigation," Opinion, Ms. at 5, Dissent, Ms. at 1-3, because the Court's sweeping expansions of existing tort law arguably have nothing to do with the brand-generic dichotomy that characterizes the pharmaceutical industry. Instead, the plaintiffs' bar will inevitably argue that the Court's Opinion effectively eviscerates basic tort limitations that apply across the board – most notably, (1) the rule against circumventing product-liability restrictions through artful pleading, and (2) long-settled limitations on the scope of tort duties.

Attempts to expand this Court's sweeping reasoning to non-pharmaceutical innovators are easily predictable. For example, an automobile manufacturer could develop a new child safety seat (and an accompanying warning label) and, to enhance the safety of drivers everywhere, decide not to

patent the product or to give the patent away. That scenario is hardly hypothetical; automobile manufacturers have done such things in the past.[3] The National Highway Transportation Safety Administration might then (as it has done before) adopt a regulation requiring all new cars to install the seats, accompanied by the warning as created by the innovator.[4] It certainly would be "foreseeable," even

[3] See generally, e.g., Mercedes Benz Auto Insurance, http://www.carinsurance.info/Mercedes_Benz_Auto_Insurance ("As proof of the company's commitment to passenger safety," Mercedes has developed "many innovations and allowed competitors to use them. The crumple zones and anti-lock brakes which are standard in today's vehicles all were developed, designed and first introduced by Mercedes-Benz."); About Volvo/ Reducing Injuries 3 Point Seatbelt, http://www.volvocars.com/us/top/about/values/pages/safety.aspx ("[I]n 1959, Volvo safety engineer Nils Bohlin invented the three-point seat belt which is still used in cars today. And to ensure it was adopted by everyone - not just Volvo drivers - we deliberately didn't patent it either.").

[4] See generally, e.g., 76 Fed. Reg. 3212, 3212 (Jan. 19, 2011) (NHTSA setting safety standard, stating: "The agency anticipates that manufacturers will meet the standard by modifying existing side impact air bag curtains"); id. at 3225 (noting, "In the middle of the 2002 model year (MY), Ford introduced the first generation of side curtain air bags that were designed to deploy in the event of a rollover crash. The rollover air bag curtain system, marketed as a 'Safety Canopy,' was introduced as an option on the Ford Explorer and Mercury Mountaineer."); Fisher v. Ford Motor Co., 224 F.3d 570, 573 (6th Cir. 2000) (addressing NHTSA's federal motor vehicle safety standard that mandated sun-visor warning labels concerning air bags

intended, that later manufacturers would reproduce the safety seat and include the same warning. But what if, after a second manufacturer makes the child safety seat — accompanied by the original warning — a child is injured in a crash, and there are allegations that the warning that accompanied the seat is inadequate? Under completely predictable suits invoking the Court's Opinion, the original manufacturer — that is, the seat innovator who wrote the warning label — could be sued for the injury caused by a product it did not make. That suit and the possibility of liability is neither equitable nor sustainable, and it certainly is not good for business in Alabama.

Similarly, an airplane manufacturer could invent a state-of-the-art machine for testing jet engines. The Federal Aviation Administration could take notice and require that the machine — along with its attendant warnings about its risk of catching loose clothing — be used industry-wide. Similar regulation has occurred in the

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and affirming preemption of state law failure-to-warn claim based on federal warning).

past.[5] What happens if an engineer is hurt when his shirt becomes caught in a later test machine – manufactured by another company, but accompanied by the innovator's warnings – and alleges that the machine's warning was inadequate? Again, using the Court's analysis here, suits will attempt to hold the innovator liable, even though it did not manufacture the offending machine.

Additional examples abound. If, as is inevitable from the Court's Opinion, the plaintiffs' bar pushes the view that traditional duty-limiting principles are out the window, a hospital will need to think twice about inventing a new MRI machine (accompanied by a radiation warning) and giving the design away. The hospital would have good reason to be concerned about potential limitless liability for its benevolence. Under a copycat suit here, if a

[5] See generally, e.g., Andrew Tarantola, Real Life Death Star? No, It's How GE Tests Jet Engines, available at http://gizmodo.com/5977823/real-world-death-star-no-its-how-ge-tests-jet-engines ("To ensure the safety of America's 730 million annual air travelers, all new jet engines must undergo arduous FAA safety testing -- including a grueling series of static ground tests subjecting them to everything from gale force winds to simulated bird strikes. . . . Technically, they're known as Turbulence Control Structures (TCS) and were patented in 1981 by a pair of Boeing engineers, Ulrich W. Ganz and Paul C. Topness. . . . [T]he TCS has garnered widespread adoption throughout the industry.").

competitor uses the design — and includes the original warning label — the innovating hospital could be adjudged liable to the competitor's patient who develops cancer allegedly caused by an inadequate warning. Such a sweeping liability rule provides the worst imaginable incentives for innovation.[6]

By ignoring the duty-limiting principles outlined in Farsian, 682 So. 2d at 407, Thompson-Hayward, 169 So. 2d at 312, and DiBiasi, 988 So. 2d at 464, this Court's Opinion

[6] By contrast, most American courts have applied traditional tort law principles to protect innovators instead of punishing them. See, e.g., Aliss J. Strong, "But He Told Me It Was Safe!": The Expanding Tort of Negligent Misrepresentation, 40 U. Mem. L. Rev. 105, 145 (2009) (noting that negligent representation requires the representation to be "made directly to the injured party about an object owned by, or a condition under the control of the person making the representations" and citing cases) (internal quotation marks and citations omitted); Lars Noah, Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product, 45 Tort Trial & Ins. Prac. L.J. 673, 694 (2010) (citing Piscitello v. Hobart Corp., 799 F. Supp. 224, 226 (D. Mass. 1992) ("It would be unfair to impose such an expansive view of tort liability on those whose original design is mimicked without the designer's permission.")); Village of Cross Keys, Inc. v. U.S. Gypsum Co., 556 A.2d 1126, 1135 (Md. 1989) ("Assuming the possible existence of a tort duty upon USG as a result of the publication of the [design specification], that duty should extend to those who seek to challenge a system they have used, and not to those who do not."); Spaulding v. Lesco Int'l Corp., 451 N.W.2d 603, 606 (Mich. Ct. App. 1990) ("Sears had no duty to warn of the alleged dangers of another's product."). This Court should do the same.

stands, at best, as an invitation for plaintiffs to press for a "foreseeability-only" duty analysis in which the identity of a product's manufacturer no longer matters. The only thing predictable about this Court's Opinion is that it will lead to more lawsuits, and this necessarily leads to less investment, less innovation, and fewer new jobs in Alabama.

## CONCLUSION

Alabama law has long recognized that where a plaintiff claims a "physical injury" caused by an inadequate product warning, the product that caused the injury and the company that manufactured that product are directly relevant to the duty analysis. The Court's Opinion eviscerates those traditional limitations and threatens to unleash the upending of traditional tort principles as they apply to all industries throughout Alabama.

The Court should grant the Application for Rehearing, withdraw the Opinion, and issue a new opinion that answers the certified question in the negative.

Respectfully submitted this 18th day of February, 2013.

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