No. 1101397

IN THE SUPREME COURT OF ALABAMA

WYETH, INC., ET AL.,

Appellants,

v.

DANNY WEEKS, ET AL.,

Appellees.

Certified Question from the United States District Court for the Middle District of Alabama, Southern Division: Case No. 1:10-cv-602

BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS AMICUS CURIAE IN SUPPORT OF THE APPELLANTS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

TREATISES

OTHER AUTHORITIES

I. INTEREST OF THE AMICUS CURIAE

Amicus Curiae Product Liability Advisory Council, Inc. ("PLAC") is a nonprofit association with more than 100 corporate members representing a broad cross-section of American and international product manufacturers.[1] These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective derives from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. Several hundred of the leading product liability defense attorneys in the country are also sustaining (nonvoting) members of PLAC. Since 1983, PLAC has filed more than 940 briefs as amicus curiae in both state and federal courts, including 17 in this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability.

[1] A list of PLAC's current corporate membership is included as Appendix A to this brief.

Many of PLAC’s members do business in the State of Alabama and have encountered product liability claims there; several of PLAC’s members are pharmaceutical companies and they therefore would face a direct impact from an adverse ruling from this Court. PLAC’s interest thus derives from the unprecedented departure from core product liability principles that the Appellees request: namely, that a brand-name drug manufacturer can be held liable for injuries caused by a generic competitor's product. More specifically, under the Appellees’ approach, a pharmaceutical company would be saddled with a common-law duty to warn the medical profession generally and the potential for unlimited liability for whatever treatment decisions allegedly flow from the breach of that duty. In pressing their claims here, the Appellees are ignoring the policy implications of their proposed fundamental shift in imposing liability against a non-manufacturer. PLAC’s members therefore have a strong interest in the outcome of this case and in preserving this Court’s long-standing precedent.

II. SUMMARY OF THE ARGUMENT

In Alabama, sellers and manufacturers of consumer products owe a duty to provide truthful and accurate information about their products to the users of those products. It has always been clear, however, that product sellers and manufacturers (including pharmaceutical companies) do not owe such a duty to persons injured by their competitors' products, no matter how similar the products may be. And that is true, even though the marketplace is crowded with copy-cat and generic products.

Appellees ask this Court to subvert this long-standing rule and permit persons injured by the ingestion of a generic drug to sue the company that sells or used to sell a brand-name pharmaceutical. To justify this extraordinary change in the law, Appellees argue that, under the learned intermediary doctrine, manufacturers of branded drugs already owe a duty to disclose information about their drugs to doctors and should therefore be liable for any injuries that can arguably be traced to the breach of that duty — even injuries to consumers who never took the brand-name drug but instead purchased a competing generic product.

Appellees' argument rests on a misunderstanding of the learned intermediary doctrine. Far from creating a new duty or expanding liability to new classes of plaintiffs, the doctrine simply provides that, in a given case, a prescription pharmaceutical manufacturer can satisfy its duty to warn consumers about the risks of its drug (the same duty it shares will all other product manufacturers) by providing the doctors who prescribe it with adequate warnings. The doctrine did not create a free-standing, general duty to warn doctors whose patients consume other, competing drugs, *i.e.*, a duty that exists outside the context of a tort claim brought by a person who claims to have been injured by the *defendant's* drug. Instead, the learned intermediary doctrine simply provides a means by which the defendant can satisfy its duty to the user of its own product in a given case.

The doctrine thus serves to shield a prescription drug manufacturer from a plaintiff's allegations that a warning should have been given directly to the plaintiff, given the practical reality that a doctor (the "intermediary") stands between the manufacturer and the patient and makes the treatment decision. But there is no basis in law for using

the learned intermediary doctrine as a sword to create an entirely new duty and cause of action against pharmaceutical companies. Appellees' quest to do so fails for this reason alone.

Extending the potential liability of the brand name manufacturer to injuries resulting from a competitor's generic product would also set a dangerous precedent for manufacturers outside the prescription drug context. Once product liability is divorced from the product in this way, there is no clear limit on a company's potential exposure. Appellees' theory could extend to any product subject to imitation, and to any entity that disseminates information about a product. The Court should not massively expand the scope of liability for product innovators and other third parties in this fashion.

III. ARGUMENT

A. Under Alabama Law, Pharmaceutical Companies' Obligation to Warn Doctors is No Broader Than (and Derives From) Their Duty to Warn Their Own Customers.

The Appellees' position in this case depends entirely on a foundational misunderstanding of Alabama law. The court apparently mistakenly believed that a pharmaceutical company owes a common-law duty to warn ***doctors*** about the

risks associated with its products that exists separate and apart from the duty it owes to the patients who purchase its products. The district court appears to have accepted Appellees' argument that such a duty exists by virtue of Alabama's adoption of the learned intermediary doctrine. With due respect to the district court, Alabama law imposes no such duty on pharmaceutical companies and never has. Accordingly, the basis underlying Appellees' argument collapses, and their claims against Wyeth and Schwarz fail as a matter of Alabama law.

1. The District Court's Reliance on the Learned Intermediary Doctrine Was Misplaced.

In addressing Wyeth and Schwarz's motion to dismiss, the district court correctly concluded that the companies owed no duty to Mr. Weeks because Mr. Weeks did not take their product. (*See Weeks v. Wyeth, Inc.*, No. 1:10-cv-602 (M.D. Ala.), ECF No. 86 at 6-7 & n. 5 (finding that "no relationship exists at all between the Weeks and the brand name defendants" and that "it was unforeseeable" that the defendants' alleged misrepresentations about their drug could cause Mr. Weeks's alleged injuries).)

In so holding, the district court sided with the overwhelming authority establishing that a brand-name

pharmaceutical company cannot be liable, under any theory, where a plaintiff's injury was caused by its competitor's generic medication. (*See id.* at 6-7.) Indeed, dozens of decisions from at least 20 other states have refused to impose liability in the circumstances Appellees present. *See, e.g.*, *Burke v. Wyeth, Inc.*, No. G-09-00082, 2009 WL 3698480, at *2 (S.D. Tex. Oct. 7, 2009), adopted (S.D. Tex. Oct. 29, 2009) (collecting cases); *Moretti v. Wyeth*, No. 2:08-CV-00396, 2009 WL 749532, at *4 n.1 (D. Nev. Mar. 20, 2009) (same). And until the district court's preliminary decision in this case, Alabama courts had reached the same result. *See, e.g.*, *Mosley v. Wyeth, Inc.*, 719 F. Supp. 2d 1340 (S.D. Ala. 2010); *Simpson v. Wyeth, Inc.*, No. 7:100cv001771, 2010 WL 5485812 (N.D. Ala. Dec. 9, 2010) (magistrate report and recommendation), *adopted by* 2011 WL 10607 (N.D. Ala. Jan. 4, 2011); *Barnhill v. Teva Pharms. USA, Inc.*, No. 06-0282, 2007 WL 5787186 (S.D. Ala. Apr. 24, 2007); *Green v. Wyeth Pharms., Inc.*, No. CV06-3917, 2007 WL 6428717 (Ala. Cir. Ct. May 14, 2007).

Without citing any authority, the court nonetheless suggested that Mr. Weeks might be able to state a claim against the branded companies on the ground that Wyeth and

Schwarz owed a freestanding duty to warn Mr. Weeks's prescribing physician (who is not, of course, a party to this action). The district court explained:

> When framed in this way, the Weeks would not be required to demonstrate that the brand name manufacturers had a duty to warn about generic MCP. The Weeks would not even have to demonstrate that the brand name defendants owed a duty to Mr. Weeks himself, only that the brand name defendants owed a duty to the prescribing physician to adequately disclose and warn about the risks associated with Reglan.

(*Weeks*, ECF No. 86 at 6; *see id.* (noting that "[t]he Weeks's claims center [] on statements the brand name defendants made or failed to make to Mr. Weeks's prescribing physician").) In other words, the district court initially suggested — pre-certification — that the brand-name pharmaceutical companies owed a duty to Mr. Weeks's doctor that was entirely unrelated to any duty owed by the company to Mr. Weeks himself.[2] This new duty is not only novel, but unprecedented.

[2] In permitting the Appellees' claims to proceed, the district court relied, in part, on its conclusion that the Weeks's claims were not subsumed within the Alabama Extended Manufacturer's Liability Doctrine to the extent they were grounded in common-law fraud or failure to warn. Even if this is the case — and PLAC submits that the better practice is for all claims of injury based on a product to have a direct tie to that product — it is irrelevant. Alabama law does not impose a duty upon pharmaceutical

To reach this conclusion, the district court appears to have relied upon the Appellees' brief. (*See Weeks*, ECF No. 86 at 6, 10.) In their brief below, Appellees argued that, by adopting the learned intermediary doctrine, the Alabama Supreme Court "implicitly" also imposed a common-law duty upon pharmaceutical companies to warn doctors that exists outside the context of product liability — *i.e.*, outside the context of a claim by a consumer or bystander plaintiff that he or she suffered physical injury caused by a product manufactured or sold by the defendant. (*See Weeks*, ECF No. 54 at 12 ("The [learned intermediary] doctrine ***presumes and implies*** that the maker and promoter of a prescription medicine will accurately disclose the drug's risks to doctors, so as to prevent harm to patients." (emphasis added)) (citing *Walls v. Alpharma USPD, Inc.*, 887 So. 2d 881 (Ala. 2004) and *McNeil v. Wyeth*, 462 F.3d 364 (5th Cir. 2006)).)

Although Appellees are correct that Alabama, like practically every other state, has adopted the learned

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companies to warn doctors that is independent of (or broader than) their core duty to the consumers of their drugs. Thus, Appellees' claims would not survive even if they are deemed to be outside of the AEMLD.

intermediary doctrine, they misread both the doctrine's purpose and its function. As explained below, by adopting the learned intermediary doctrine, this Court intended to ***limit*** the scope of a prescription drug manufacturer's duty to warn. It did not intend to ***expand*** that duty well beyond the duty owed by manufacturers of other consumer products.

2. The Learned Intermediary Doctrine Provides Only That a Drug Manufacturer Can Satisfy its Duty to Warn Consumers of its Drugs by Warning the Doctor Intermediary.

To understand what the learned intermediary doctrine is (and what it is not), it is helpful to return to first principles and examine both the purpose of the doctrine and the context in which it was adopted.

a. Product Manufacturers Have a Duty To Warn Their Customers Regarding Their Products.

The learned intermediary doctrine evolved directly out of product liability principles applicable to consumer products generally. As expressed by the Restatement (Second) of Torts:

> One who sells any product in a defective condition unreasonably dangerous to the user or consumer . . . is subject to liability for physical harm thereby caused to the ultimate user or consumer . . . if [] the seller is engaged in the business of selling such a product, and [the product] it is expected to and does reach the user or consumer

> without substantial change in the condition in which it is sold.

RESTATEMENT (SECOND) OF TORTS § 402A(1). Under section 402A (long-ago adopted in Alabama and in many other states), sellers of unreasonably dangerous products owe a duty to warn "***consumer[s] or user[s]***" of that product. *See id.* Indeed, by limiting the scope of product manufacturers' duty in this way, section 402A simply adopted a principle that was already well-established in Alabama. *See generally Atkins v. Am. Motors Corp.*, 335 So. 2d 134 (Ala. 1976) (adopting section 402A and noting its compatibility with product claims arising in negligence). Thus, product sellers in Alabama have long been under a duty to warn *their product's consumers* (or foreseeable users) of dangers inherent in *their products*. *See, e.g.*, *Stone v. Smith, Kline & French Labs.*, 447 So. 2d 1301, 1303, 1305 (Ala. 1984).

It is also true beyond peradventure that product sellers (including pharmaceutical companies) do not have (and have never had) a duty to warn about dangers inherent in the use of products sold or manufactured by their competitors. *Mosley v. Wyeth, Inc.*, 719 F. Supp. 2d 1340, 1346-48 (S.D. Ala. 2010); *see also Pritchett v. ICN Med.*

Alliance, 938 So. 2d 933, 937 (Ala. 2006) (noting that whether a duty exists depends on several factors, "including the relationship between the parties" (citation omitted)); *Enoch v. Firestone Tire & Rubber Co.*, 534 So. 2d 266, 270 (Ala. 1988) (affirming summary judgment on plaintiff's claims, including negligence and defective design, where plaintiff lacked "concrete facts" that defendants made or sold a tire rim that exploded); *Thompson-Hayward Chem. Co. v. Childress*, 169 So. 2d 305, 312 (Ala. 1964) ("The rule, upon which plaintiffs' right to recover is based, imposes the duty on one who . . . manufactures or sells an imminently dangerous article and fails to warn. It is not alleged that [defendant] manufactured [or sold] the dangerous article. How, then, did [defendant] owe a duty to warn?").

Product liability claims that sound in fraud are subject to the same limitation. Under the Third Restatement of Torts, for example, "[o]ne engaged in the business of selling or otherwise distributing products" can be liable for a misrepresentation made "in connection with the sale of a product." RESTATEMENT (THIRD) OF TORTS, PRODUCTS LIABILITY (1998) § 9; *see also id.* at cmt. a (section 9

"app[ies] to commercial product sellers"). But this section of the Restatement neither suggests, nor cites any precedent for the proposition that liability for product-related misrepresentation can be extended to an entity not in the chain of sale of the manufacturer's own product.

Liability for the sellers of products is circumscribed to users of the manufacturer's product for good reason:

> As one noted commentator points out, where misstatements are claimed to be the cause of loss, even a "reasonable anticipation that the statement will be communicated to others whose identity is unknown to the defendant, or even knowledge that the recipient intends to make some commercial use of it in dealing with unspecified third parties, is not sufficient to create a duty of care towards them." The reason for such a rule is obvious. To quote Prosser again, it is required in order to avoid "[t]he spectre of unlimited liability, with claims devastating in number and amount crushing the defendant because of a momentary lapse from proper care. . . ."

Demuth Dev. Corp. v. Merck & Co., Inc., 432 F. Supp. 990, 993-94 (E.D.N.Y. 1977) (internal citation omitted and alterations in original) (quoting W. Prosser, LAW OF TORTS, 708 (4th ed. 1971)).

In short, whether based on fraud, negligence, or strict liability, standing for product-liability claims has always been confined to individuals who claim to have been injured by *the defendant's product*. *See Smith v. Wyeth,*

Inc., 657 F.3d 420, 423 (6th Cir. 2011) ("A threshold requirement of any products-liability claim is that the plaintiff assert that the defendant's product caused the plaintiff's injury.").

b. The Duty to Warn Has Been Limited for Prescription Drugs Because of the Unique Circumstances They Present.

Prescription drugs are fundamentally different from other consumer products, both in their means of acquisition (exclusively through a learned intermediary's prescription) and their inherent potential for risk. *See*, *e.g.*, RESTATEMENT (SECOND) OF TORTS § 402A cmt. k ("There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs."). Accordingly, Alabama, like almost every other state, has adopted the "learned intermediary doctrine," which modifies (and indeed ***narrows***) a manufacturer's duty to warn consumers about prescription medications. *See, e.g.*, *Stone*, 447 So. 2d at 1303, 1305 (endorsing the learned intermediary doctrine over 25 years ago, holding that "an adequate warning to the prescribing physician, but not to the ultimate consumer, [is] sufficient as a matter

of law"). Under this doctrine, a pharmaceutical "manufacturer's duty to warn is limited to an obligation to advise the prescribing physician of any potential dangers that may result from the use of *its product*." *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313-14 (11th Cir. 2000) (emphasis added).

This Court has repeatedly endorsed an explanation of the doctrine from the Fifth Circuit Court of Appeals:

> We cannot quarrel with the general proposition that where *prescription* drugs are concerned, the manufacturer's duty to warn is ***limited*** to an obligation to advise the prescribing physician of any potential dangers that may result from the drug's use. This special standard for prescription drugs is an understandable ***exception*** to the Restatement's ***general rule*** that one who markets goods must warn foreseeable ultimate users of dangers inherent in his products. See RESTATEMENT (SECOND) OF TORTS, Section 388 (1965). Prescription drugs are likely to be complex medicines, esoteric in formula and varied in effect. As a medical expert, the prescribing physician can take into account the propensities of the drug as well as the susceptibilities of his patient. His is the task of weighing the benefits of any medication against its potential dangers. The choice he makes is an informed one, an individualized medical judgment bottomed on a knowledge of both patient and palliative. Pharmaceutical companies then, who must warn ultimate purchasers of dangers inherent in patent drugs sold over the counter, in selling prescription drugs are required to warn only the prescribing physician, who acts as a "learned intermediary" between manufacturer and consumer.

Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974) (quoted in *Stone*, 447 So. 2d at 1304-05); *see also* RESTATEMENT (SECOND) OF TORTS § 388 (addressing liability for "[o]ne who supplies . . . a chattel for another to use"); *Nail v. Publix Super Mkts., Inc.*, No. 1091740, 2011 WL 1820087, at *5 (Ala. May 13, 2011).

Rather than creating any *additional* duty, then, the doctrine substitutes a patient/consumer's physician — the so-called "learned intermediary" — as the individual the pharmaceutical manufacturer can warn in order to satisfy its duty to the end user of its products. As the Fifth Circuit has more recently explained: "The learned-intermediary doctrine states that, in some situations, a warning to an intermediary fulfills a supplier's ***duty to warn consumers***." *Ackermann v. Wyeth Pharms.*, 526 F.3d 203, 207 (5th Cir. 2008) (emphasis added). This Court recently said the same thing when it observed that "the ***duty at issue***" in the cases in which the Court adopted the learned intermediary doctrine "was a drug manufacturer's or a drug dispenser's ***duty to warn customers*** of the potential risks or side effects of a drug." *Nail*, 2011 WL 1820087, at *5 (emphasis added). The doctrine is thus rooted in

traditional product liability principles, and operates only in the context of a claim by a "customer" against the manufacturer of the injury-causing drug.

The learned intermediary doctrine does not in any way undermine the core principle that product manufacturers are liable only for injuries caused by their own products. The only duty modified by the doctrine is the duty to warn the customers of the manufacturer. The only doctors that must be warned are the doctors of those customers.

An Alabama federal district court recognized as much in rejecting the same flawed interpretation of the learned intermediary doctrine advanced by Appellees here. According to that court: "As a matter of law, the [brand-name pharmaceutical companies] have ***no duty*** to communicate any information regarding the risk of taking this product ***to anyone other than their own consumers***." *Simpson v. Wyeth, Inc.*, No. 7:100cv001771, 2010 WL 5485812, at *5 (N.D. Ala. Dec. 9, 2010) (magistrate report and recommendation) (emphasis added), *adopted by* 2011 WL 10607 (N.D. Ala. Jan. 4, 2011).

Product liability law in Alabama can thus be summarized as follows:

1) Product manufacturers owe a duty to warn their consumers about the risks associated with their products.
2) Product manufacturers *do not* owe a duty to the consumers of their competitors' products.
3) Under the learned intermediary doctrine, pharmaceutical manufacturers may satisfy their duty to warn consumers about their drugs by providing an adequate warning to their consumers' doctors.
4) The learned intermediary doctrine *does not* impose on a pharmaceutical manufacturer an obligation to warn any physician whose patient does not ingest the manufacturer's own drugs.[3]

[3] Even if pharmaceutical companies had a duty to warn doctors that existed independent of their obligations to their actual customers, however, this would not help to salvage Appellees' argument. Indeed, if pharmaceutical companies were found to have such a duty, it would at best give rise only to a claim *by the doctor* against the pharmaceutical company. *Compare*, *e.g.*, *Vitolo v. Dow Corning Corp.*, 634 N.Y.S.2d 362 (N.Y. Sup. Ct. 1995) (permitting physician to proceed with suit against device manufacturer for damage "he has suffered [] to his professional practice and to his professional reputation" based on problems with manufacturer's devices) *with Barnett v. Mentor H/S, Inc.*, 133 F. Supp. 2d 507, 511 (N.D. Tex. 2001) (granting summary judgment, finding doctor had no evidence to support claims that device manufacturer "committed fraud by deceiving buyers into believing that the implant devices were free of defects"). Under this

5) The learned intermediary doctrine *does not* expand the class of persons who may sue drug manufacturers for failing to disclose risk information beyond those individuals who were actually injured by the manufacturer's drug.

6) The learned intermediary doctrine *does not* give individuals who ingested and were allegedly injured by the generic form of a drug standing to sue the manufacturer of the branded version of the drug.

3. Appellees' Claims Fail As a Matter of Law Because The Brand Name Defendants Had No Duty to Warn Either Mr. Weeks or His Physician.

The district court agreed that the branded defendants here owed no duty of any kind to Mr. Weeks under Alabama law because Mr. Weeks took a drug manufactured by another company. (*See Weeks*, ECF No. 86 at 6-7 & n. 5.) The court nevertheless found that Mr. Weeks could state a claim

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scheme, doctors would *not* have standing to file suit on behalf of their patients claiming physical injury. *See Barnett*, 133 F. Supp. 2d at 513 (rejecting doctor's product liability claim "because he seeks economic losses only"). Nor could patients sue pharmaceutical companies for breach of any duty owed to doctors — which breach causes not physical injury, but reputational loss or other economic harm. Thus, even if it existed under Alabama law, an independent duty to warn doctors would run only to the doctor — and would only give rise to the doctor's claims on his or her own behalf.

against the brand name companies because, under the learned intermediary doctrine, they owed a separate duty to disclose risk information about their drug to Mr. Weeks's physician. But as shown above, the learned intermediary doctrine creates no such obligation. The obligation to warn doctors under that doctrine derives from and does not exist apart from the core duty to warn customers. The warning to the physician is simply a way for the defendant manufacturer to satisfy its duty to the customer. Because the branded manufacturers owed no duty to warn Mr. Weeks, they likewise owed no duty to warn Mr. Weeks's physician. Thus, the duty to disclose that is the linchpin of the district court's analysis does not exist as a matter of Alabama law. And without that duty, Appellees' claims fail as a matter of law.

B. Permitting Liability Against an Entity that Did Not Make the Injury-Producing Product Creates a Troubling Precedent.

Appellees' arguments turn products liability law on its head, unnecessarily punishing innovators for torts allegedly committed by their direct competitors and potentially transforming innovators into ultimate product insurers.

In the pharmaceutical context, this expansion of liability would have obvious and widespread consequences — but not only for brand-name product innovators who are sued by plaintiffs who ingested a competitor's generic medication. Without even considering the wide-ranging implications such a ruling could have in discouraging pharmaceutical companies from developing new medications and bringing them to market, there would also be immediate implications for pharmaceutical companies who produce and sell medications in the same "class" as the medication a plaintiff ingested.

By way of example, there is a "class" of medications called selective serotonin reuptake inhibitors. Medications belonging to this class are not chemically identical or bio-equivalent, but are often prescribed by the same doctors to the same categories of patients. Indeed, it is not uncommon for the same doctors to prescribe several of these drugs to a single patient before settling on the one that works best. Complicating matters further, there is overlap and even duplication between the FDA-mandated prescribing information for these drugs. Many SSRIs have the same (or very similar) risks. Under the

circumstances, it is entirely possible that a doctor might rely on something he or she saw (or failed to see) in one SSRI company's package insert in prescribing another company's drug. It is also possible that the doctor might routinely read the package inserts for all the SSRIs and factor them all into his or her prescribing decisions. Under Appellees' theory, all the SSRI companies have a duty to warn doctors generally. If a patient suffers an adverse event of a type that should arguably have been disclosed by all the SSRI companies, are they all potentially liable? Under the Appellees' reasoning, the answer would appear to be yes. Indeed, once the product itself ceases to define the scope of the duty to warn, it becomes possible (particularly with the benefit of hindsight) to "foresee" a thousand different scenarios where one drug manufacturer might be on the hook for an injury caused by another company's drug.

Moreover, under Appellees' theory, a brand-name manufacturer would remain "on the hook" indefinitely, even after it stops making and selling its branded product. In fact, both of the brand-name defendants here have been out of the business of selling Reglan for a number of years

(nearly a decade in the case of Wyeth). And yet, under Appellees' theory, they must act as the effective insurers of products made and sold by others for as long as those products remain on the market. This result is contrary to a core tenet of product liability law: that the product manufacturer is in the best position to "insure" against the risks of its products. *See* RESTATEMENT (SECOND) OF TORTS § 402A cmt. c ("[P]ublic policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production against which liability insurance can be obtained; and that the consumer of such products is entitled to the maximum of protection at the hands of someone, and the proper persons to afford it are those who market the products.").

Stepping outside the prescription pharmaceutical context, it does not require much of a leap to envision expansion of liability to other consumer products. Were liability against product innovators permitted, the creator of any well-known product susceptible of imitation could be liable for failure to warn of dangers supposedly lurking in competing products.

As one commentator has noted, the principle of liability for a competitor's "copycat" product could be seen to be applicable to "other types of consumer goods, ranging from nonprescription drugs and foods to household chemicals and appliances; in other words, crossover tort litigation could occur in any market served by brand-name companies that actively promote their wares but face competition from largely identical but lower-priced store brands." 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). Competing product manufacturers would risk exposure whenever warnings discuss shared product hazards. One family may own different makes of cars; if there is claimed reliance on one company's inadequate warnings about tire inflation or infant car seat installation in order to make a product liability or fraud claim about a different car, Appellees' misrepresentation theory could create endless liability.

Finally, if there is a perceived desire to extend product innovator liability in the manner Appellees request, it should be the legislature, not the courts, that makes that public policy judgment and change. "It is well

established that the legislature, and not this Court, has the exclusive domain to formulate public policy in Alabama." *Boles v. Parris*, 952 So. 2d 364, 367 (Ala. 2006); *see Cline v. Ashland, Inc.*, 970 So. 2d 755, 758 (Ala. 2007) (See, J., concurring specially) ("The legislature is entrusted with making the public policy of this State, whether or not it is public policy of which this Court would approve."); *Keck v. Dryvit Sys., Inc.*, 830 So. 2d 1, 11 (Ala. 2002) ("The imposition of such a responsibility is a matter best left to the Legislature."). The district court here did not reference any support for extending liability to third-party claims stemming from a product; instead, it merely noted that it saw "no reason to import that requirement [from the AEMLD that defendant made the injurious product] into other independent torts simply because those torts are based on facts involving a product that caused harm." (*Weeks*, ECF No. 86 at 9.) Nor did the district court cite any support for using the learned intermediary doctrine affirmatively to create a new duty for pharmaceutical companies. Because it is within the purview and responsibility of the legislature, not this Court, to expand tort liability in the manner Appellees

request, this Court should reject Appellees' effort to expose product innovators to new bases for liability under Alabama law.

IV. CONCLUSION

For the foregoing reasons, PLAC respectfully requests that the Court answer the certified question in the negative, holding that a pharmaceutical company product innovator may not be held liable under theories of fraud, negligence, or misrepresentation where a plaintiff claims injury from a medication manufactured and distributed by another company.

Respectfully submitted this 12th day of December, 2011.

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APPENDIX A
Corporate Members of the
Product Liability Advisory Council

As of 12/7/11

3M
Altec, Inc.
Altria Client Services Inc.
Astec Industries
Bayer Corporation
Beretta U.S.A. Corp.
BIC Corporation
Biro Manufacturing Company, Inc.
BMW of North America, LLC
The Boeing Company
Bombardier Recreational Products, Inc.
BP America Inc.
Bridgestone Americas, Inc.
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Chrysler Group LLC
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Crown Equipment Corporation
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The Dow Chemical Company
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Mazak Corporation
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Niro Inc.
Nissan North America, Inc.
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Pella Corporation
Pfizer Inc.
Polaris Industries, Inc.
Porsche Cars North America, Inc.
Purdue Pharma L.P.
Remington Arms Company, Inc.
RJ Reynolds Tobacco Company
Schindler Elevator Corporation
SCM Group USA Inc.
Shell Oil Company
The Sherwin-Williams Company
Smith & Nephew, Inc.

St. Jude Medical, Inc.
Stanley Black & Decker, Inc.
Subaru of America, Inc.
Techtronic Industries North America, Inc.
Teva Pharmaceuticals USA, Inc.
Thor Industries, Inc.
TK Holdings Inc.
The Toro Company
Toyota Motor Sales, USA, Inc.
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen Group of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Whirlpool Corporation
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.

CERTIFICATE OF SERVICE

I hereby certify that I have served a copy of the foregoing **BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS AMICUS CURIAE IN SUPPORT OF THE APPELLANTS** on all counsel of record via the Court's Online Information Service as follows:

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This 12th day of December, 2011.

s/Franklin P. Brannen, Jr.