NO. 1210140

IN THE SUPREME COURT OF ALABAMA

MARK BLACKBURN,

Plaintiff – Appellant,

v.

SHIRE US INC and SHIRE LLC

Defendants – Appellees.

On Certified Questions from the United States Court of Appeals for the Eleventh Circuit

Case No. 20-12258

AMICUS CURIAE BRIEF OF THE ALABAMA DEFENSE LAWYERS ASSOCIATION AND DRI

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INTEREST OF AMICUS CURIAE

The ADLA is a non-profit association of approximately 1,000 Alabama lawyers who devote a substantial portion of their professional practice to the defense of civil lawsuits. Founded in 1964, ADLA's purpose includes promoting improvement in the administration and quality of justice. Consistent with its stated purpose, ADLA, by and through its *Amicus Curiae* Committee, often participates in cases that involve important questions of law to assist the Court in its consideration and resolution of those cases.

ADLA and its undersigned counsel have no pecuniary interest in the outcome of this case.

DRI (www.dri.org) is an international membership organization composed of more than 16,000 attorneys, corporations, and in-house counsel involved in the defense of parties in civil litigation. DRI's mission includes promoting appreciation of the role of defense lawyers in the civil justice system, addressing substantive and procedural issues germane to defense lawyers and their clients, improving the civil justice system, and preserving the civil jury. To help foster these objectives, DRI participates through its Center for Law and Public Policy as amicus curiae in carefully

selected appeals presenting questions that are of national importance to civil defense attorneys, their clients, and the conduct of civil litigation.

DRI, its members, and their clients have a significant interest in preserving the largely uniform application of the learned intermediary doctrine across the states. Adopting the standards suggested by the Eleventh Circuit would make Alabama an outlier in its approach to the doctrine in a way that would hurt pharmaceutical manufacturers nationwide.

STATEMENT OF THE CASE

ADLA and DRI adopt the Statement of the Case submitted by Defendants-Appellees Shire US, Inc. and Shire, LLC.

STATEMENT OF ISSUES

The United States Court of Appeals for the Eleventh Circuit, pursuant to Rule 18 of the Alabama Rules of Appellate Procedure, certified two questions to this Court. ADLA and DRI will address only Certified Question 1 (the "Certified Question") which states:

> Consistent with the learned intermediary doctrine, may a pharmaceutical company's duty to warn include a duty to provide instructions about how to mitigate warned-of risks?

STATEMENT OF FACTS

ADLA and DRI adopt the Statement of Facts submitted by Defendants-Appellees Shire US, Inc. and Shire, LLC.

SUMMARY OF THE ARGUMENT

This Court should answer the first certified question posed by the Eleventh Circuit in the negative. Several reasons compel this conclusion. First, since Alabama's adoption of the Learned Intermediary Doctrine in *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301 (Ala. 1984), this Court has repeatedly limited the drug manufacturer's duty to providing warnings to the prescribing physician about risks associated with the medication. Most recently, in *Weeks v. Wyeth*, 159 So. 3d 649 (Ala. 2014), *abrogated by statute on different grounds*, this Court described in detail the application of the Learned Intermediary Doctrine under Alabama law as the duty to warn about risks associated with the prescription drug. *Weeks* forecloses any duty to provide recommendations about medical monitoring protocols or testing regimes to the prescribing physician. There is no reason to change long-settled Alabama law in response to the certified question posed by the Eleventh Circuit.

Second, any ruling adopting an expanded duty on the part of the pharmaceutical company to provide monitoring or testing protocols to the prescribing physician as to how to mitigate the warned-of risks associated with the medication eliminates the requirement that a plaintiff prove proximate causation in claims involving prescription medications.

Finally, policy reasons support a negative response to the certified question. The expanded duty proposed by Blackburn, which would require a treatment protocol to mitigate each warned-of risk, would interfere with and undermine the physician-patient relationship and trespasses into the practice of medicine.

ARGUMENT

A. Under the Learned Intermediary Doctrine, Alabama law does not include a duty to provide instructions to the prescribing physician about mitigating warned-of side effects.

Since its adoption of the Learned Intermediary Doctrine in *Stone v. Smith, Kline & French Laboratories*, 447 So. 2d 1301 (Ala. 1984), this Court has consistently held that the pharmaceutical manufacturer's duty to warn is limited to providing information about the risks associated

with its prescription medication. In *Stone*, this Court, in response to a certified question posed by the United States Court of Appeals for the Eleventh Circuit, adopted the Learned Intermediary Doctrine. *Stone*, 447 So. 2d at 1305. There, the Eleventh Circuit propounded three certified questions to this Court. *Id.* at 1302-1303. The third question asked the following: "If the adequacy of the warning determines whether an unavoidably unsafe prescription drug is unreasonably dangerous, is an adequate warning to the prescribing physician, but not to the ultimate consumer, sufficient as a matter of law?" *Id.* at 1303. This Court answered that question "in the affirmative." *Id.* at 1305. In doing so, the Court quoted with approval the "sound reasoning" of the United States Court of Appeals for the Fifth Circuit in *Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir. 1974).

In *Reyes*, the Fifth Circuit stated "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." *Reyes*, 498 F.2d at 1276. This Court described the Fifth Circuit's opinion in *Reyes* as the "proper understanding" of "the physician's role in prescribing ethical drugs, and the significance of a

drug manufacturer's warnings in undertaking that responsibility." *Stone*, 447 So. 2d at 1304. The Fifth Circuit concluded in *Reyes*, and the Alabama Supreme Court adopted in *Stone*, that "[p]harmaceutical 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." *Stone*, 447 So. 2d at 1305, quoting *Reyes*, 498 F.2d at 1276. Thus, the pharmaceutical manufacturer's duty to warn is limited to potential dangers inherent with the prescription medication.

The *Stone* case provides sound guidance here because the facts presented in that case so closely parallel those in the present case. In *Stone*, like here, there was no dispute that the prescribing physician was aware of the risk of the side effect plaintiff claimed to experience (in *Stone*, cholestatic jaundice). *Stone*, 447 So. 2d at 1304. Notwithstanding the prescribing physician's awareness of the risk, plaintiffs in *Stone* contended that the manufacturer had a duty to provide not just a warning about the risk, but further medical guidance, without which purportedly the physician was "incapable of making an informed choice

to prescribe Thorazine, because he was unable to predict the occurrence of an adverse reaction." *Id.*

While the proposed additional duty to warn in *Stone* was not phrased precisely the same as Blackburn here, the plaintiffs in *Stone* sought to impose a responsibility on the drug manufacturer to provide information beyond the specific risks associated with that medication. That is the exactly what Blackburn seeks here by contending that the drug manufacturer must give his prescribing physician recommendations about a testing protocol in addition to a warning about the risk. Disagreeing with that argument, in *Stone* this Court rejected any duty to warn beyond the duty to warn of the risk on the part of the manufacturer. *Id.* at 1304-1305.

The holding in *Stone*, standing alone, requires this Court to answer the Certified Question in the negative. *Stone* certainly did not create an obligation on the part of the drug manufacturer to recommend any sort of testing or other monitoring regime for the purpose of detecting a warned-of side effect. This Court should decline Blackburn's invitation to do so here.

Twenty years after *Stone*, this Court reaffirmed the scope of the Learned Intermediary Doctrine in *Walls v. Alpharma USPD, Inc.*, 887 So. 2d 881 (Ala. 2004). In *Walls*, consistent with its holding in *Stone*, this Court articulated the scope of the Learned Intermediary Doctrine under Alabama law by stating: "Under the learned intermediary doctrine, a 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." *Walls*, 887 So. 2d at 883, citing *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313 (11th Cir. 2000). Again, like this case, *Walls* involved a certified question to the Alabama Supreme Court from a federal court, this time the United States District Court for the Northern District of Alabama. While the District Court certified two questions, only the first is relevant to the issues presented here. That question asked: "Does a pharmacist have a duty to warn of foreseeable injuries from the use of the prescription drug he/she is dispensing under AEMLD [Alabama Extended Manufacturer's Liability Doctrine], common-law negligence or other Alabama law?" *Walls*, 887 So. 2d at 883.

In determining that a pharmacist had no such duty, this Court cited with approval decisions from a number of courts around the country that

had previously considered the issue. In particular as it relates to the role of the prescribing physician in the physician-patient relationship, this Court noted:

> Neither manufacturer nor pharmacist has the medical education or knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude into the physician-patient relationship. In deciding whether to use a prescription drug, the patient relies primarily on the expertise and judgment of the physician. Proper weighing of the risks and benefits of a proposed drug treatment and determining what facts to tell the patient about the drug requires an individualized medical judgment based on knowledge of the patient and his or her medical condition.... Requiring the pharmacist to warn of potential risks associated with a drug would interject the pharmacist into the physician-patient relationship and interfere with ongoing treatment. We believe that duty, and any liability arising therefrom is best left with the physician.

Walls, 887 So. 2d at 886, citing *McKee v. American Home Products Corp.*, 113 Wash.2d 701, 712, 782 P.2d 1045, 1051 (1989). The Alabama Supreme Court adopted this reasoning and determined that a pharmacist had no duty to warn his or her customer. *Walls*, 887 So. 2d at 886.

The logic of this Court's decision in *Walls* continues to apply with full force and supports limiting the duty to warn to providing information about risks to the prescribing physician so that he or she can make the

medical judgment necessary to prescribe the medication. It does not impose on the drug manufacturer the duty to interfere with the physician-patient relationship.

Several years after the *Walls* case, this Court again affirmed the application of the Learned Intermediary Doctrine and addressed the role of the drug manufacturer in connection with prescription medications in *Springhill Hospitals, Inc. v. Larrimore*, 5 So. 3d 513 (Ala. 2008). In *Larrimore*, this Court stated that the "learned-intermediary doctrine is more than just a narrow rule of law regarding a manufacturer's or pharmacist's limited duty to warn. It addresses questions of liability in light of the relationships between the parties involved in the distribution, prescribing, and use of prescription drugs." *Larrimore*, 5 So. 3d at 518.

In further describing the relationship between the manufacturer and the prescribing physician, this Court again quoted with approval the language from *Walls* which noted that, among other things, the drug manufacturer does not possess the "knowledge of the medical history of the patient which would justify a judicial imposition of a duty to intrude into the physician-patient relationship." *Id.* at 518, quoting *Walls*, 887 So. 2d at 886. The Court stated that "the physician, not the pharmacist,

has the medical education and training and the knowledge of a patient's individual medical history necessary for properly prescribing medication." *Larrimore*, 5 So. 3d at 519. The prescribing physician's medical education and training and his or her knowledge of the patient's medical history support the limitation of the duty to warn to risks associated with the prescription medication.

Most recently, this Court thoroughly considered the scope of the duty to warn in the context of the Learned Intermediary Doctrine in *Weeks v. Wyeth*, 159 So. 3d 649 (Ala. 2014) *abrogated by statute on different grounds.* In *Weeks*, this Court described in detail the parameters of the Learned Intermediary Doctrine, consistent with long-settled Alabama law, by stating:

> In *Stone v. Smith, Kline & French Laboratories,* 447 So.2d 1301 (Ala.1984), this Court adopted the learned-intermediary doctrine in a case addressing whether a manufacturer's duty to warn extends beyond the prescribing physician to the physician's patient who would ultimately use the drugs. The principle behind the learned-intermediary doctrine is that prescribing physicians act as learned intermediaries between a manufacturer of a drug and the consumer/patient and that, therefore, the physician stands in the best position to evaluate a patient's needs and to assess the risks and benefits of a particular course of treatment for the patient. A consumer can obtain a prescription drug only through a physician or other qualified health-care provider. 21 U.S.C. § 353(b)(1). Physicians are trained to understand the highly technical

warnings required by the FDA in drug labeling. 21 C.F.R. § 201.56. The learned-intermediary doctrine was established in *Marcus v. Specific Pharmaceuticals,* 191 Misc. 285, 77 N.Y.S.2d 508 (N.Y.Sup.Ct.1948), as an absolute defense for "failure to warn" cases. Mitesh Bansilal Shah, Commentary, *As a Matter of Fact or a Matter of Law: The Learned Intermediary Doctrine in Alabama,* 53 Ala. L. Rev. 1299, 1301 (2002).

"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 a 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." *Reyes v. Wyeth Labs.,* 498 F.2d 1264, 1276 (5th Cir.1974).

The learned-intermediary doctrine recognizes the role of the physician as a learned intermediary between a drug manufacturer and a patient. As the United States Court of Appeals for the Eleventh Circuit has explained:

"In cases involving complex products, such as those in which pharmaceutical companies are selling prescription drugs, the learned intermediary doctrine applies. Under the learned intermediary doctrine, a 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. This standard 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.' As such, we rely on the expertise of the physician intermediary to bridge the gap in special cases where the product and related warning are sufficiently complex so as not to be fully appreciated by the consumer.... '[U]nder the "learned intermediary doctrine" the adequacy of [the

> defendant's] warning is measured by its effect on the physician, ... to whom it owed a duty to warn, and not by its effect on [the consumer].'" *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313–14 (11th Cir. 2000) (citations omitted).
>
> A prescription-drug manufacturer fulfills its duty to warn the ultimate users of the risks of its product by providing adequate warnings to the learned intermediaries who prescribe the drug. Once that duty is fulfilled, the manufacturer has no further duty to warn the patient directly. However, if the warning to the learned intermediary is inadequate or misrepresents the risk, the manufacturer remains liable for the injuries sustained by the patient. The patient must show that the manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury. In short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient.

Weeks, 159 So. 3d at 672-673. In *Weeks*, this Court continued to limit the drug manufacturer's duty, under the Learned Intermediary Doctrine, to warn of risks associated with the medication.

This delineation of the duty has been confirmed multiple times by this Court over nearly four decades. It is consistent with well-established understanding of the role played by the prescribing physician. Any different rule would only serve to confuse the well-established relationship between the patient, prescribing-physician and drug

manufacturer. The *Stone*, *Walls*, *Larrimore* and *Weeks* cases are clear about what duty is owed and leave no room for such confusion.

Accepting Blackburn's argument that a duty exists to provide a testing protocol in conjunction with a prescription medication would be a major departure from existing law. There is no reason to supplant long-settled Alabama law to expand the clearly defined duty belonging to prescription drug manufacturers. As this Court has recognized, stare decisis is "[t]he doctrine of precedent, under which it is necessary for a court to follow earlier judicial decisions when the same points arise again in litigation." *Goldome Credit Corp. v. Burke*, 923 So. 2d 282, 292 (Ala. 2005) citing *Black's Law Dictionary* 1443 (8th ed. 2004). Stare decisis exists for the purpose of bringing predictability and stability to the law, "even when [the court is] enticed to embrace what appears to be a more logically sound rule." *Goldome Credit*, 923 So. 2d at 292. As this Court has recognized, it may overrule prior decisions only when convinced "beyond ... doubt that such decisions were wrong when decided or that time has [effected] such change as to require a change in the law." *Id.* at 292. Stare decisis requires the Court to uphold its longstanding interpretation in multiple cases of the duty to warn under the Learned

Intermediary Doctrine as most recently discussed in *Weeks*, which when applied to the facts of this case, runs contrary to expanding the duty to warn.

Expansion of the duty to warn under the Learned Intermediary Doctrine is not supported by references to the term "instructions" in other contexts. Use of the word "instructions" in cases involving other non-prescription drug products does not support the imposition of a duty to provide a medical monitoring protocol for every warned-of risk associated with a medication. Furthermore, Plaintiff's focus on the term "instructions" is misleading. In the context of prescription drugs, manufacturers do provide information which addresses the dosing and strength of the medication thereby instructing the prescribing physician as to how to prescribe the medication. Prescription drugs are unique in that a person needs the prescription for the drug from a physician before purchasing and using that product. The process requires the physician to exercise his or her medical judgment as to whether to prescribe the drug in the first place. There is no comparable analogy with any other type of product due to the involvement of professional medical judgment prior to the patient obtaining the drug.

Expansion of the well-established duty to warn in the context of prescription medications is not supported for another reason. Regardless of how framed, the real issue presented in any case involving allegations of failure to warn is whether the warning provided is adequate. In this context, the issue is whether the information provided by the drug manufacturer is adequate to warn the prescribing physician of the risks associated with the pharmaceutical product. The inquiry begins and ends there. There is no reason to impose a new broad and unworkable obligation on drug manufacturers when the core question will be the same – did the manufacturer provide an adequate warning?

The prior opinions of this Court have never included any requirement that a prescription drug manufacturer provide medical testing protocols in conjunction with its warning about potential risks associated with its medications. Blackburn and his *amici* do not identify any Alabama cases involving prescription drugs which define the duty to warn in that manner. To the contrary, almost forty years of Alabama law clearly establishes that the duty to warn requires information only about risks associated with the medication. That clear and well-defined duty should not be expanded here.

B. Proof of proximate causation, a fundamental legal requirement, is eliminated by an expansion of the duty to warn.

The expanded duty arguments advanced in this case run afoul of another well-settled principle of Alabama law involving prescription medications. Bedrock Alabama law requires a plaintiff in a pharmaceutical product liability case to prove proximate causation. *E.R. Squibb & Sons, Inc. v. Cox*, 477 So. 2d 963 (Ala. 1985). In the context of failure to warn claims like those presented here, proof of proximate cause requires the plaintiff to prove that a different warning would have caused the prescribing physician not to prescribe the drug to the plaintiff. On this point, *Weeks* is again determinative.

Under *Weeks*, a plaintiff "must show that the manufacturer failed to warn the physician of a risk not otherwise known to the physician and that the failure to warn was the actual and proximate cause of the patient's injury." *Weeks*, 159 So. 3d at 673. "In short, the patient must show that, but for the false representation made in the warning, the prescribing physician would not have prescribed the medication to his patient." *Weeks*, 159 So. 3d 673-674. Thus, Alabama law is clear that

proof of proximate cause requires the plaintiff to show that the drug would not have been prescribed had the proper warning been provided.

This longstanding legal requirement would be effectively eviscerated by an expanded duty to provide medical monitoring recommendations in connection with a prescription drug. To do so would allow a plaintiff to argue speculatively that had the information regarding a medical monitoring protocol been provided by the drug manufacturer, the drug may still have been prescribed but would have been done in a different manner – exactly what Blackburn asserts here. The expansion of the duty to warn becomes effectively limitless when all a plaintiff has to contend is that more information would have led to a different prescribing practice even if the drug would have nonetheless still been prescribed. There is no support in Alabama law for such a departure from well-defined requirement of proof of proximate cause. In fact, this argument runs contrary to clear Alabama law on this point as set out in *Weeks*. The effective elimination of the traditional proximate causation requirement is another reason to decline to expand the duty to warn.

C. A strong policy reason supports rejecting the expanded duty offered by Blackburn.

There is a strong policy reason which supports the rejection of the expansion of the duty to warn under the Learned Intermediary Doctrine and supports answering the Certified Question in the negative. Any expansion of the duty warn to include medical testing protocols as suggested by Blackburn clearly trespasses into the practice of medicine. The practical effect of expanding the duty to warn would require a pharmaceutical manufacturer to instruct the prescribing physician as to how to practice medicine, including, but not limited to, specifically recommending certain tests and the timing of when those tests should be performed. Any such requirement clearly goes beyond the accepted role of a pharmaceutical manufacturer to provide information about the risks associated with its medications. This Court has recognized and described the physician's role in the prescribing of medications in *Stone*, *Walls* and *Weeks*. That well-established role should not be so radically revised by expanding the duty to warn as suggested here.

Moreover, the suggested expansion of the duty to warn is not justified because of the information possessed by the prescribing physician about both "patient and palliative." *Stone*, 447 So. 2d at 1305,

quoting *Reyes*, 498 F.2d at 1276. Since the adoption of the Learned Intermediary Doctrine in *Stone*, this Court has taken great care to delineate and describe the proper role of the prescribing physician in the context of prescription medications. *Stone*, 447 So. 2d at 1304; *Walls*, 887 So. 2d at 886; *Larrimore*, 5 So. 3d at 518-519; *Weeks*, 159 So. 3d at 672-673. In fact, this Court has quoted the language from *Reyes* describing the prescribing physician's role on multiple occasions. Over the nearly four decades since *Stone* was decided, the role of the physician in prescribing medications has not changed. For the same reasons presented in those cases, there is no basis, factual or legal, to justify requiring a pharmaceutical manufacturer to intrude into the practice of medicine by making recommendations about a testing regimen.

There is no practical limit to the expansion of the duty to warn to include a medical testing regimen. To place upon the pharmaceutical manufacturer the responsibility to advising the prescribing about what diagnostic tests to run and when to run them would turn the traditional relationship between manufacturer and prescriber on its head. Sound policy requires that this Court not adopt such an expansive and unworkable duty.

CONCLUSION

Settled Alabama law, under the Learned Intermediary Doctrine, limits a drug manufacturer's duty to providing warning about the risks associated with the prescription medication. Alabama law has consistently set out this duty for nearly forty years, and there is no reason or basis to expand it now, particularly under the facts of this case. The expanded duty sought in this case eliminates the fundamental requirement of proof of proximate cause and improperly interferes with the well-established physician-patient relationship. For all these reasons, this Court should answer the Certified Question in the negative.

CERTIFICATE OF COMPLIANCE

Pursuant to Rules 21(d) and 32(d) of the Alabama Rules of Appellate Procedure, I hereby certify that this document contains 4225 words. I further certify that this document was prepared using the proportionally spaced typeface Century Schoolbook font in 14-point type.

/s/ Frederick G. Helmsing, Jr.

CERTIFICATE OF SERVICE

I hereby certify that on the 14th day of April, 2022, I electronically filed the foregoing pleading with the Appellate Courts' Online Information Service and pursuant to the Alabama Rules of Appellate Procedure, I have electronically served a true and correct copy of the foregoing pleading to the following counsel of record for the parties to this appeal:

/s/ Frederick G. Helmsing, Jr.