CASE NO. 1210140

IN THE SUPREME COURT OF ALABAMA

MARK BLACKBURN,

Plaintiff-Appellant,

v.
SHIRE US INC., SHIRE LLC,

Defendants-Appellees.

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

No. 20-12258

AMICUS CURIAE BRIEF OF ALABAMA ASSOCIATION FOR JUSTICE AND AMERICAN ASSOCIATION FOR JUSTICE

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INTEREST OF AMICUS CURIAE

Amici are organizations of lawyers and individuals that seek to protect the constitutional right to a trial by jury guaranteed by the Seventh Amendment to the United States Constitution.

Alabama Association for Justice ("ALAJ") is an organization of Alabama lawyers representing persons harmed by the misconduct of others and who seek justice in the courtroom. The goals of ALAJ are holding wrongdoers accountable through the remedies provided by our civil justice system, ensuring that our clients and their families are fairly compensated, and preserving the right to trial by jury.

American Association for Justice ("AAJ") is a national, voluntary bar association established in 1946 to strengthen the civil justice system, preserve the right to trial by jury, and protect access to the courts for those who have been wrongfully injured. With members in the United States, Canada, and abroad, AAJ is the world's largest plaintiff trial bar. AAJ's members primarily represent plaintiffs in personal injury actions, employment rights cases, consumer cases, and other civil actions, including in Alabama courts. Throughout its 75-year history, AAJ has served as a leading advocate for the right of all Americans to seek legal

recourse. Neither ALAJ nor AAJ have a pecuniary interest in the outcome of this case.

Amici have hundreds, if not thousands, of members who specialize in products liability cases involving drugs and medical devices, including representing consumers in multidistrict litigations ("MDLs"). Several drug and device litigations in the past have relied on the general products liability principle that manufacturers have a duty to provide adequate instructions. *Amici* believe that the Alabama Supreme Court's ruling will affect Alabama citizens' rights in cases where their doctors would have chosen a different course of action had a drug or device company provided adequate instructions on how to safely use the product and minimize certain risks.

STATEMENT OF THE CASE

Amici adopt the Appellant's Statement of the Case.

STATEMENT OF THE ISSUES

Although the Eleventh Circuit presented two questions in this appeal, ALAJ and AAJ address only Certified Question 1:

> 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?

SUMMARY OF THE ARGUMENT

The Alabama Supreme Court should answer Certified Question 1 in the affirmative for three main reasons. First, the "duty to warn" actually includes two duties: (1) to provide warnings and (2) to provide instructions for safe use. The *Restatement Second*, for example, says warning defects may be based on inadequate "directions or warning." This Court has previously ruled that the warning requirements under the Alabama Extended Manufacturer's Liability Doctrine ("AEMLD") are the same as the *Restatement Second*. The Court should follow the same reasoning and clarify that the AEMLD's duty to warn is consistent with the *Restatement Second*. Second, under the learned intermediary doctrine, the duty to provide both warnings and instructions affects Alabama doctors' ability to make informed decisions on how best to treat their patients. Third, Alabama's statutory definition of a products liability action expressly includes instructions.

ARGUMENT

I. The duty to warn includes a duty to provide both warnings and instructions for safe use.

The duty to warn is "comprised of two separate duties: (1) the duty to *warn*, to provide information on hidden dangers in a product; and (2)

the duty to *instruct*, to provide information on how to avoid those dangers and use the product safely." DAVID G. OWEN, PRODUCTS LIABILITY LAW, 570 (4th ed. 2022) (emphasis in original). Professor Owen's most recent *Hornbook Series* on *Products Liability Law* explains that there are two duties under one umbrella:

> The "duty to warn" is an umbrella term for describing a manufacturer's informational obligations to those who purchase and use its products. This duty actually is comprised of two quite separate obligations: the duty to *warn*—to inform buyers and users of hidden dangers in a product; and the duty to *instruct*—to inform buyers on how to *avoid* a product's dangers in order to use it safely.

Id. at 557-58 (emphasis in original); see also AM. L. PROD. LIAB. 3D § 32:20 (2001) (stating that "the duty to warn actually consists of two duties"). The term "warning defect" also includes "both failures to warn of hidden risks and failures to instruct properly to alleviate risks in a product's use." 1 OWEN & DAVIS ON PROD. LIAB. § 9:1 n.1 (4th ed. 2016).

A. The AEMLD's duty to warn is consistent with the Restatement Second, which recognizes both a duty to warn and instruct.

This Court has arguably already adopted the duty to instruct by ruling that the AEMLD's warning requirements are the same as the *Restatement Second*. See Ex parte Chevron Chem. Co., 720 So. 2d 922,

927 (Ala. 1998) (quoting RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965)). *Restatement Second's* comment j is titled "[d]irections or warning," and states: "[i]n order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use." RESTATEMENT (SECOND) OF TORTS § 402A cmt. j (1965). For "poisonous drugs," a "warning as to use may be required." Id. Comment k also provides that prescription drugs are not defective if "accompanied by proper directions and warning[s]." Id. at § 402A cmt. k.

The Alabama Supreme Court judicially created the AEMLD in Casrell v. Altec Industries, Inc., 335 So.2d 128 (Ala. 1976) and Atkins v. American Motors Corp., 335 So.2d 134 (Ala. 1976). Alabama adopted a modified version of the *Restatement Second* and retained the tort concept of fault, instead of complete "strict" liability. See, e.g., Casrell, 335 So. 2d at 132 (stating that the AEMLD retains the "traditional negligence" concept of fault); Spain v. Brown & Williamson Tobacco Corp., 872 So. 2d 101, 111 (Ala. 2003) ("The AEMLD doctrine is based in tort law, having evolved from negligence law and having been influenced by *Restatement (Second) of Torts*.").

In Atkins, this Court cited specifically to *Restatement Second's* comments j and k when it defined defenses like assumption of the risk. See Atkins, 335 So. 2d at 143 (citing to "Comment g, h, i, j, and k to § 402A of the Restatement for a discussion of defective condition, unreasonably dangerous, *directions and* warnings, and unavoidably unsafe products") (emphasis added). This Court also attached an appendix of the *Restatement Second*, which included comments j and k. See id. at 143 n.5 (explaining that while this Court's "holding modifies the Restatement's theory of strict liability, the Comment, in large measure, retains its utility"). Since *Atkins*, this Court has continued to rely on the *Restatement Second* in interpreting Alabama's warning law.

This Court relied on the *Restatement Second's* comments j and k in Stone v. Smith, Kline & French Laboratories, and explained that "the Restatement's blueprint for the liability of drug manufacturers substantially comports with our remodeling of Section 402A in Casrell v. Altec Industries, Inc., 335 So.2d 128 (Ala. 1976), and Atkins v. American Motors Corp., 335 So.2d 134 (Ala. 1976)." 447 So. 2d 1301, 1303 n.2 (Ala. 1984); see also Griggs v. Combe, Inc., 456 So. 2d 790, 792 (Ala. 1984); Chevron, 720 So. 2d at 927 (citing RESTATEMENT (SECOND) OF TORTS §

402A, cmt. j (1965)). This Court, in Chevron, further addressed the difference between negligent failure to warn and the AEMLD's failure to warn. 720 So. 2d at 929. This Court concluded that the "standards for warnings" are the *same* under the AEMLD, the *Restatement Second*, and negligent failure to warn. Id. The Court explained that it declined to alter these requirements due to "the wealth of authority and the cogent rationale for interpreting [the *Restatement Second*] § 402 A as the drafters of the *Restatement* wrote it." Id. at 929.

This Court should similarly interpret the AEMLD's duty to warn to include directions and warnings as the drafters of the *Restatement* wrote it. See Chevron, 720 So. 2d at 929. If this Court clarifies that the AEMLD's duty to warn is the same as the *Restatement Second*, it would preserve Alabama's commitment to fault-based principles. See id. at 928 (citing Klem v. E.I. DuPont De Nemours Co., 19 F.3d 997, 1001–03 (5th Cir. 1994)); see also James B. Sales, The Duty to Warn and Instruct for Safe Use in Strict Tort Liability, 13 ST. MARY'S L.J. 521, 585 (1982) (explaining that the duty to warn falls within negligence, not strict liability, because the manufacturer's conduct is important "in

determining whether a warning or instructions should accompany a product to the ultimate user").

B. The Restatement Third also supports the dual duty to provide warnings and instructions.

The *Restatement Third* similarly provides that a product may be defective due to "inadequate instructions or warnings." RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 2(c) (1998). The *Restatement Third* also specifically states that a drug or medical device "is defective if [it] . . . is not reasonably safe due to inadequate instructions or warnings . . . provided to prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings." RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(b); (d)(1).

The *Restatement Third* also aligns with the AEMLD's commitment to fault-based principles because it similarly "defines a manufacturer's responsibility for warning defects in prescription drugs in conventional negligence terms." See David G. Owen, Dangers in Prescription Drugs: Filling A Private Law Gap in the Healthcare Debate, 42 CONN. L. REV. 733, 759 (2010). Professor Owen further explained that nearly all state's warning requirements are grounded in negligence:

> [W]hile most courts in this context continue to apply 'strict' liability by name to warning cases, the principles they in fact apply are nothing more than negligence. The Third Restatement follows this approach in limiting a manufacturer's warning responsibility in prescription drug cases to a duty to provide "reasonable instructions or warnings regarding foreseeable risks of harm."

Id. at 753 (citing RESTATEMENT (THIRD) OF TORTS: PRODS. LIAB. § 6(d) (1998)). The Court should therefore look to both the *Restatement Second* and *Third*, as well as the overwhelming majority of states, which recognize that the duty to warn includes both a duty to provide warnings and instructions.

C. Alabama should join the national consensus and clarify that the duty to warn includes a duty to provide warnings and instructions.

Amici ALAJ and AAJ have been unable to find *any* case in which a court ruled that its state's duty to warn did not include a duty to provide instructions.[1] There are also *no* state statutes that expressly exclude a

[1] The closest example was a Michigan appellate court case that found Michigan law did not impose a duty to instruct. Antcliff v. State Emp. Credit Union, 290 N.W.2d 420, 425 (Mich. App. 1980). The Michigan Supreme Court disagreed and decided that Michigan law does recognize the duty to warn and instruct, although it ultimately decided that there was no duty in that particular case due to "a known or obvious product-connected danger." See Antcliff v. State Emps. Credit Union, 327 N.W.2d 814, 816-21 (Mich. 1982).

duty to provide instructions. For instance, twenty-six states have statutorily defined a products liability claim or an underlying warning-defect claim. Nineteen of those states, including Alabama, expressly include "instructions" in their statutory definitions. Ala. Code § 6-5-501; Ariz. Stat. § 12-681; Ark. Code § 16-116-202; Colo. Stat. § 13-21-401; Conn. Gen. Stat. § 52-572; Kan. Stat. §§ 60–3302; 05; Ky. Stat. § 411.300(1); La. Stat. § 9:2800.53(9); Miss. Code § 11-1-63; Neb. Stat. 25-21,180; N.J. Stat. § 2A:58C-2; N.Y. Ins. Law § 107; N.C. Gen. Stat. §§ 99B-1(3); 99B-5; N.D. Cent. Code § 28-01.3-01(2); Ohio Code § 2307.76; Or. Stat. § 30.900; S.D. Codified Laws § 15-2-12.2; Tenn. Code § 29-28-102(6); Wash. Code §§ 7.72.010; 30. The seven remaining states have recognized the duty to instruct through caselaw.[2] See, e.g., Buckner v. Milwaukee Elec. Tool Corp., 166 Cal. Rptr. 3d 202, 208 (Cal. Ct. App. 2013) ("Under California's product liability law, '[a] product may be defective if it is dangerous because it lacks adequate warnings or instructions.'") (additional citation omitted).

[2] The seven remaining states were California (Cal. Civ. Code § 1714.45(a)(c)); Delaware (Del Code. Tit. 18, § 8002); Indiana (Ind. Code § 34-6-2-115); Missouri (Mo. Stat. § 537.760(3)(b)); Oklahoma (Okla. Stat. Tit. 36, § 6453(9)); Texas (Tex. Civ. Prac. & Rem. Code § 82.001); and Vermont (Vt. Stat. Tit. 8, § 6051).

Several courts have specifically recognized that a drug or device manufacturer's duty to warn includes a duty to provide instructions to physicians. Those decisions show that at least sixteen states recognize a duty to provide adequate instructions in drug or device cases. See Shanks v. Upjohn Co., 835 P.2d 1189, 1200 (Alaska 1992) (in a drug case, the Alaska Supreme Court stated that failure-to-warn claims may "be predicated on the inadequacy of the directions or instructions for the safe use of the product"); Myers v. Hoffman-La Roche, Inc., 170 P.3d 254, 262-64 (Ariz. Ct. App. 2007), rev. denied and ordered depublished 183 P.3d 544 (Ariz. 2008) (In a drug case, the Arizona appellate court explained that the warning of a risk is different from "adequate directions on how to safely use the product in order to avoid the identified harm."); Oja v. Howmedica, Inc., 111 F.3d 782, 792 n.5 (10th Cir. 1997) (In applying Colorado law in a hip-replacement case, the Tenth Circuit found that the district court's jury instruction was correct regarding the device manufacturer's duty to warn, including "to give physicians adequate warnings and instructions concerning methods for minimizing danger and injury."); Lacy v. G.D. Searle & Co., 567 A.2d 398, 400 (Del. 1989) (in adopting the learned-intermediary doctrine, explaining that a drug or

device manufacturer's duty to warn includes "to fully apprise the physician of the proper procedures for use") (quoting Terhune v. A. H. Robins Co., 577 P.2d 975, 978 (Wash. 1978))); Buckner v. Allergan Pharms., Inc., 400 So. 2d 820, 823 (Fla. Dist. Ct. App. 1981) (explaining that a drug's labeling is only adequate if it "fully apprise[s] the physician of the proper procedures for use and the dangers involved" (quoting Terhune, 577 P.2d at 978)); Ortho Pharms. Corp. v. Chapman, 388 N.E.2d 541, 549 (Ind. App. 1979) (a drug is not defective if "'properly labeled and carries the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved'" (quoting Terhune, 577 P.2d at 978)); Wooderson v. Ortho Pharms. Corp., 681 P.2d 1038, 1052 (Kan. 1984) (drug manufacturers must provide "'the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved'") (quoting Terhune, 577 P.2d at 978)); Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 269-70 (5th Cir. 2002) (applying Louisiana law); Tenuto v. Lederle Labs., 695 N.Y.S.2d 259, 266 (N.Y. Sup. Ct. 1999) (in a vaccine case, finding that the "failure to include the available information about IPV precautions with respect to the steps a physician could take to avoid

the risk of contact polio raises issue of fact as to whether [the defendant] provided reasonable instructions or warnings"); Edwards v. Basel Pharms., 933 P.2d 298, 300 (Okla. 1997) (stating that a drug is not defective if it is "'labeled and carries the necessary instructions and warnings to fully apprize the physician of the proper procedures for use and the dangers involved'") (additional citation omitted); Incollingo v. Ewing, 282 A.2d 206, 214 (Pa. 1971) (In a drug case, the Pennsylvania Supreme Court affirmed that it was a fact question whether the drug's label adequately instructed that three administrations of the drug separated by six to nine months constituted "intermittent" therapy, thus requiring blood studies.) (overruled on other grounds); Bristol-Myers Squibb Co. v. Gonzales, 561 S.W.2d 801 (Tex. 1978) (In a drug case, concluding that there was sufficient evidence to support the jury finding that the warnings were inadequate, though reversal and new trial were required on other grounds, when there was evidence that the drug company should have instructed physicians to: (a) treat infections with a less-noxious alternative; (b) irrigate the wound only one time as a post-surgical wash; and (c) test a patient's hearing and kidney function to determine safe dosage.); Wyeth v. Levine, 555 U.S. 555, 581 (2009) (The

Supreme Court applied Vermont law and, in addition to addressing preemption, affirmed the Vermont Supreme Court's upholding of the jury's finding on failure to warn in a case where Wyeth warned of the risk of gangrene upon injection but failed to instruct physicians on how to minimize the risk of gangrene by using the IV-drip method.); Talley v. Danek Med., Inc., 179 F.3d 154, 163 (4th Cir. 1999) (applying Virginia law and stating that "the manufacturer of the drug or device owes the patient only the duty to warn the physician and to provide the physician with adequate product instructions"); Terhune, 577 P.2d at 978 (the Washington Supreme Court explaining that drug manufacturers must provide "the necessary instructions and warnings to fully apprise the physician of the proper procedures for use and the dangers involved"); Thom v. Bristol-Myers Squibb Co., 353 F.3d 848, 850 (10th Cir. 2003) (In applying Wyoming law, the Tenth Circuit reversed the district court's finding that the mere reference to an adverse effect was enough; the jury could have found the warnings were inadequate due to evidence that the drug company should have instructed that medical intervention was required within four to eight hours to reduce the adverse effect.).

The Fifth Circuit, in Stahl, addressed this same question under Louisiana law. 283 F.3d at 269-71. Stahl involved a plaintiff who developed cholestatic hepatitis after taking Lamisil, a drug manufactured by Novartis. Id. at 260. One of the plaintiff's failure-to-warn claims alleged that Novartis should have recommended that physicians conduct weekly or biweekly blood testing. Id. at 269. Novartis argued that it was not a proper failure to warn claim because the blood-testing recommendations were not "warnings." Id. The Fifth Circuit found this argument "unpersuasive" and concluded:

> [I]t is an accepted tenet of Louisiana products liability law that a manufacturer's duty to warn includes a duty to provide adequate instructions for safe use of a product. *See Hines v. Remington Arms Co., Inc.*, 648 So.2d 331, 337 (La. 1994). There appears to be no compelling reason to exempt recommended medical monitoring schemes—which are, in essence, instructions for safe use of prescription drugs—from a drug manufacturer's duty to warn.

Id. at 269-70. The Fifth Circuit reasoned that: (a) Louisiana's statutory definition included instructions; (b) the *Restatement Third's* Section 6(b) notes that a drug or device is defective if it has inadequate warnings or instructions; and (c) an earlier statement by the Louisiana Supreme Court said that inadequate warning claims could be based on

instructions. Id. (additional citations omitted). This Court should follow the same reasoning here in interpreting Alabama law.

Here, Shire US Inc. and Shire LLC ("Shire") make the same argument that the Fifth Circuit rejected in Stahl. Compare id. at 269 ("Novartis contend[ed] that this claim [wa]s not appropriately classified as a failure-to-warn claim because the blood testing recommendations contained in the package insert do not actually constitute 'warnings.'") with (Eleventh Cir. Def. Appellees Shire Resp. Brief at 23) (Shire contends that "[a] recommendation for renal monitoring is not a warning about a risk and cannot be the basis of a failure-to-warn claim"). This Court, like the Fifth Circuit's reasoning in Stahl, should find that the AEMLD recognizes a duty to provide instructions because: (a) Alabama's statutory definition includes instructions (see infra at Section III); (b) both *Restatements Second* and *Third* include instructions; and (c) the Alabama Supreme Court has ruled that Alabama's warning standards are equivalent to the *Restatement Second*. See Stahl, 283 F.3d at 269-71.

D. The Court should be cautious to distinguish a duty to instruct from a duty to train.

The Court should not be persuaded by cases that found no duty to train because a duty to provide instructions is distinguishable from a

duty to provide training to physicians. The Minnesota Supreme Court addressed this distinction in Glorvigen v. Cirrus Design Corp., 816 N.W.2d 572 (Minn. 2012). In that case, it was *undisputed* that the airplane manufacturer's duty to warn included a duty to provide adequate instructions; instead, the dispute centered on whether Minnesota law required the manufacturer to provide a specific flight lesson. Id. at 582. The court concluded that, while "the duty to warn requires a supplier or manufacturer to provide adequate instructions and warnings to foreseeable users . . . there is no duty for suppliers or manufacturers to *train* users in the safe use of their product." Id. at 583 (emphasis in original; additional citation omitted); see also Jennifer A. Eppensteiner and Regina M. Nelson, Case Law Developments: "Failure to Train" and Medical Device Misuse Claims, 55 No. 4 DRI FOR DEF. 31 (2013) (Defense Research Institute article that did not dispute that device manufacturers have a duty to provide instructions but used Glorvigen as support for their contention that device manufacturers should not have a duty to provide training to physicians).

II. Whether drug and device manufacturers have a duty to provide instructions affects Alabama doctors' ability to make informed decisions in treating their patients.

The duty to warn of risks and how to avoid them gives doctors the power to make informed decisions "on whether to buy and use particular products (with particular benefits and detriments), and, if so, on how to use them safely." See DAVID G. OWEN, PRODUCTS LIABILITY LAW, 559 (4th ed. 2022). This duty to provide warnings and instructions protects the "user's right of self-determination." Id. In fact, requiring warnings and instructions shifts risk-benefit decisions about product hazards from manufacturers to product users. Id. at 558. Drug and device manufacturers should have a duty to provide adequate instructions to ensure Alabama's doctors are fully informed when making their risk-benefit decisions. See id.

Risk-benefit decisions are critical in medical practice, especially in deciding whether or how to use a medical product. See, e.g., Stone, 447 So. 2d at 1305 (the learned intermediary has "'the task of weighing the benefits of any medication against its potential dangers'") (quoting Reyes v. Wyeth Labs., 498 F.2d 1264, 1276 (5th Cir. 1974))). This choice must be "'an informed one, an individualized medical judgment bottomed on a

knowledge of both patient and palliative.'" Stone, 447 So. 2d at 1305 (quoting Reyes, 498 F.2d at 1276). When a prescribing doctor "heeds" a warning or instruction, this means the learned intermediary would have incorporated the additional information into his or her risk-benefit calculation. Eck v. Parke, Davis & Co., 256 F.3d 1013, 1021 (10th Cir. 2001) (quoting Thomas v. Hoffman-LaRoche, Inc., 949 F.2d 806, 813 (5th Cir. 1992)).

In some circumstances, a prescribing doctor may conduct a risk-benefit calculation and decide that a drug's instructions are not important. In other circumstances, a doctor may consider that instruction pertinent to treating and keeping his or her patients safe. While each circumstance is fact-specific, one thing is certain—doctors cannot make informed risk-benefit calculations without adequate information. See Stone, 447 So. 2d at 1305.

Defendants in drug and device litigations often argue that manufacturers should not be required to tell doctors how to practice medicine and, as they contend, instructions just tell doctors what they

already know.[3] The effect of instructions on physicians, however, is not so black and white. See W. Kip Viscusi, Using Warnings to Extend the Boundaries of Consumer Sovereignty, 23 HARV. J.L. & PUB. POL'Y. 211, 228–29 (1999) (explaining that instructions are more effective when they provide the doctor with "new information," rather instructions that "simply serve as reminders").

While a specialist may already know the information contained in an instruction, for instance, a general practitioner may not. See David G. Owen, Dangers in Prescription Drugs: Filling A Private Law Gap in the Healthcare Debate, 42 Conn. L. Rev. 733, 756 (2010) ("In the context of drug warnings, the manufacturer must convey all material information on possible risks to doctors, comprehensible to the general practitioner as well as to the specialist."). Manufacturers would still owe a duty to the prescribing doctor, whether they were a specialist or general

[3] The *Drug & Device Law* blog, for instance, is a blog authored by defense lawyers that suggests the issue here is about "the line between providing risk information to a doctor so that he/she can make an informed treatment decision and telling doctors how to practice medicine." See Michelle Yeary, Eleventh Circuit Certifies Two Learned Intermediary Questions to Alabama Supreme Court, DRUG & DEVICE LAW BLOG (Dec. 7, 2021), https://www.druganddevicelawblog.com/2021/12/eleventh-circuit-certifies-two-learned-intermediary-questions-to-alabama-supreme-court.html.

practitioner. See id. Another scenario is when a drug or device is an innovative concept that even the veteran specialist has not yet used in his or her practice. See Charles J. Walsh and Alissa Pyrich, FDA Efforts to Control the Flow of Information at Pharmaceutical Industry–Sponsored Medical Education Programs: A Regulatory Overdose, 24 SETON HALL L. REV. 1325, 1330–31 (1994) (explaining that "[e]ven sophisticated health care professionals depend on pharmaceutical manufacturers to provide accurate and reliable information about when and how to use their products").

Manufacturers are in the best position to convey information about their drugs and devices because they are considered experts on those products. See, e.g., O'Hare v. Merck & Co., 381 F.2d 286, 291 (8th Cir. 1967) ("A manufacturer is held to the skill of an expert in its particular field of endeavor, and is obligated to keep informed of scientific knowledge and discoveries concerning that field."). Drug or device manufacturers' cost of providing additional instructions is also minimal in comparison to the societal costs of doctors not being able to make informed decisions. See DAVID G. OWEN, PRODUCTS LIABILITY LAW, 558 (4th ed. 2022) (providing warnings or instructions is far less costly than,

for example, redesigning a product); see also Moran v. Faberge, Inc., 332 A.2d 11, 15 (Md. 1975) (a manufacturer's cost of giving an adequate warning "is usually so minimal, amounting only to the expense of adding some more printing to a label").

For these reasons, this Court should clarify that drug manufacturers have a duty to provide both warnings and instructions for safe use. Any other result would permit drug manufacturers to provide Alabama doctors with only *partial* information, which will have a direct impact on their risk-benefit calculations. See, e.g., Stone, 447 So.2d at 1305 (doctors must weigh the risks and benefits of using medical products).

III. Alabama's statutory definition of a products liability action contemplates defects in both warnings and instructions.

Alabama Code Sections 6-5-501(2) and 521(a) expressly include "instructions" in defining a product liability action. The Court interprets statutes by looking at the plain meaning. Forest Lab'ys, LLC v. Feheley, 296 So. 3d 302, 310 (Ala. 2019) (citing City of Prattville v. Corley, 892 So. 2d 845, 847 (Ala. 2003)). If the language is unambiguous, there is no need for judicial construction. Feheley, 296 So. 3d at 310 (citing First Union Nat'l Bank of Florida v. Lee Cty. Comm'n, 75 So. 3d 105, 111-12

(Ala. 2011). The Alabama Legislature is "presumed to be aware of existing law and judicial interpretation when it adopts a statute . . . and [this Court] presume[s] that the legislature does not intend to make any alteration in the law beyond what is explicitly declares." Feheley, 296 So. 3d at 313 (quoting Grimes v. Alfa Mut. Ins. Co., 227 So. 3d 475, 489 (Ala. 2017) (additional citations and internal quotations omitted).

Alabama Code Sections 6-5-501(2) and 521(a) define a "'product liability action'" as one due to injury "caused by the manufacture, construction, design, formula, preparation, assembly, installation, testing, warnings, instructions, marketing, packaging, or labeling of a manufactured product." Both sections further say that the action may be based on: (1) "negligence," (2) "innocent or negligent misrepresentation," (3) "the manufacturer's liability doctrine," (4) "the Alabama extended manufacturer's liability doctrine, as it exists or is hereafter construed or modified," (5) "breach of any implied warranty," or (6) "breach of any oral express warranty and no other." Ala. Code, 1975, §§ 6-5-501(2); 521(a).

Under the plain language of Sections 6-5-501(2) and 521(a), products liability actions may be based on defective "instructions." See Feheley, 296 So. 3d at 310. This Court should find no need for further

construction. Id. The only conceivable ambiguity could be that the definitions say, "when such action is based upon . . . the Alabama extended manufacturer's liability doctrine, as it exists or is hereafter construed or modified." Ala. Code §§ 6-5-501(2); 521(a). If the Court finds that this phrase creates an ambiguity, the Court should still conclude that the AEMLD recognizes a duty to provide instructions because the Court has ruled that the AEMLD's warning requirements are the same as the *Restatement Second*. See Chevron, 720 So. 2d at 929. Therefore, the language in Sections 6-5-501(2) and 521(a) align with the *Restatement Second* in that they all contemplate defects in instructions.

CONCLUSION

The Court should answer Certified Question 1 in the affirmative for three main reasons. First, the AEMLD derives from the *Restatement Second*, which expressly recognizes that manufacturers have a duty to provide adequate directions and warnings. The Court ruled that the AEMLD's warning requirements are the same as the *Restatement Second*, which also aligns with modern negligence principles. Second, a drug manufacturer's duty to provide instructions affects Alabama doctors' ability to make informed decisions. Third, Alabama's statutory

definition of a products liability action contemplates instructions for safe use. Therefore, ALAJ and AAJ respectfully request that this Court answer Certified Question 1 in the affirmative.

Dated: March 10, 2022.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that this brief complies with the font and word limitations set forth in Ala. R. App. P. 32. The type used is Century Schoolbook 14 and the brief contains 5,149 words.

/s/ Ryan J. Duplechin

CERTIFICATE OF SERVICE

I hereby certify that this filing has been served on this date via email and/or by mail pursuant to Alabama Rule of Appellate Procedure 57 on this 10th day of March 2022, to all counsel of record.

/s/ Ryan J. Duplechin