Case No.1101397

IN THE
SUPREME COURT OF ALABAMA

WYETH, INC., et al.	§	
	§	
Appellants,	§	On Appeal from the
	§	United States District
vs.	§	Court for the Middle
	§	District of Alabama,
DANNY WEEKS AND VICKI WEEKS	§	Southern Division
	§	Case No. 1:10-cv-602
Appellees.	§	

BRIEF ON BEHALF OF DRI-THE VOICE OF THE DEFENSE BAR AND ALABAMA DEFENSE LAWYERS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS, WYETH, INC., ET AL.

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INTEREST OF *AMICI CURIAE*

Amicus curiae DRI – The Voice of the Defense Bar ("DRI") is an international organization comprising approximately 22,000 attorneys defending businesses and individuals in civil litigation. Committed to enhancing the skills, effectiveness, and professionalism of defense lawyers around the globe, DRI seeks to address issues germane to defense lawyers and the civil justice system. DRI has long been a voice in the ongoing effort to make the civil justice system more fair, efficient, and consistent. To promote these objectives, DRI participates as *amicus curiae* in cases that raise issues of importance to its membership and the judicial system. This is such a case.

The Alabama Defense Lawyers Association ("ADLA") is a non-profit association of approximately 1,100 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 ADLA's stated purpose, the Association, by and through its *amicus curiae* committee, often seeks to participate in cases that involve important questions of

law in order to assist the Court in its consideration and resolution of those cases.

DRI and ADLA's interest in this case stems from their concern that Plaintiffs' theory would mark a radical departure from well-established principles governing product-liability actions and the imposition of duties in other tort litigation. Because DRI's members are involved in litigation in state and federal courts nationwide, and ADLA's members, in particular, are involved in litigation in Alabama's courts, DRI and ADLA are well-positioned to assist the Court by offering context for the certified question.

In particular, Plaintiffs' "innovator liability" theory would impose liability on manufacturers for products they did not make or distribute. That theory directly contradicts the well-established law of Alabama and a host of other jurisdictions. As the federal district court in this case observed, "Alabama law does not support the imposition on a manufacturer to disclose information to a consumer who is injured by another manufacturer's product." *Weeks v. Wyeth, Inc.*, No. 1:10-cv-602, 2011 WL 1216501, at *3 (M.D. Ala. Mar. 31, 2011). Nevertheless, these

Plaintiffs would impose on the brand-name defendants "a duty to disclose information about Reglan, the product they did manufacture, to [the plaintiff's] physician." *Id*. at *12.

Plaintiffs' theory, and the district court's preliminary conclusion that such a duty may exist under Alabama law, conflicts with decisions from other courts in this State, every federal appellate court to consider the issue, and scores of additional courts nationwide, all of which have refused to impose liability on brand-name drug manufacturers for harm allegedly caused by other manufacturers' products. Plaintiffs' expansive approach to tort liability cannot be reconciled with longstanding principles of Alabama tort law and could drastically increase liability and litigation costs for manufacturers of brand-name products. Finally, Plaintiffs' resolution of the certified question undermines separation-of-powers principles and the constraints on the judiciary's powers. The decision is therefore of great interest to DRI, ADLA, and their members.

SUMMARY OF THE ARGUMENT

The certified question presents this Court with the opportunity to reaffirm that, under Alabama law, a defendant owes no duty to a plaintiff with whom it has no relationship. The question arises in the context of Plaintiffs' claim that brand-name manufacturers of Reglan can be held liable for injuries caused by ingestion of generic metoclopramide. This so-called "innovator-liability" suit is brought under the guise of a cognizable tort duty owed by the brand-name manufacturer, even though Plaintiffs admit that they ingested a generic formulation of the drug manufactured by a different defendant.

Alabama law commands rejection of Plaintiffs' effort to expand well-established tort law principles in this manner. Under Alabama law, there must be a duty, typically existing when there is some sort of relationship between the parties, to impose tort liability. *Pritchett v. ICN Med Alliance*, 938 So.2d 933, 937-38 (Ala. 2006); *Patrick v. Union State Bank*, 681 So.2d 164, 1369 (Ala. 1996). Lack of a relationship between brand-name Reglan manufacturers and users of generic metoclopramide, like Plaintiffs here, has prompted federal district courts in Alabama deciding cases

materially identical to this one to dismiss plaintiffs' claims for lack of a duty. *Simpson v. Wyeth*, No. 7:10-CV-01771-HGD, 2010 WL 5485812, (N.D. Ala. Dec. 9, 2010), *report and recommendation adopted by* 2011 WL 10607 (N.D. Ala. Jan. 4, 2011); *Mosley v. Wyeth, Inc.*, 719 F. Supp. 2d 1340, 1347 (S.D. Ala. 2010);*Overton v. Wyeth, et.al.*, No. CA 10-0491-KD-C, 2011 WL 1343392 (S.D. Ala. Mar. 15, 2011), *report and recommendation adopted by* 2011 WL 1343391 (S.D. Ala. Apr. 7, 2011). These decisions, reached in accordance with settled Alabama law concerning the imposition of a duty, are consistent with the overwhelming majority of decisions to address the issue nationwide. See, *e.g.*, *Foster v. American Home Products Corp.*, 29 F.3d 165, 171 (4th Cir. 1994); *Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613–14 (8th Cir. 2009), *rev'd on other grounds sub nom. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011).

The United States Supreme Court's recent decision that state-law failure-to-warn claims against generic drug manufacturers are preempted does not call into question the propriety of dismissing innovator-liability suits brought against brand-name manufacturers. *PLIVA, Inc. v. Mensing*,

__U.S. __; 131 S.Ct. 2567 (2011). *Mensing* presented the question of whether FDA regulations preempt certain state-law failure-to-warn claims against generic manufacturers. *Id*. at 2572. The Supreme Court's resolution of this federal preemption question therefore does not, and could not, alter the substantive requirements of Alabama tort law. Not surprisingly, numerous courts have already expressly rejected plaintiffs' arguments that *Mensing* transforms innovator liability into a viable theory against brand-name manufacturers. Accordingly, to the extent Plaintiffs here make that argument, it must fail.

Plaintiffs' attempt to create an entirely new and different theory of tort liability, if accepted by this Court, would result in a radical and unfounded expansion of Alabama tort law and have devastating impacts on the industry. The legislative branch has the tools to fully study and assess the impact of a change of this nature. Any potential expansion of liability should be assessed by the legislature through the traditional lawmaking process. Consistent with Alabama's rigorous system of separated powers, Ala. Const. Art III, § 43, this Court should adhere to its well-established tort principles, one of which

requires a duty as a prerequisite to liability, and defer to the legislature to make any rule changes like the recognition of innovator-liability suits.

ARGUMENT

Innovator-Liability Claims Like The One At Issue Here Are Properly Rejected By This Court Under Well-Established Tort Law Duty Principles, And Nothing In *PLIVA, Inc. v. Mensing* Changes That.

A. Adoption of Plaintiffs' innovator-liability theory would stretch Alabama's tort law principles out of shape and put Alabama in conflict with nearly every other court to consider the issue.

The certified question presents this Court with the opportunity to reaffirm two core tort principles: first, that claims for harm caused by a product — no matter their labels — are product-liability claims that require proof that the defendant manufactured or sold the harm-causing product; and second, that a duty to warn or disclose turns on relationship. The brand-name defendants and other *amici* will likely address the first of these hornbook principles. We focus briefly on the second.

That Alabama law requires a legal duty to impose liability is, of course, well-established. Whether to impose a duty on a particular defendant turns on "(1) the nature of the defendant's activity; (2) the relationship between the parties; and (3) the type of injury or harm threatened." *Pritchett v. ICN Med Alliance, Inc.*, 938 So.2d 933, 937-38 (Ala. 2006)(internal quotation omitted).

Of these, relationship between the parties is paramount. *See, e.g.*, *DiBiasi v. Joe Wheeler Elec. Membership Corp.*, 988 So. 2d 454, 460-61 (Ala. 2008); *Thompson-Hayward Chem. Co. v. Childress*, 169 So. 2d 305 (Ala. 1964). Even the related consideration of "foreseeability" of injury focuses on the relationship between the parties. *See DiBiasi*, 988 So. 2d at 460-61; *Keck v. Dryvit Sys., Inc.*, 830 So. 2d 1, 10-11 (Ala. 2002); *Patrick v. Union State Bank*, 681 So.2d 1364, 1369 (Ala. 1996), citing *Morgan v. South Central Bell Telephone Co*, 466 So.2d 107, 114 (Ala. 1985); *Alabama Dep't of Corrections v. Thompson,* 855 So.2d 1016, 1023 (Ala. 2003); *Franklin County School Bd v. Lake Asbestos of Quebec, Ltd.*, 1986 WL 69060, at *6 (N.D. Ala. 1986) (in discussing the traditional elements of a negligence claim, noting that element of duty "necessarily impl[ies] a relationship between the plaintiff and the defendant").

For this reason, courts applying Alabama law have consistently refused to impose a duty on manufacturers or sellers when the complained-of injury did not result from use of that manufacturer's or seller's product. See *Walls v. Alpharma USPD, Inc.*, 887 So.2d 881 (Ala. 2004), quoting *Toole v. Baxter Healthcare Corp*, 235 F.3d 1307, 1313-14

(11th Cir. 2000) ("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*."). *See, e.g.*, *Hogue v. Logan's Roadhouse, Inc.*, 61 So.3d 1077, 1080 (Ala. Civ. App. 2010), *cert. den'd* 11/12/10 (noting that pursuant to Alabama's products-liability law, the Alabama Extended Manufacturer's Liability Doctrine, "a plaintiff must prove he suffered injury or damages to himself or his property by one who sold a product in a defective condition unreasonably dangerous to the plaintiff as the ultimate user or consumer…"); *Weeks*, 2011 WL 1216501, at *3 ("Alabama law does not support the imposition on a manufacturer of a duty to disclose information to a consumer who is injured by another manufacturer's product.").

Lack of a relationship between brand-name Reglan manufacturers and users of generic metoclopramide has prompted federal district courts in Alabama deciding cases materially identical to this one to dismiss plaintiffs' claims for lack of a duty. For example, in *Simpson v. Wyeth*, No. 7:10-CV-01771-HGD, 2010 WL 5485812, (N.D. Ala.

Dec. 9, 2010), *report and recommendation adopted by* 2011 WL 10607 (N.D. Ala. Jan. 4, 2011), the Northern District of Alabama concluded that because "neither Wyeth, Pfizer, or Schwarz produced or distributed the [generic] metoclopramide ingested by plaintiffs, the Reglan manufacturers do not owe a duty that gives rise to a cause of action for fraudulent misrepresentation or failure to warn." *Id*. at *5 (citing *Walls*, 887 So. 2d 881). The Southern District of Alabama reached the same conclusion in *Mosley v. Wyeth, Inc.*, 719 F. Supp. 2d 1340, 1347 (S.D. Ala. 2010) (granting summary judgment to Reglan defendants on the basis of a lack of "binding authority for the assertion that a manufacturer of brand-name drugs owes a duty to consumers of the generic version of their products"). The *Mosley* rationale was reaffirmed, even after the *Weeks* decision, in *Overton v. Wyeth, et.al.*, No. CA 10-0491-KD-C, 2011 WL 1343392 (S.D. Ala. Mar. 15, 2011), *report and recommendation adopted by* 2011 WL 1343391 (S.D. Ala. Apr. 7, 2011).

These decisions, reached in accordance with settled Alabama law concerning the imposition of a duty, are consistent with the overwhelming majority of decisions to

address the issue nationwide. The United States Court of Appeals for the Fourth Circuit led the way in its pathmarking decision in *Foster v. American Home Products Corp.*, 29 F.3d 165, 171 (4th Cir. 1994). The Sixth and Eighth Circuits have since followed, as have dozens upon dozens of state courts and federal district courts. *See Smith v. Wyeth, Inc.*, 657 F.3d 420, 424 (6th Cir. 2011) ("As have the majority of courts to address this question, we reject the argument that a name-brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company."); *Mensing v. Wyeth, Inc.*, 588 F.3d 603, 613–14 (8th Cir. 2009), *rev'd on other grounds sub nom. PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567 (2011) (following "the overwhelming majority of courts considering this issue").[1]

[1] Only two courts have imposed a duty on brand-name manufacturers for harm caused by their generic competitors' products. *See Conte v. Wyeth, Inc.*, 85 Cal.Rptr.3d 299 (2008); *Kellogg v. Wyeth, Inc.*, 762 F.Supp.2d 694 (D. Vt. 2010). Those decisions are outliers that have had no meaningful impact on the law; state and federal appellate courts have overwhelmingly rejected the rationale underlying these decisions.

This Court now has the opportunity to join the nationwide consensus and reaffirm that, under Alabama law, a defendant owes no duty to a plaintiff with whom it has no relationship. And in a product-use case, where, as in this case, a plaintiff did not use a particular defendant's product, there can be no duty-imposing relationship.

In short, the correct answer to this Court's certified question is perhaps best articulated in *Overton v. Wyeth,* where the Southern District of Alabama stated:

> As this Court has explained, where a plaintiff presents "no evidence or argument tending to establish that a relationship existed between" the plaintiff and certain brand-name manufacturers of metoclopramide, cites "no binding authority for the assertion that a manufacturer of brand-name drugs owes a duty to consumers of the generic version of their products" or "the contention that an injury resulted from consumption of a generic version of the drug can be considered a 'proximate consequence' of a manufacturer's alleged misrepresentation regarding the brand-name version of the drug," she cannot succeed on either a claim of fraudulent or negligent misrepresentation under Alabama law.

Overton, 2011 WL at *7.

Alabama courts should not depart from their long-standing tort principles to create a claim here against the brand-name manufacturers.

B. Nothing in *PLIVA, Inc. v. Mensing* breathes life into Plaintiffs' innovator-liability theory or justifies abandoning settled Alabama tort principles.

Plaintiffs in other Reglan/metoclopramide cases have attempted to avoid the crush of precedent rejecting innovator liability by invoking the Supreme Court's recent decision in *PLIVA, Inc. v. Mensing*, __ U.S. __, 131 S. Ct. 2567 (2011). *See, e.g.*, *Metz v. Wyeth LLC*, __ F. Supp. 2d __, No. 8:10–CV–2658–T–27AEP, 2011 WL 5826005 (M.D. Fla. Nov. 18, 2011). The effort, if made here, will fail.

In brief, *Mensing* held that because FDA regulations prohibit generic drug manufacturers from "independently" or "unilaterally" changing their products' labeling, state-law failure-to-warn claims against them are preempted. 131 S. Ct. at 2579. In the wake of *Mensing*, some Reglan/metoclopramide plaintiffs, in an effort to revive innovator-liability claims against brand-name manufacturers, have argued (1) that *Mensing* rejected the interpretation of the generic-drug regulations suggested by the Fourth Circuit in its leading *Foster* decision, (2) that many subsequent decisions rejecting innovator liability have cited or relied on *Foster*, and, therefore (3) that *Mensing* undermines the reasoning of those decisions. With respect, the argument is badly flawed.

Every court to address it has rejected it – as explained below, with good reason.

1. *Mensing* does not alter the applicable state law.

Mensing held, as a matter of federal law, that FDA regulations preempt certain state-law failure-to-warn claims against generic manufacturers. *See* 131 S.Ct. at 2572. That holding rests, in particular, on the basis that the regulations prohibit general manufacturers from "independently" or "unilaterally" altering the content of their products' warning labels. *Id*. at 2579. The certified question asks something different: it involves the *state-law* requirements incumbent on plaintiffs who assert claims (against brand-name manufacturers) for harm caused by a product. The two questions – generic-manufacturer liability under federal law and brand-manufacturer liability under state law – are totally separate. *Mensing*, therefore, has no bearing on the state law at issue here.[2]

[2] In fact, far from overturning the decisions rejecting Plaintiffs' theory of innovator liability, *Mensing* actually reaffirms them. *Mensing* involved claims against both brand-name defendants and the generic manufacturers that actually made the product taken by the plaintiff. The district court dismissed both the innovator-liability claims asserted against the name-brand defendants as contrary to

(Continued on next page.)

2. *Mensing* does not undermine *Foster*.

Innovator-liability plaintiffs who have invoked *Mensing* have trained their fire on the Fourth Circuit's leading decision in *Foster*. But *Mensing* only (arguably) related to *Foster* on one minor point unnecessary to the Fourth Circuit's holding. Specifically, the *Foster* court rejected an argument raised by the plaintiffs that they would be

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(Continued from previous page.)
Minnesota law and the claims against the generic manufacturers are preempted under federal law. *Mensing v. Wyeth, Inc*., No. 07-3919, 2008 WL 4724286, at *3-*5 (D. Minn. Oct. 27, 2008), *aff'd* 588 F.3d 603, 612-14 (8th Cir. 2009). The Eighth Circuit affirmed the district court's dismissal of the claims against both sets of defendants. *Mensing v. Wyeth, Inc*., 588 F.3d 603,612-14 (8th Cir. 2009), *rev'd on other grounds sub nom. PLIVA, Inc. v. Mensing*, 131 S.Ct. 2567 (2011). That was the final word on the claims of innovator liability in *Mensing*. Neither party sought certiorari on the innovator liability issue, so the Eighth Circuit's affirmance of dismissal remains good law. Even more to the point, both the majority and dissent in the Supreme Court's *Mensing* decision appeared to agree that the brand-name manufacturers could not be liable for injuries caused by other manufacturers' generic products. *See Mensing*, 131 S.Ct. at 2581-82; *id*. at 2592 (Sotomayor, J., dissenting). Thus, what Plaintiffs argue *Mensing* did by implication is flatly refuted by what the Court explicitly said.

"unable to recover from the generic manufacturer on a negligent misrepresentation theory because the generic manufacturer did not formulate any of the representations it made regarding its product." 29 F.3d at 169. In particular, the plaintiffs argued that generic manufacturers were prohibited by federal law from independently changing their warning labels. The Fourth Circuit rejected that reading of FDA's regulations, reasoning that nothing in federal law prohibited generic manufacturers from changing their products' labeling. *Id*. at 170. *Mensing*, 131 S.Ct. at 2575-76.

Of course in *Mensing*, the Supreme Court held that generic manufacturers cannot, in fact, independently change their labeling. Plaintiffs in other Reglan/metoclopramide cases have tried to make much of this distinction and have argued that it somehow "call[s] into question" *Foster*'s reasoning. *Gross v. Pfizer, Inc.*, No. 8:10-cv-00110, 2011 WL 4005266, at *2 (D. Md. Sept. 7, 2011). That is incorrect, as many courts (whose decisions are described below, *see infra* at pgs. 16-19) have already concluded. In fact, these dueling interpretations of the CBE regulations' application to *generic* manufacturers are irrelevant to

Foster's ultimate holding rejecting innovator liability claims against brand-name manufacturers. The *Foster* court did not decide that generic manufacturers could unilaterally change their warning labels. No issue relating to generic manufacturers was before the court. Whatever the court might have said in dicta, then, about generic manufacturers had nothing to do with the court's explicit *holding* that a plaintiff cannot sue a brand-name manufacturer that did *not* manufacture the allegedly injurious drug. The Fourth Circuit's holding – squarely applicable here and followed by scores of courts since – turned on its twin conclusions (1) that plaintiffs may not creatively plead around traditional product-liability doctrines by recasting their claims in fraud or misrepresentation terms and (2) that a manufacturer owes no duty of care or disclosure unless a plaintiff used its product. 29 F.3d at 168-71.

3. Courts have unanimously concluded that *Mensing* does not give credence to the innovator-liability theory.

Experience has borne out that *Mensing* did not transform innovator liability into a viable theory overnight. Six

courts deciding Reglan/metoclopramide cases have expressly rejected that very argument.

In the *Mensing* case itself, the Eighth Circuit rejected the plaintiffs' invocation of innovator liability as a means of holding the brand-name manufacturers liable. *See supra* at pgs. 12-13. After the Supreme Court reversed the Eighth Circuit's decision about whether claims against generic manufacturers were preempted, the Eighth Circuit clerk vacated the court's earlier judgment in whole. *See* Order Reversing and Reopening Judgment, *Mensing*, No. 08-3850 (Aug. 18, 2011), ECF No. 3819768. The brand-name defendants moved to reinstate the judgment as to them, and the Eighth Circuit agreed, thereby rejecting the notion that the Supreme Court's decision affected its earlier decision that had rejected the innovator-liability theory against the brand-name manufacturers. *See* Order Reinstating Opinion in Part, *Mensing*, No. 08-3850 (Sept. 29, 2011), ECF No. 3834382.

The Sixth Circuit, too, has rejected this argument. On a post-*Mensing* appeal of a summary judgment for brand-name Reglan manufacturers on state-law grounds in which the district court rejected the innovator-liability theory, the

court affirmed. *See Smith*, 657 F.3d at 423–24. *Smith* is particularly relevant here because the Sixth Circuit reached that conclusion even with the benefit of supplemental briefing on the effects of *Mensing* on the plaintiffs' innovator-liability theory. *See id.* Doc. 6111043270 at *9–*10 (Aug. 15, 2011) (Plaintiffs-Appellants' Supplemental Letter Brief Regarding *PLIVA, Inc. v. Mensing*).

Finally, four federal district courts have expressly rejected plaintiffs' arguments that *Mensing* undermined *Foster* and breathed life into the innovator-liability theory. These courts have all held that "[t]he Supreme Court's holding in *Mensing* neither created nor abrogated any duty under [state] law with regard to brand-name-manufacturers." *Gross v. Pfizer, Inc.*, No. 8:10-cv-00110, 2011 WL 4005266, at *2 (D. Md. Sept. 7, 2011); *see also Phelps v. Wyeth, Inc.*, No. 6:09-cv-06168-TC, slip op. at 5 (D. Or. Nov. 23, 2011), *report and recommendation of magistrate judge* ("Plaintiffs are correct in asserting that the *Foster* court's first determination has been abrogated by *Mensing*. However, that does not mean that the [*Foster*] court's entire analysis of the name-brand manufacturer's

liability is undermined. Whether or not the generic manufacturer is able to independently change its label does not change the [*Foster*] court's ... ultimate conclusion."); *Metz*, 2011 WL 5826005, at *1–*3 (holding that the rationale of *Foster* and the "nearly unanimous" precedent from other courts on this issue remain valid after *Mensing*, as the Fourth's Circuit's understanding of the regulations applicable to generic manufacturers in *Foster* was "dicta ... [and] by no means central to [its] ultimate holding"); *Morris v. Wyeth, Inc.*, No. 3:09-cv-00854, 2011 WL 4975317, at *2-*3 (W.D. La. Oct. 19, 2011) (holding that *Mensing* did not change Louisiana law related to brand-name manufacturers).

These decisions reflect the common-sense conclusion that nothing in *Mensing's* decision about federal preemption altered state law or breathed life into this innovator-liability theory. *Mensing* cannot undermine the state-law principles that bar the Weekses' claims against the brand-name defendants here.

C. Separation-of-powers principles dictate that the novel form of liability that Plaintiffs' suit envisions must be created, if at all, through the legislative process.

In this case, application of established Alabama tort law mandates dismissal of the brand-name manufacturers. These state law tort principles, which have developed and solidified over time, recognize that the concept of "duty" is not infinitely elastic, but rather has outer limits. In particular, those settled principles recognize that before a duty of care or disclosure may be imposed, a defendant must have a meaningful relationship with the complaining plaintiff – and, more specifically, when the plaintiff alleges injury from product use, the defendant must actually have manufactured or sold the product about which the plaintiff complains. *See, e.g.*, *DiBiasi*, *supra*; *Thompson-Hayward*, *supra*; *Keck*, *supra*; *Pritchett*, *supra*.

Plaintiffs here envision an entirely new and different theory of tort liability. Under their theory, a brand-name drug manufacturer can be deemed to owe a duty – and thus can be held liable – to a plaintiff who never took its product and with whom, accordingly, it had no relationship at all. The radical expansion of tort liability that Plaintiffs' theory would impose – effectively casting

brand-name drug manufacturers in the role of insurers – is laden with public-policy considerations. To mention just one, Plaintiffs' novel theory would result in unpredictable – and potentially unconstrained – liability that could well impede brand-name manufacturers' ability to continue with the research and development that allows for the creation of new and potentially life-saving drugs. At the very least, it is very likely that brand-name manufacturers would be forced to raise prices to account for this unpredictable downside risk, to the detriment of consumers.

Given the existence of such profound and delicate policy considerations, Plaintiffs' proposed innovator-liability rule is one that should be taken up, if at all, only by the legislature. If there is to be newly expanded liability, the legislative branch (whether state or federal) should inform the judiciary through the traditional lawmaking process, a process that provides for both oversight and public input. No matter how much contextual information litigants seek to provide to courts as part of a discrete case or controversy, the judiciary, as an institution, lacks the tools to fully study and assess the impact of a change of this nature.

Alabama, of course, has one of the most rigorous separation-of-powers doctrines in the nation. Unlike its federal counterpart, Alabama's system of separated powers is enshrined in the very text of this State's Constitution:

> In the government of this state, except in the instances in this Constitution hereinafter expressly directed or permitted, the legislative department shall never exercise the executive and judicial powers, or either of them; the executive shall never exercise the legislative and judicial powers, or either of them; *the judicial shall never exercise the legislative and executive powers, or either of them; to the end that it may be a government of laws and not of men.*

Ala. Const. Art III, § 43.

As this Court has emphasized, under the Constitution, "the judiciary's definitive function is to resolve disputes or controversies," not to make "policy pronouncements." *Ex parte James*, 836 So. 2d 813, 865 (Ala. 2002). Citing President George Washington's 1796 farewell address, the Court further stressed that "although the encroachment" by the judiciary on the powers of the political branches "may seem to remedy an urgent wrong, the precedent of giving, by mere acquiescence to the judiciary, too much power to one branch always leads to an even greater wrong – the loss of

the balance of power in a constitutional government." *Id*. at 865.

In the light of these fundamental separation-of-powers considerations, this Court should adhere to well-established tort principles, which as applied here mandate dismissal of the brand-name manufacturers, who did not manufacture the product that allegedly caused Plaintiffs' injury. To accept Plaintiffs' theory would be to eviscerate long-standing law, expand the concept of duty to unfounded proportions, and constitute impermissible judicial policymaking.

CONCLUSION AND RELIEF

Plaintiffs' theory in this case threatens to create broad new liability for brand-name drug manufacturers. It conflicts with fundamental principles of Alabama tort law and interferes with the basic goals of the civil justice system, including its effort to connect liability with a defendant's conduct and to fairly resolve disputes. For all the foregoing reasons, DRI and ADLA urge this Court to answer "no" to the certified question.

Respectfully submitted,

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DATED: December 12, 2011

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CERTIFICATE OF SERVICE

I hereby certify that I have this 12th day of December, 2011, served a copy of the above and foregoing document by United States Mail and/or electronic mail, upon the following:

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