No. 1101397

SUPREME COURT OF ALABAMA

WYETH, INC., et al,

Defendant-Appellants,

v.

DANNY WEEKS AND VICKI WEEKS,

Plaintiffs-Appellees.

BRIEF OF ALABAMA POLICY INSTITUTE AS AMICUS CURIAE IN SUPPORT OF DEFENDANTS/APPELLANTS WYETH LLC, PFIZER, INC., AND SCHWARZ PHARMA, INC.

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

Richard B. Garrett
D. Cameron Smith

Counsel for Alabama Policy Institute

ALABAMA POLICY INSTITUTE
402 Office Park Drive,
S. 300
Mountain Brook, Al 35225
(205)870-9900
rbg@rsjg.com
camerons@alabamapolicy.org

STATEMENT REGARDING ORAL ARGUMENT

Amicus Curiae Alabama Policy Institute does not request to participate in oral argument. The Alabama Policy Institute encourages the Court to hear oral argument before so substantially liberalizing Alabama tort law.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases **Page(s)**

STATUTES:

OTHER AUTHORITIES:

IDENTITY AND INTEREST OF AMICUS CURIAE

The Alabama Policy Institute (API) is a non-partisan, non-profit research and educational organization dedicated to the principles of limited government, free markets, fiscal responsibility, the rule of law, judicial restraint, and strong families. Established in September 1989, API bases its pursuits on the founding fathers' ideals of liberty and the equality of all people under the law. API studies important matters of policy by researching the issues being debated in Montgomery and Washington, D.C. and then offering its analysis and ideas through reports and publications to public servants, citizens, and the media. As a "think tank," API addresses a wide range of emerging policy issues in the areas of economics, education, the environment, government, family, and society.

As part of its dedication to the principles of judicial restraint and the rule of law, API has an interest in opposing judicial activism regardless of the political makeup of the court. API similarly desires to promote a commonsense tort law that properly compensates those injured by the negligent, wanton, or intentional acts of

others but that, at the same time, is predictable and fair. For these reasons, API strongly opposes this Court's opinion of January 11, 2013, which substantially liberalizes tort liability and flatly contradicts the holdings of more than 75 cases around the country, applying the law of at least 25 other states.

API is gravely concerned that this unprecedented expansion of tort liability will impair business investment in Alabama, curtail research and development on potentially lifesaving drugs, and increase the cost of those drugs to consumers. In addition, API agrees with Defendants/Appellants and other amici curiae who have pointed out that such a monumental change in tort law should be made, if at all, only by the Legislature, which, unlike a court, is capable of considering the multi-faceted factual and policy considerations involved in such a change. Indeed, the Alabama Legislature has recently addressed issues of tort law - and has done so in a manner designed to curtail, not expand, manufacturer liability.

As a public policy institute promoting the principles of the rule of law and judicial restraint, API urges this

Court to withdraw its opinion and to answer "No" to the certified question.

SUMMARY OF THE ARGUMENT

With all due respect, this Court's surprising opinion is bad law, bad policy, and ultimately bad for the citizens of the state of Alabama.

The radical changes to Alabama tort law brought on by the Court's opinion are particularly striking given that they come against such a decisive backdrop: Nearly every court that has considered this issue has rejected the "innovator-liability" theory. The latest count appears to be 76 to 2 against adoption of this theory.

Perhaps most striking of all is the fact that this Court's members, all of whom (1) campaigned as judicial conservatives, (2) purport to oppose judicial activism, and (3) claim to adhere to the separation of powers found in our federal and state constitutions, have birthed an expansive new theory of tort liability - one heretofore recognized only in two quintessentially liberal states - Vermont and California. In addition, and to make matters worse, ***every*** court that has been asked to adopt this theory in the wake of the U.S. Supreme Court's decision in PLIVA, Inc., v. Mensing, 546 U. S. ___, 131, S. Ct. 2567 (2011),

has rejected it, and ***every*** court that has considered whether PLIVA supports innovator liability has held - contrary to this Court's opinion - that it does not.

Moreover, even on its own terms, the opinion is both unfair and inconsistent with long-established tort law. It adopts an aggressive theory of tort liability - "innovator liability" - that imposes liability on brand name drug manufacturers for the products of their competitors, even years after the brand name manufacturers cease to produce the product. Because this Court's opinion creates liability for brand name manufacturers without requiring a corresponding "relationship" with an injured party, there is no conceivable way that manufacturers can project, provide for, and (most likely) insure against such open-ended risk. Since generic manufacturers might continue to market their products for 10, 20, 30, or more years after the brand name product has left the market, there is literally no time limit on how long brand name manufacturers might be liable for their competitors' products.

The extensive, unlimited, and open-ended liability created by the Court's opinion will also harm the lives, health, and pocketbooks of Alabama consumers. Because resources will undoubtedly be diverted from research and development to prepare for uncertain future liability, some valuable and potentially lifesaving medicines may not be developed in the future. Even for those that are, their cost will inevitably be higher. Thus, Alabama consumers will pay a price for this Court's abrupt, retroactive change in the law - both with their health and with their wallets.

Finally, given the numerous and complex ramifications of this significant change in the law - not only to the pharmaceutical industry but also to other industries - a court is not an appropriate forum in which to decide such issues. A proper application of separation of powers would delegate consideration of such drastic change to the elected representatives of the people, who have the resources to analyze the myriad complexities and consequences - many of them unintended - of such a change in the law. Indeed, the Alabama Legislature, the appropriate policy-making body in Alabama, has already

addressed questions of tort liability in a manner inconsistent with this Court's opinion.

ARGUMENT

I. THE COURT'S OPINION IS UNFAIR AND INCONSISTENT WITH LONG-ESTABLISHED PRODUCT LIABILITY AND TORT LAW.

For years, Alabama product liability law has consistently held that a manufacturer or seller is liable only for products that it has made or sold and only to someone with whom it has a preexisting "relationship." See, e.g., Thompson-Hayward Chem. Co., v. Childress, 169 So.2d 305 (Ala. 1964); DiBiasi v. Joe Wheeler Elec. Membership Corp., 988 So.2d 454 (Ala. 2008); Keck v. Dryvit Sys., Inc., 830 So.2d 1 (Ala. 2002). This Court has also consistently held that a plaintiff cannot circumvent these product liability requirements by pleading his claim under another label. Pfizer, Inc. v. Farsian, 682 So.2d 405 (Ala. 1996); Bailey v. Faulkner, 940 So. 2d 247 (Ala. 2007).

Neither the learned intermediary doctrine nor the U. S. Supreme Court decision in PLIVA, Inc., v. Mensing, 546 U. S. ___, 131, S. Ct. 2567 (2011), alters these fundamental principles of Alabama tort law. As has been explained in numerous other briefs, the learned intermediary doctrine does not impose on a brand name drug manufacturer a new and

independent duty to provide warnings to a physician about a competitor's generic product. Rather, recognizing the inherent complexity of pharmaceutical products, the doctrine merely provides that a manufacturer's obligation to warn about its own product can be met by warning the consumer's physician. See Walls v. Alpharma USPD, Inc., 887 So. 2d 881, 883 (Ala. 2004).

As has also been explained, PLIVA's holding that federal law preempts some claims against generic drug manufacturers does not, and cannot, change any state's preexisting tort law. Put simply, federally imposed limitations on claims against generic drug manufacturers do not require (or permit) this Court to find another deep pocket for plaintiffs to sue. Liability limitations imposed by federal law are best addressed by federal actors - most notably, the United States Congress and the Food and Drug Administration (FDA) -- rather than individual state courts. Indeed, since this Court's decision, FDA has "confirm[ed]" that it is actively considering a regulation that would overrule PLIVA and permit failure-to-warn suits against generic manufacturers. Greg Ryan, FDA Mulls Dramatic Shift In Generic-Drug Labeling Regs, Law360 (Feb.

11, 2013). As the Department of Justice explained in a brief recently filed in the United States Supreme Court, FDA's change would overrule PLIVA and "eliminate[e] preemption of failure-to-warn claims against generic-drug manufacturers." Brief for the United States at 15 n.2, Mutual Pharm. Co. v. Bartlett, No. 12-142.

As pointed out by Appellants in their Application for Rehearing, such a sweeping and erroneous change in the law also implicates due process rights, since this Court's opinion would retroactively impose liability on a straight "foreseeability" ground based on events that occurred at a time when most courts had held that generic companies could independently strengthen their warnings - and thus were subject to warning-based claims.

The unilateral expansion of Alabama tort law brought on by the Court's opinion is particularly striking given that they come against such a stark backdrop: Nearly every court to consider this issue has rejected the innovator-liability theory. At latest count, 76 courts had rejected the theory, while only two had accepted it. The two courts that have adopted the theory are a California state court in Conte v.

Wyeth, Inc., 85 Cal. Rptr. 3d 299 (Cal. App. 1st Dist. 2008), and then a Vermont federal district court in Kellogg v. Wyeth, 762 F. Supp. 2d 694, 699 (D. Vt. 2010).

Perhaps even more striking is the fact that this Court's members, all of whom claim (1) to be judicial conservatives, (2) to oppose judicial activism, and (3) to adhere to the separation of powers, have decreed an expansive new theory of tort liability - one previously recognized only in -Vermont and California. In addition, and to make matters worse, ***every*** court that has addressed this theory post-PLIVA has rejected it, and ***every*** court that has considered whether PLIVA supports innovator liability has held - contrary to this Court's opinion - that it does not.

As the Chamber of Commerce and Business Council of Alabama pointed out in their merits-stage amicus brief, "When basic principles of law are contorted and twisted, business, and the economy more generally, suffers." Here, as explained below, it is not only businesses, but also Alabama consumers, who will suffer from the dramatic and unforeseeable change in the law that this Court's opinion

brings about. API is concerned not only about the business climate in Alabama but also about the consumers who stand to benefit from new pharmaceutical developments. There is reason to believe that brand name drug manufacturers will exit the market in the attempt to limit liability.

Accordingly, API urges this Court to revisit this issue and then enter an opinion that comports with long-standing Alabama law and that is consistent with (1) principles of judicial restraint and (2) the vast majority of other courts that have addressed this issue.

II. THE COURT'S RADICAL CHANGE TO ALABAMA TORT LAW WILL HARM ALABAMA PATIENTS AND CONSUMERS.

As amicus PhRMA stated in its merits-stage amicus brief, "When a company is exposed to liability that bears no relationship to its products, sales, or revenue, the company is both prevented from recapturing the research and development investment in that medicine and discouraged from making future investments." The time and expense required for researching, developing, testing, and applying for and obtaining approval for a new medicine are enormous. And yet, American drug manufacturers have invented and brought to market new medicines that are near-miraculous in

their ability to cure and prevent diseases that were long thought to be intractable. These medicines have increased both the longevity and quality of life for millions of Alabamians.

As a result of pharmaceutical advances, for instance, vaccines have virtually eliminated polio. Premature babies who would have perished decades ago are now able to survive, in part because of medicines that treat the conditions of prematurity. Diabetics, those with heart disease, those with high blood pressure and many others are able to live fulfilling lives because of medicines that have been developed over the past years. The list goes on and on.

The plaintiffs' radical innovator-liability theory will force drug manufacturers to divert a significant portion of the money that currently goes into research and development of new drugs to premiums or other set-asides to cover future liability for their competitor's products - possibly years beyond the time when they are actually selling their own name brand drug. The sheer unpredictability of these new potential liabilities will likely result in resources

used to develop innovative drugs being redirected to defend lawsuits. This is especially true in regard to medicines that help the most vulnerable, such as infants, pregnant mothers, and the elderly, because these are the medicines often targeted in lawsuits. Excessive liability risk has been blamed for keeping many vaccine innovators from the market. See, e.g., W. Kip Viscusi, Corporate Risk Analysis: A Reckless Act?, 52 Stan. L. Rev. 547, 583 (2000) ("Liability hazards led many firms to exit the vaccine market. Now there are only single-product monopolies supplying many of the vaccines for major illnesses, including polio, measles, rabies, mumps, and rubella.").

And even if a drug is brought to market, it might be produced in smaller quantities. For instance, fewer manufacturers are willing to produce flu vaccines on account of liability concerns. See Devon Herrick, What's Behind the Flu Vaccine Shortage, National Center for Policy Analysis (Oct. 28, 2004), http://www.ncpa.org/pub/ba493.

In addition to diminished production runs (or the possible absence) of medicines, the diversion of funds for unquantifiable future liability will also certainly result

in increases in the costs of medicines. These increased costs will hit Alabama's most vulnerable citizens the hardest - those without insurance, with high co-pays, and those with limited resources to spend on medicine.

III. THIS COURT HAS INTERPRETED ALABAMA LAW IN A MANNER INCONSISTENT WITH THE ACTS OF ALABAMA'S LEGISLATURE, A BODY SPECIFICALLY CHARGED WITH ADDRESSING COMPLEX POLICY ISSUES SUCH AS THOSE RAISED IN THE COURT'S OPINION.

Courts are ill-suited to deal with complex policy issues, many of which have numerous ramifications and unintended consequences. Courts are bound by the record in specific controversies and do not have either staffs or resources to research the vast data that are involved in complex policy issues. Legislative and regulatory bodies, by contrast, are uniquely suited for such analysis and, under separation of powers principles, are the only bodies so constituted.

Innovator liability is the very sort of complex policy issue best suited for the political branches. Legislators and regulators have the capacity to research and publicly debate the nuances of pharmaceutical-manufacturer liability, including the plaintiffs' innovator-liability

theory. In particular, those bodies can receive testimony from injured consumers of generic pharmaceuticals and experts from the brand name pharmaceutical industry who could quantify the effect of the adoption of this theory on research and development, product costs, and other factors. Any emergent policy could then be refined through the legislative and/or regulatory process, giving due consideration and weight to prospective versus retroactive application, balancing cost and liabilities among the various parties and other factors to ensure an equitable and thorough result.

Perhaps, then, it should come as no surprise that (as already noted) FDA has announced that it is presently considering a federal regulation that would permit generic drug manufacturers to strengthen the warnings on their products. FDA's change would overrule PLIVA and "eliminate[e] preemption of failure-to-warn claims against generic-drug manufacturers." Brief for the United States at 15 n.2, Mutual Pharm. Co. v. Bartlett, No. 12-142.

Of course, at the state level, the Alabama Legislature is the proper government body to consider sweeping changes

to Alabama tort law. Accordingly, at the very least, this Court should consider the policy context created by the Alabama Legislature and the Governor in interpreting such laws.[1]

The Alabama Legislature has clearly demonstrated its willingness to address questions of tort liability. On June 9, 2011, Governor Robert Bentley signed into law five separate tort reform measures designed to limit liability and restore the balance between business productivity and reasonable compensation for injury.[2]

Two of the reform measures provide specific insight as to how the Alabama Legislature and Governor would approach the innovator-liability theory adopted by this Court. Senate Bill 59 reduced the statute of repose for commencing

---

[1] This Court has long expressed a policy of deferring to the elected representatives of the people. See, eg., Lockridge v. Adrian, 638 So. 2d 766 (Ala. 1994).

[2] The reform measures were Senate Bill 184, codified at Alabama Code §§ 6-5-501 and 6-5-521; Senate Bill 212, codified at Alabama Code § 6-5-410; Senate Bill 187, codified at Alabama Code § 12-21-160; Senate Bill 207, codified at Alabama Code § 8-8-10; and Senate Bill 59, codified at Alabama Code §§ 6-5-221, 6-5-222, 6-5-225, and 6-5-227.

a civil action against an architect, engineer, or builder from 13 years to 7 years. By enacting Senate Bill 59, the Legislature evidenced a clear intent not only to clarify but also to reduce the time in which liability may attach.

Senate Bill 184 specifically prevents product liability actions against distributors that are not also the manufacturers of the injury-causing product. Thus, even when a direct relationship exists between a seller and the injured party, the Legislature has recognized the importance of the nexus between manufacturing a product and bearing liability for injuries caused by it.

The Court's opinion in this case flies in the face of these recent legislative pronouncements. Far from recognizing commonsense limitations on manufacturer liability, the opinion vastly expands it - both by rejecting any requirement of a "relationship" between plaintiff and defendant and by allowing liability to continue in perpetuity.

Rather than engaging a quasi-legislative - if well-meaning - effort to "fix" a problem created by federal actors, this Court should answer "No" to the certified

question and leave creation of new theories of liability to the political branches.

CONCLUSION

This Court's opinion adopting innovator liability flatly contravenes the principles of judicial restraint. Not only is it unfair and inconsistent with long-established Alabama tort and products liability law, it is also contrary to the decisions of the vast majority of other courts that have considered this issue. Adoption of the innovator-liability theory will harm patients and consumers in Alabama, both in the loss of future pharmaceutical innovation and the increased costs of medication. If such a dramatic policy shift is to be effected, it should be effected by the people of Alabama through their elected representatives in the Legislature. The Legislature, not this Court is the proper forum to consider these complex and multifaceted policy issues.

Respectfully submitted,

s/ Richard B. Garrett
Richard B. Garrett
D. Cameron Smith

Counsel for Alabama Policy Institute

ALABAMA POLICY INSTITUTE
402 Office Park Drive,
S. 300
Mountain Brook, Al 35225
(205)870-9900
rbg@rsjg.com
camerons@alabamapolicy.org

CERTIFICATE OF SERVICE

I hereby certify that I have served a copy of the foregoing by United States mail and/or electronic mail upon the following:

Kevin C. Newsom
knewsom@babc.com

Edward Simmons Sledge, III
sledge@mcdowellknight.com

Lindsey C. Boney, IV
lboney@babc.com

Hugh M. Stanley
hstanley@tuckerellis.com

Philip H. Butler
pbutler@babc.com

Richard Dean
richard.dean@tuckerellis.com

George R. Parker
gparker@babc.com

Richard A. Oetheimer
roetheimer@goodwinprocter.com

Steven Frank Casey
scasey@joneswalker.com

Frederick G. Helmsing, Jr.
fhelmsing@mcdowellknight.com

Henninger S. Bullock
hbullock@mayerbrown.com

William C. Waller, Jr.
CWaller@ball-ball.com

Andrew J. Calica
acalica@mayerbrown.com

Christopher Boyce Hood
chood@hgdlawfirm.com

Christopher G. Hume, III
chume@ball-ball.com

David A. Lester
dlester@joneswalker.com

William L. Bross, IV
wlbross@hgdlawfirm.com

William Lewis Garrison, Jr.
wlgarrison@hgdlawfirm.com

Jonathan I. Price
jprice@goodwinprocter.com

F. Chadwick Morriss
cmorriss@cov.com

this the 18th day of February, 2013.

s/ *Richard B. Garrett*
Of Counsel