Nos. 1071704 & 1071759

IN THE SUPREME COURT OF ALABAMA

SMITHKLINE BEECHAM CORP. d/b/a GLAXOSMITHKLINE,
Appellant,

v.

STATE OF ALABAMA,
Appellee.

NOVARTIS PHARMACEUTICALS CORPORATION
Appellant,

v.

STATE OF ALABAMA,
Appellee.

On Appeals from the Circuit Court of Montgomery County (CV-2005-219.68 and CV-2005-219.52)

BRIEF OF THE WASHINGTON LEGAL FOUNDATION AND THE ALABAMA CIVIL JUSTICE REFORM COMMITTEE AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS

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BRIEF OF THE WASHINGTON LEGAL FOUNDATION AND THE ALABAMA CIVIL JUSTICE REFORM COMMITTEE AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS

INTERESTS OF *AMICI CURIAE*

The interests of the *amici curiae* are more fully set forth in the accompanying motion for leave to file this brief.

In brief, the Washington Legal Foundation (WLF) is a public interest law and policy center with supporters in all 50 states, including many in Alabama. WLF regularly appears before federal and state courts to promote economic liberty, free enterprise, and a limited and accountable government.

In particular, WLF has devoted substantial resources to tort reform issues, and has regularly urged courts both to enforce reasonable dollar limitations on damages awards and to restrict liability awards to those cases in which the plaintiff can demonstrate that the defendant actually caused the injuries of which (s)he complains. See, e.g., Raytheon Technical Services Co. v. Hyland, 273 Va. 292 (2007); 3M Company v. Johnson, 895 So. 2d 151 (Miss. 2005).

The Alabama Civil Justice Reform Committee (ACJRC) is a statewide trade association representing more than 100 trade associations and businesses working together to foster a fair and balanced civil justice system in Alabama. It has appeared in judicial proceedings to encourage adoption of rules designed to promote those goals, and each year

develops a legislative agenda on civil justice reform.

WLF and ACJRC are concerned that the legal theory being pressed by the State of Alabama in this case would, if adopted by this Court, constitute a dramatic change in the law and significantly expand the business community's potential tort liability. The State of Alabama is asking the Court to uphold multi-million fraud judgments even though it candidly admits that: (1) none of the defendants' alleged misrepresentations were ever conveyed directly to the State; (2) it allegedly relied on the defendants' statements without ever having bothered to ask either the defendants or other knowledgeable individuals or entities the meaning of key terms used in those statements; and (3) the State did not change its course of conduct even after it alleges it finally discovered all relevant details regarding the defendants' pricing policies. WLF and ACJRC are concerned that if fraud liability can be upheld under these circumstances, the requirement that a plaintiff in a fraud case demonstrate "reasonable reliance" on the defendant's alleged misrepresentation will have been robbed of all meaningful content.

WLF and ACJRC are also concerned by an increasingly common practice of the office of the Alabama Attorney General: hiring plaintiffs' tort lawyers on a contingency

fee basis to represent the State in damages actions filed against members of the business community. As this case well illustrates, WLF and ACJRC are concerned that such hiring decisions may cause those nominally representing the State to ignore their independent obligation to ensure that justice is done, and instead to pursue litigation strategies designed to maximize monetary recovery for the State (and thus to maximize contingent attorney fees), without regard to the effects that the judgments they obtain may have on the State's system of justice. WLF and ACJRC are filing their brief in order to counteract what they view as the adverse effects of the hiring decisions described above.

STATEMENT OF THE CASE

The cases were tried together in the Circuit Court of Montgomery County, Alabama. The Appellants raise virtually identical issues on appeal. Accordingly, although this brief focuses on the appeal of SmithKline Beecham Corp. D/b/a/ GlaxosmithKline ("GSK"), the arguments made herein apply equally to the appeal of Novartis Pharmaceutical Corporation ("Novartis").

The court below held that the State of Alabama was entitled to recover from Appellant GSK $81 million in allegedly excess payments, paid by Alabama Medicaid to pharmacists and physicians in connection with the federal

Medicaid program. Alabama contends that it made the payments in reasonable reliance on allegedly misleading pricing information provided by GSK to First DataBank (which Alabama had hired to collect pricing information from numerous drug companies). Alabama contends that had GSK not provided the allegedly inaccurate information, it would have paid the pharmacists and doctors considerably reduced reimbursements for the GSK-manufactured prescription drugs they supplied to Alabama Medicaid patients.[1]

The trial revealed that there are remarkably few material facts disputed by the parties. The principal factual dispute is whether Alabama Medicaid officials actually believed that when GSK published a WAC, it was representing to the public that the listed price was the actual transaction price paid by a typical wholesaler to GSK, including all discounts. Alabama officials testified

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[1] Alabama faults GSK for allegedly providing inflated figures for Wholesale Acquisition Cost (WAC) regarding GSK prescription drugs. WAC is a pharmaceutical pricing term that refers to prices charged wholesalers by drug manufacturers. First DataBank collects information regarding WACs from virtually all pharmaceutical manufacturers. It adds either 20% or 25% to those figures to compute an Average Wholesale Price (AWP) for each drug and then forwards both WACs and AWPs to a variety of payers, including Alabama Medicaid. The crux of the disagreement between the parties is the "correct" meaning of the terms WAC and AWP; e.g., whether WAC should be understood as including an adjustment to reflect any discounts from list price granted to a wholesaler by a drug manufacturer.

to such a belief and said that they established reimbursement rates in reliance on that belief. In contrast, GSK introduced evidence suggesting that Alabama officials could not have so believed, that they did not act in reliance on such a belief, and that any such reliance would have been unreasonable.

Otherwise, the evidence at trial was largely uncontroverted. As GSK explains in detail in its brief, the undisputed evidence at trial indicated that all relevant actors other than Alabama Medicaid did not believe that WACs represented actual transaction prices paid by wholesalers, including all discounts; and did not believe that AWP represented the average of actual transaction prices paid by pharmacies to wholesalers, including discounts. Those other actors included the federal government and First DataBank. Alabama did not dispute that all major pharmaceutical manufacturers disagreed with Alabama's understanding of what was meant by WAC. Indeed, in January 2005 Alabama also filed suit against 71 other pharmaceutical manufacturers, alleging that each engaged in essentially the same fraudulent conduct of which it accuses GSK and Novartis.

The evidence is uncontroverted that Alabama Medicaid officials arrived at their understanding of what was meant by the terms WAC and AWP without consulting with GSK, First

DataBank, or the federal government – Alabama Medicaid apparently took the position that the terms were self-explanatory. Nor does Alabama contend that GSK ever issued any statements that WAC was a fully discounted price; to the contrary, the evidence at trial indicated that in every instance in which it supplied WACs to First DataBank, GSK reminded First DataBank that the figures did not reflect discounts provided to wholesalers.

Alabama contends that it first became aware of GSK's fraudulent statements during the two-year period prior to filing suit in January 2005. The evidence at trial was undisputed that Alabama Medicaid officials did not change their reimbursement rates to pharmacists and other providers after becoming aware that GSK's pricing data did not reflect discounts granted to wholesalers. Rather, in the years since their alleged epiphany, those officials have maintained the same reimbursement rate in effect since 1987: WAC + 9.2%, plus a dispensing fee.[2]

SUMMARY OF ARGUMENT

A plaintiff in a fraud action must, among other things demonstrate both that it relied on the defendant's alleged

[2] Virtually all GSK drugs were and are reimbursed at WAC + 9.2%. For reasons explained in GSK's brief, a very small percentage of those drugs were instead reimbursed at AWP - 10%.

misrepresentation and that its reliance was reasonable. Alabama failed to present substantial evidence at trial with regard to either of those two required showings. Accordingly, the trial court erred in failing to grant GSK's motion for judgment as a matter of law.[3]

Alabama contends that its Medicaid reimbursement rates for pharmacies and doctors were established in reliance on the accuracy of the pricing information provided by GSK to First DataBank, and that it would have paid reimbursement at lower rates had it realized that the pricing information did not reflect dollar amounts actually paid by wholesalers to GSK. But all the evidence at trial belied that reliance claim. In particular, the evidence demonstrated that even after Alabama Medicaid officials acknowledged that they had "become aware" that WACs supplied by GSK did not reflect discounts granted by GSK to wholesalers, the State took no steps to reduce reimbursement rates. Alabama law is clear that a fraud plaintiff will not be deemed to have relied on alleged misrepresentations when it does not change its conduct after discovering the truth.

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[3] *Amici* agree with GSK's other contentions, including that Alabama failed to establish <u>any</u> of the elements of a cause of action for fraud, and that the action is barred by the applicable statute of limitations. However, rather than duplicating legal arguments raised by GSK in support of those contentions, *amici* focus this brief on reliance issues.

Moreover, it clearly was not reasonable for Alabama to have taken any measures in reliance on GSK's alleged misrepresentations. Alabama officials contend that they interpreted the term "Wholesale Acquisition Cost" to refer to the net dollar amount paid by a wholesaler to obtain a prescription drug after taking all discounts into account. But that interpretation is hardly a reasonable one in the absence of any effort to check with others more familiar with its usage within the pharmaceutical industry; the phrase is not one in common usage among non-specialists and thus is not one that has acquired a commonly accepted meaning within the general population.

Thus, any reasonable person – before taking steps in reliance on WAC pricing information – would initiate inquiries regarding what that information was intended to convey. Yet, Alabama Medicaid officials claim to have relied on the information without making any such inquiries. It never asked GSK, First DataBank, or the federal government what was meant by WAC. The evidence at trial indicated that Alabama Medicaid officials would have received a truthful answer had they bothered to ask: WAC was set by GSK (and other drug manufacturers) without taking into account discounts provided to wholesalers. Moreover, Alabama cannot assert that its reliance was rendered reas-

onable by any acts undertaken by GSK: GSK had no contractual relationship with Alabama Medicaid officials to supply them with WACs, nor was there evidence at trial that those officials arrived at their understanding of WAC based on anything said by GSK.

Amici respectfully submit that the expansive arguments advanced by Alabama in this case serve neither the ends of justice nor the long-term economic interests of the State. If fraud liability can be upheld here based on the evidence presented at trial, the "reasonable reliance" requirement will essentially have been written out of Alabama law. Such a dramatic change in the law may in the short term serve Alabama's desire to increase government revenues. But the long-term effects would be uniformly negative. If Alabama develops a reputation as a State that looks to tort actions against deep-pocketed out-of-state corporations as a convenient source of revenue, those corporations will become less willing to locate their operations within the State.

Moreover, this suit and the 72 other suits filed to date by Alabama against major pharmaceutical companies are likely to have long-term adverse effects on health care delivery. The apparent motivation for the suits is an understandable concern among State budget officials regarding rising health care expenditures; the suits are

viewed as one means of holding down costs. But even though the suits are of dubious merit and many are likely to be dismissed eventually, the substantial cost of defending these suits and similar suits in other States inevitably has adverse effects on industry profitability – and ultimately decreases the willingness of investors to put up the hundreds of millions of dollars necessary to develop and gain marketing approval for each and every new life-saving product.

Health care has improved markedly in the U.S. in recent decades due to new therapies developed by the pharmaceutical industry – and many of those therapies not only have increased life expectancies but also have decreased overall health care expenditures. *Amici* respectfully request that the Court make clear in no uncertain terms that Alabama government officials should not resort to overly expansive fraud claims against pharmaceutical companies as a means of reducing the Medicaid program's net costs.

ARGUMENT

I. THE STATE FAILED TO PRESENT SUBSTANTIAL EVIDENCE THAT IT RELIED ON THE ALLEGED MISREPRESENTATIONS

In the absence of substantial evidence from Alabama to support each of the elements of its fraud claim, GSK is entitled to judgment as a matter of law. Waddell & Reed, Inc. v. United Investors Life Ins. Co., 875 So. 2d 1143,

1152 (Ala. 2003). Alabama failed to introduce substantial evidence to support its claim that it relied to its detriment on GSK's alleged misrepresentations.

Alabama Medicaid officials testified that prior to January 2005 they believed that the WAC pricing information provided by GSK reflected actual transaction prices paid by wholesalers to GSK. But under Alabama law, a belief in the truthfulness of an alleged misrepresentation is not sufficient to demonstrate reliance. Rather, a fraud plaintiff must also demonstrate that "the misrepresentation actually induced the injured party to change its course of action." Hunt Petroleum Corp. v. State of Alabama, 901 So. 2d 1, 4 (Ala. 2004). As this Court explained in Hunt:

> [E]ven if we were to accept the State's argument that it "assumed" that the monthly royalty reports generated by Hunt were correct, that assumption does not constitute actual reliance. As we stated in [Liberty Nat'l Life Ins. Co. v.] Allen, 699 So. 2d [138,] 142 [(Ala. 1997)], "in order to sustain an action alleging fraud, the plaintiff must prove not only that he or she relied on the representation, but also that he acted upon that reliance."

Hunt, 901 So. 2d at 7.

As GSK has explained at length, Alabama did not present substantial evidence to support its claim that it would have reduced its Medicaid reimbursement payments to pharmacies and doctors had it known that WACs did not represent actual transaction prices. The most telling evidence undercutting

that claim is Alabama's conduct following its alleged "discovery" (in the period just prior to the filing of this lawsuit in January 2005) that WACs supplied by GSK did not reflect discounts granted by GSK to wholesalers. From that time forward, Alabama took no steps to reduce reimbursement rates. Rather, the reimbursement rate first established for pharmacies in 1987 (WAC + 9.2%, plus a dispensing fee) remains in effect to this very day.

Indeed, it was just such a failure by the State of Alabama to change its position following its discovery that it had received misleading information that caused the Court to conclude in Hunt and another natural gas lease case, Exxon Mobil Corp. v. Alabama Dep't of Conservation and Natural Res., 986 So. 2d 1093 (Ala. 2007), that Alabama had never in fact taken any actions in reliance on the defendant's alleged misrepresentations. That conclusion was made crystal clear in two of the concurring opinions in Exxon. In an opinion concurring in part and concurring in the judgment, Justice See (joined by Justices Smith and Bolin) explained:

> Even after Exxon informed DCNR that it was calculating its royalty obligations based on an interpretation of the leases at variance with DCNR's interpretation, the State nevertheless did nothing different. . . . The State never attempted to cancel the leases and never exercised its right to take gas in kind. That the State did nothing different after Exxon explained in February 1995 that it did not agree with the State's

> interpretation of the leases strongly suggests that the state would have acted no differently had it had that information before February 1995.

Exxon, 986 So. 2d at 1128 (See, J., concurring in part and concurring in the judgment) (emphasis added).

Similarly, Justice Lyons concluded:

> Because of this inactivity during the period after DCNR had full disclosure, attribution of reliance damages in the form of the State's monetary loss between December 1993, when production began, and December 1994, when disclosure took place, is simply too speculative to support a conclusion that DCNR reasonably relied to its detriment for the period during which DCNR was ignorant of Exxon's interpretation of the leases.

Id. at 1133 (Lyons, J., concurring in part and concurring in the result).

That Alabama did not take steps after January 2005 to reduce reimbursement to pharmacies in hardly surprising, in light of the history of lengthy negotiations among stakeholders regarding appropriate reimbursement rates. For example, as GSK explains in more detail in its brief, each time Alabama officials have recommended reducing the reimbursement rate for pharmacies, pharmacists have complained that the reduced figure would make it uneconomical for them to continue to handle Medicaid prescriptions. Alabama has a strong interest in ensuring that Medicaid recipients have ready "access" to pharmacies that handle Medicaid claims, so it is unsurprising that the State would be careful not to drop reimbursement rates to the point that large numbers of

pharmacists would opt not to participate. See 42 U.S.C. § 1396a(a)(30)(A); 42 C.F.R. § 447.204. But given the State's apparent belief that current rates are necessary to ensure participation in Medicaid by pharmacists, it has failed to put forth substantial evidence that it would have decreased those rates had GSK not supplied "false" WAC data.

Indeed, complaints from pharmacists concerning inadequate reimbursement rates continue to this day. For example, the federal Centers for Medicare and Medicaid Services (CMS) in July 2007 adopted new regulations that imposed a federal upper payment limit for Medicaid pharmacy reimbursement at 250% of "average manufacturing price." Pharmacists "blasted" the new regulation, stating that it would cause "thousands" of independent pharmacists to leave the Medicaid program and threatening litigation to overturn the regulation. See "As CMS Drops AMP Rule, Pharmacists Look to Congress, Courts," INSIDE CMS (July 12, 2007). In sum, the evidence indicates that Alabama maintained the Medicaid reimbursement rate at WAC + 9.2% not because it was defrauded by GSK but because it feared that many Alabama pharmacies would not participate in Medicaid if rates were lowered.

II. THE STATE FAILED TO PRESENT SUBSTANTIAL EVIDENCE THAT ANY RELIANCE WAS REASONABLE

Even if Alabama could show that it actually relied on

GSK's alleged misrepresentations in setting reimbursement rates, it failed to provide substantial evidence that its reliance was reasonable. Alabama cannot point to a single decision of this Court in which reliance was held to be reasonable under facts even remotely resembling those in this case.

Alabama contends that pricing information provided by GSK was not the actual "Wholesale Acquisition Cost" for its products. But such a contention is based on the assumption that the phrase "Wholesale Acquisition Cost" must state an actual, discounted transaction price. This is objectively and verifiably incorrect. Indeed, as explained at length in GSK's brief, everyone in the Medicaid and pharmaceutical-pricing community has known for years (if not decades) that WAC reflects a undiscounted "list" price. Alabama simply cannot credibly claim that it was somehow ignorant of what every other market participant – including not only manufacturers but also the federal government, First DataBank, non-profit watchdogs, and industry commentators – knew to be true.

In the face of a mountain of evidence to the contrary, Alabama officials contend that they interpreted the term "Wholesale Acquisition Cost" to refer to the net dollar amount paid by a wholesaler to obtain a prescription drug

after taking all discounts into account. But they cannot point – on their side of the ledger, so to speak – to a single statute or any industry standard that adopts their interpretation. Nor is Alabama's interpretation somehow compelled by a natural reading of the words contained in the phrase; the phrase is not one in common usage among non-specialists and thus is not one that could have acquired a commonly accepted meaning within the general population. Given the clarity of WAC's meaning – i.e, as an undiscounted list price – within the pharmaceutical-pricing industry and the absence of a counterweight, either in the plain meaning or elsewhere, Alabama's current assertion that it has always understood WAC to state an actual, discounted price cannot be taken seriously.

At the very least, any reasonable person – before taking steps in reliance on WAC pricing information – would initiate inquiries regarding what that information was intended to convey. Yet, Alabama Medicaid officials claim to have relied on the information without making any such inquiries. They never asked GSK, First DataBank, or the federal government what was meant by WAC. The evidence at trial indicated that Alabama Medicaid officials would have received a truthful answer had they bothered to ask: WAC was set by GSK (and other drug manufacturers) without taking

into account discounts provided to wholesalers. In light of its utter failure to take simple steps to verify what others meant when they used the term WAC, Alabama's alleged reliance on its unique understanding of the term's meaning cannot as a matter of law be deemed reasonable.

Alabama's "reasonable reliance" argument is far weaker here than it was in either Hunt or Exxon. In those cases, the parties had negotiated contract terms with reasonably clear meanings. Thus, Alabama could plausibly argue that it reasonably believed that royalty payments made by oil lessees pursuant to those contracts had been computed based on Alabama's understanding of contractual terms.[4] In contrast, because in this case Alabama has not entered into any contract with GSK regarding WAC pricing data, it had no reason to believe that it had reached a mutual understanding with GSK regarding what GSK intended to convey when it released WAC figures.

In the trial court, Alabama asserted that its reliance on WAC information it obtained from First DataBank was

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[4] Although it expressed serious doubts regarding whether Alabama could have met the "reasonable reliance" standard had it relied to its detriment on such disputed contract terms as "gross proceeds," see, e.g., Hunt, 901 So. 2d at 3, the Court ultimately did not need to reach the question in either case, because in both cases the Court determined that Alabama had not actually relied on the alleged misrepresentations.

reasonable because it had no other source of information about drug pricing. That assertion is patently incorrect. As GSK has shown, drug pricing information was all around the State if it would just look. Federal regulators, non-profit agencies, and academic commentators were all clear in defining WAC as an undiscounted list price. Moreover, Alabama, if it was uncertain, was free at any time to contact GSK, First DataBank, or the federal government to discern what drug manufacturers meant by WAC – and to adjust its reimbursement rates accordingly.

Alabama also asserted in the trial court that its "reasonable reliance" claim was stronger than in fraud cases in which the plaintiff alleged that (s)he had reasonably relied on an oral misrepresentation made by the defendant, even though the terms of a written contract between the parties (not carefully read by the plaintiff) contradicted the alleged oral misrepresentation. Under such circum-stances, the Court has uniformly held that a plaintiff does not act reasonably in relying on an oral misrepresentation when (s)he had the capability of reading and understanding the written contract yet failed to do so. See, e.g., AmerUs Life Ins. Co. v. Smith, ___ So. 2d. ___, 2008 Ala. LEXIS 202 (Sept. 19, 2008); Foremost Ins. Co. v. Parham, 693 So. 2d 409 (Ala. 1997). Alabama asserted that the Foremost line of

cases is inapplicable because "unlike many fraud cases that depend on a contract, the State of Alabama did not have a contract with GSK on which it could rely." State's Opposition to GSK's Post-Judgment Motions at 7-8.

Alabama's effort to distinguish the Foremost line of cases is unavailing. Indeed, the reasonable reliance claims were far more plausible in those cases than they are here. At least the plaintiff in those cases could point to communications addressed directly to them and containing provably false claims. Here, Alabama has had no direct dealings with GSK regarding WAC, save for an instance when GSK told Alabama Medicaid in no uncertain terms that WAC was a list price that did not include discounts. See GSK Br. 26-27. For the most past, Alabama relied on information supplied by GSK to a third party without ever bothering to contact GSK to inquire regarding what GSK meant by the term WAC.

In sum, Alabama has failed to provide substantial evidence that it acted reasonably when it allegedly relied on its unique understanding of WACs supplied by GSK when establishing reimbursement rates for GSK's drugs. As the Court has explained, "Foremost ended the era of 'ostrichism'" during which fraud plaintiffs could allege "reasonable reliance" despite having failed to undertake

steps that would have revealed to them that reliance was unreasonable. Ex parte Carver, 742 So. 2d 168, 172-73 (Ala. 1999).

III. THE EXPANSIVE ARGUMENTS ADVANCED BY THE STATE SERVE NEITHER THE ENDS OF JUSTICE NOR THE LONG-TERM ECONOMIC INTERESTS OF ALABAMA

Amici WLF and ACJRC were prompted to file this brief not simply because of their belief that the huge judgments entered against GSK and Novartis, as well as a similar judgment entered against AstraZenaca Pharmaceuticals, are unwarranted. They were also prompted by a grave concern that the judgments below, if upheld on appeal, would expand potential fraud liability considerably by essentially writing the "reasonable reliance" requirement out of Alabama law.

Such a dramatic change in the law may well, in the short term, serve Alabama's desire to increase government revenues. But the long-term effects would be uniformly negative. The increased ease with which fraud allegations could be proven would undoubtedly lead to a significant increase in the number of such cases filed in Alabama courts against members of the business community – thereby increasing the costs of doing business within the State.

Moreover, the business community would likely come to fear suits not merely from the plaintiffs' bar. The trilogy of Hunt, Exxon, and these 73 suits against the pharmaceutical industry has caused businesses nationwide to sit up and take notice – and not in a good way. The lawsuits

suggest to some that State officials in Alabama are willing to advance virtually any legal argument – no matter how implausible – in pursuit of revenues for the State. This Court made clear in Hunt and Exxon that it does not condone such legal adventurism; *amici* urge the Court to send an equally clear message in this case. Otherwise, if Alabama develops a reputation as a State that looks to tort actions against deep-pocketed out-of-state corporations as a convenient source of revenue, those corporations will become less willing to locate their operations within the State.

Amici are also concerned that the 73 suits filed against major pharmaceutical companies – along with similar suits filed in other states by Alabama's contingency fee counsel – are likely to have long-term adverse effects on health care delivery. The apparent motivation for the suits is an understandable concern among State budget officials regarding rising health care expenditures; the suits are viewed as one means of holding down costs. But even though the suits are of dubious merit and many are likely to be dismissed eventually, the substantial cost of defending these suits[5] and similar suits in other States inevitably

[5] GSK has chosen to fight what it views as a legally unjustified suit. Other pharmaceuticals have rationally concluded that although the suits against them are without merit, it would be less expensive to settle than to pay lawyers to seek ultimate vindication in the Alabama Supreme

has adverse effects on industry profitability – and ultimately decreases the willingness of investors to put up the hundreds of millions of dollars necessary to develop and gain marketing approval for each and every new life-saving product. Recent studies have concluded that the average cost of bringing new pharmaceutical products to market is as high as $1.7 billion. *See* Pharmacy Times, "Drug Development" (Dec. 2005) (available at http://www.pharmacytimes.com/Article.cfm?Menu=1&ID=2865). Tufts University pegs the average cost of developing a new biotechnology product at $1.2 billion. Tufts Center for the Study of Drug Development, Average Cost to Develop a New Biotechnology Product Is $1.2 Billion (Nov. 9, 2006) (available at http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=69). Because the theory underlying Alabama's claims makes no rational sense,[6] drug companies have no means of avoiding the litigation costs incurred in cases of this sort – and

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Court. Thus, for example, Bristol-Myers Squibb paid to settle in advance of trial of the WAC-based fraud claims asserted against it by Alabama.

[6] Alabama contends that GSK was motivated by a desire to increase profits by "marketing the spread" between a provider's drug-acquisition costs and the reimbursement it obtains from Medicaid. But as GSK has pointed out: (1) 99% of the GSK drugs at issue here were sold through pharmacists; and (2) pharmacists have no control over which brand-name drug their customers are prescribed, and thus have no means of steering customers toward those drugs with the largest "spreads." See GSK Br. at 44-47.

thus development of new, life-saving therapies becomes a considerably less attractive investment.

Health care has improved markedly in recent decades due to new therapies developed by the pharmaceutical industry. See, e.g., Center for Disease Control and Prevention, National Center for Health Statistics, "Health, United States, 2006: With Chartbooks on Trends in the Health of Americans" (2006) ("new drugs and expanded uses of existing drugs" have been major contributors to the decline in heart disease and stroke mortality). Moreover, while increased use of prescription drugs generally increases Medicaid costs associated with purchasing those drugs, the overall effect is often a net decrease in health care expenditures, because effective use of medications often leads to reduced hospitalizations. For example, a recent study concluded that increased patient adherence to medicines used to treat diabetes, hypertension, and high cholesterol yielded between $4 and $7 of savings for every additional dollar spent on drugs. M.C. Sokol, et al., "Impact of Medication Adherence on Hospitalization Risk and Healthcare Cost," Medical Care (June 2005).[7]

[7] Indeed, at least some Alabama Medicaid officials appear to recognize the cost-effectiveness of increase use of prescription drugs:

Although the pharmacy program is an optional service

Amici respectfully submit that state governments that seek to control health care costs by filing "innovative" fraud claims against the pharmaceutical industry are not serving the best interests of their state or of the Nation's health care delivery system. Such suits will discourage investment and thereby result in the development of fewer new drugs in future years – a result that has negative implication both for public health and for health care costs.

CONCLUSION

Amici curiae the Washington Legal Foundation and the Alabama Civil Justice Reform Committee respectfully request that the Court reverse the judgments of the Circuit Court and direct entry of judgment for GSK and Novartis as a matter of law.

Respectfully submitted,

> under federal Medicaid rules, it is economically vital to the Medicaid program. Treating illnesses with prescription drugs is usually much less expensive and often as effective as alternatives such as hospitalization and/or surgery. For this reason, the pharmacy program represents one of the most cost-effective services.
>
> Realistically, modern medical treatment would be impossible without drugs. In recent years, medical professionals have been very successful in finding medications that make more expensive alternatives unnecessary.

Alabama Medicaid, 2004 Annual Report at 39-40 (DX 339).

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