Nos. 1071439, 1071440, 1071704, 1071759

IN THE SUPREME COURT OF ALABAMA

ASTRAZENECA LP, AND ASTRAZENECA PHARMS. LP	SMITHKLINE BEECHAM CORP. D/B/A GLAXOSMITHKLINE	NOVARTIS PHARMACEUTICALS CORP.
Appellants,	Appellant,	Appellant,
v.	v.	v.
STATE OF ALABAMA,	STATE OF ALABAMA,	STATE OF ALABAMA,
Appellee.	Appellee.	Appellee.

BRIEF OF NATIONAL ASSOCIATION OF MANUFACTURERS, CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, AND AMERICAN PETROLEUM INSTITUTE AS *AMICI CURIAE* IN SUPPORT OF APPELLANTS

From the Circuit Court of Montgomery County, Alabama, Case Nos. CV-2005-219.10, CV-2005-219.11 CV-2005-219.52, CV-2005-219.68

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The *amici* adopt this brief for use in the following additional cases:

SmithKline Beecham Corp. d/b/a GlaxoSmithKline, Appellant, v. State of Alabama, Appellee, No. 1071704.

Novartis Pharmaceuticals Corp., Appellant, v. State of Alabama, Appellee, No. 1071759.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page

CASES

STATUTES

INTEREST OF *AMICI CURIAE*[1]

The National Association of Manufacturers ("NAM") is the nation's largest industrial trade association, representing small and large manufacturers in every industrial sector and in all fifty states. NAM's mission is to enhance the competitiveness of manufacturers and improve American living standards by shaping a legislative and regulatory environment conducive to U.S. economic growth and to increase understanding among policymakers, the media, and the general public about the importance of manufacturing to America's economic strength.

The Chamber of Commerce of the United States of America ("U.S. Chamber") is the world's largest business federation. The U.S. Chamber represents an underlying membership of more than three million businesses and organizations of every size, in every business sector, and from every region of the country. An important function of

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[1] Washington, D.C., counsel for the amici work at a firm that represents Aventis Pharmaceuticals, Inc. and Sanofi-Synthelabo, Inc. in AWP-related litigation in Alabama. This brief is being filed only on behalf of the amici. The views expressed herein do not necessarily reflect the views of any other clients of the firm.

the U.S. Chamber is to represent the interests of its members in court on issues of national concern to the business community. Accordingly, the U.S. Chamber has filed more than 1,000 *amicus curiae* briefs in state and federal courts.

The American Petroleum Institute ("API") is a nationwide, not-for-profit trade association representing over 400 companies engaged in all aspects of the petroleum industry, including exploration, production, refining, transportation and marketing. API frequently represents its members in judicial and regulatory matters affecting the petroleum industry in the United States.

Amici are concerned with the adverse ramifications of this case, which extend well beyond the pharmaceutical industry. The Montgomery County Circuit Court's rulings send a message that entire industries may be held liable, purportedly for fraud, even when the practices at issue were sanctioned by the government and widely understood by regulators. Moreover, the decision in the AstraZeneca case goes a step further by permitting a $120 million punitive damage award, on top of already substantial compensatory

damages, for regulated conduct that was not fraudulent, let alone reprehensible.

STATEMENT OF THE CASE

In January 2005, the State filed suit against seventy-three pharmaceutical manufacturers alleging fraud in the reporting of prices for drugs covered under Medicaid. The State alleged that the manufacturers fraudulently misrepresented the prices of their products to an independent price reporting service because the companies reported "list" prices instead of prices that included discounts and rebates.

Two of these proceedings are now before this Court. In February 2008, a Montgomery County jury found AstraZeneca liable for fraudulent misrepresentation and suppression. The jury awarded $40 million in compensatory damages and $175 million in punitive damages. The trial court subsequently remitted the punitive damage award to $120 million - the maximum allowed by statute in Alabama. Then, in June 2008, after a consolidated trial, a separate Montgomery County jury returned verdicts against both GlaxoSmithKline and Novartis Pharmaceuticals Corporation for fraudulent misrepresentation only. The jury awarded

$81 million in compensatory damages against GlaxoSmithKline and $32 million in compensatory damages against Novartis. The jury rejected the State's request for punitive damages against both defendants.

In each of these cases, the State, represented by specially-retained outside counsel on a contingency fee basis, claims that it did not understand that the reported prices were list prices. The State further claims that because the State unwittingly used the reported list prices in its Medicaid reimbursement formulas (allegedly believing that they were discounted prices), the State over-reimbursed Alabama pharmacists and physicians who dispensed drugs to Medicaid patients.

Despite the fact that the pharmaceutical manufacturer defendants did not receive any of the State's alleged over-reimbursements, the State now contends that the manufacturers should pay huge amounts to make up for those alleged over-reimbursements. Tellingly, however, notwithstanding the fact that the State filed these lawsuits more than three years ago, we understand that the State has not changed its Medicaid reimbursement methodology (nor, indeed, since 1991) and has continued to

rely on the same reported prices that it has been claiming since then to be fraudulent.

Central to the cases are two pricing benchmarks -- one called Average Wholesale Price ("AWP") and the other called Wholesale Acquisition Cost ("WAC"), both of which, the evidence overwhelmingly shows, have been understood by the government (including Alabama Medicaid officials) for many years to be "list" prices that did not include discounts. This common understanding is directly at odds with the litigation position now being taken by the State and should, in and of itself, defeat the State's claims.

STATEMENT OF THE ISSUES

In AstraZeneca v. State of Alabama, SmithKline Beecham Corp. d/b/a GlaxoSmithKline v. State of Alabama, and Novartis Pharm. Corp. v. State of Alabama, whether price reporting conventions that were consistent with longstanding and well-documented industry practice, and that the evidence clearly shows to have been understood and accepted by federal and state regulators, can form the basis for a claim of fraud.

In AstraZeneca v. State of Alabama, whether the $120 million punitive damages award against the defendant, which is in addition to a $40 million compensatory damage award, can be upheld when the conduct at issue was consistent with longstanding and well-documented industry practice and understood and accepted by federal and state regulators (and therefore not fraudulent), and whether a punitive damages award under these circumstances is consistent with the Due Process Clause of the Fourteenth Amendment and Article I, § 13 of the Alabama Constitution.

INTRODUCTION AND SUMMARY OF ARGUMENT

At their core, these cases involve the question of whether, under Alabama law, manufacturers may be held liable for fraud (and, in the case of AstraZeneca, penalized with a substantial punitive damage award), based on conduct that was common industry practice, and understood and accepted by federal and state regulators for decades. The answer is clearly no.

Since 1991, Alabama has chosen to use AWP (minus a discount) and WAC (plus a mark-up) as pricing benchmarks in its Medicaid reimbursement formulas that determine how much to pay Alabama pharmacies that dispense drugs to Medicaid

patients. Numerous government publications and other public reports clearly demonstrate that Medicaid regulators understood that both AWP and WAC were "list" prices for pharmaceutical products, exclusive of discounts and rebates. Substantial evidence also shows that the federal and state regulators, as well as First DataBank (the price reporting service retained by Alabama), knew and accepted that AWPs were higher than the actual or average price paid to wholesalers by pharmacies (even after the wholesalers added a mark-up) and that WAC list prices were higher than the fully discounted prices that wholesalers could obtain from manufacturers. In spite of this evidence -- which comes from multiple sources, including the State's own files -- the State claims that defendants intentionally misled the Alabama Medicaid Agency into believing that the AWPs and WACs reported for their products reflected fully discounted prices. Moreover, the State makes this claim in the face of clear evidence that regulators had a contrary understanding, and despite the lack of evidence that any of the pharmaceutical defendants ever said anything to the State about AWP or WAC that was inaccurate.

The State's knowledge, or at best willful ignorance, of the commonly accepted meaning and usage of AWP and WAC alone should preclude a finding of fraud. Moreover, the State's continued use of AWP and WAC in its reimbursement formulas, even after filing suit, demonstrates that the State did not rely on any alleged material misrepresentation or suppression of fact. Finally, even if the State presented sufficient evidence to support finding of fraud against any defendant -- which it clearly did not - AstraZeneca's conduct clearly lacked the high level of reprehensibility necessary to sustain a punitive award.

Amici will show that allowing these verdicts to stand would have implications beyond the pharmaceutical industry. These cases are part of a growing trend of state attorneys general hiring private plaintiffs' lawyers, paid on a contingency fee basis, to sue entire industries and seek windfall awards, when legislators and regulators properly charged with balancing often competing policy considerations have made prior decisions to permit the conduct being challenged. As these cases stand now, they send a dangerous message that manufacturers that follow standard, well-known, and accepted business practices in

areas that are highly regulated by federal and state governments can nevertheless be held liable years later for fraud and subject to multi-million dollar awards, including punitive damages.

ARGUMENT

I. THIS APPEAL INVOLVES A GROWING TREND OF STATE ATTORNEYS GENERAL HIRING PRIVATE CONTINGENCY FEE COUNSEL TO SEEK A WINDFALL RECOVERY AGAINST ENTIRE INDUSTRIES

The cases before this Court are part of growing trend of state attorneys general hiring private plaintiffs' lawyers on a contingency fee basis to sue entire industries and seek windfall awards. States and localities have hired contingency fee lawyers to attack a wide range of manufacturers and service providers, including automobile manufacturers and health insurance companies.

Such litigation is particularly questionable where, as here, it challenges conduct that legislators and regulators properly charged with balancing often competing policy considerations have permitted. Cf. Victor E. Schwartz & Leah Lorber, State Farm v. Avery: State Court Regulation Through Litigation Has Gone Too Far, 33 Conn. L. Rev. 1215 (2001).

Aside from constitutional concerns, see, e.g., People ex rel. Clancy v. Superior Ct., 705 P.2d 347 (Cal. 1985) and Meredith v. Ieyoub, 700 So. 2d 478 (La. 1997), contingency fee arrangements involving the state raise questions as to whether the litigation is driven by justice or profit. As United States Court of Appeals for the Eleventh Circuit Judge William H. Pryor, Jr. observed when he was Attorney General of Alabama:

> For a long time, contingent fee contracts were considered unethical, but that view gave way to the need for poor persons with valid claims to have access to the legal system. Governments do not have this problem. Governments are wealthy, because they have the power to tax and condemn. Governments also control access to the legal system. The use of contingent fee contracts allows governments to avoid the appropriation process and create the illusion that these lawsuits are being pursued at no cost to the taxpayers. These contracts also create the potential for outrageous windfalls or even outright corruption for political supporters of the officials who negotiated the contracts.

William H. Pryor, Jr., Curbing the Abuses of Government Lawsuits Against Industries, Speech Before the American Legislative Exchange Council, Aug. 11, 1999, at 8; see also William H. Pryor, Jr., Comment, 31 Seton Hall L. Rev. 604 (2001) (symposium panel on "State Attorney General

Litigation: Regulation Through Litigation and the Separation of Powers").[2]

In addition to the constitutional and ethical questions raised by such arrangements, contracting out of the state's enforcement power to private contingency fee attorneys facilitates what has been called "regulation through litigation." See Robert B. Reich, Regulation is out, Litigation is in, USA Today, Feb. 11, 1999, at A15; see also John Fund & Martin Morse Wooster, The Dangers of Regulation Through Litigation: The Alliance of Plaintiffs' Lawyers and State Governments (Am. Tort Reform Found.

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2 Editorials and op-eds stemming from such lawsuits have been highly critical of the practice of paying private attorneys to prosecute civil enforcement claims on behalf of the State based on their success in bringing in the greatest monetary award. See, e.g., Adam Liptak, A Deal for the Public: If You Win, You Lose, N.Y. Times, July 9, 2007, at 10 (stating that any recovery belongs to the state's taxpayers and a large portion of it should not be diverted to private lawyers); Andrew Spiropoulos, New AG Model Harms State, The Oklahoman, July 8, 2007, at 17A (opining that the state's hiring contingency fee lawyers "not only undermines the fair and impartial administration of justice[, but] . . . will economically harm, not benefit, the state"); Editorial, Prosecution for Profit, Wall St. J., July 5, 2007, at A14 (urging against use of contingency fee agreements by governments as antithetical to neutrality).

2000), at http://www.heartland.org/Article.cfm?artId=8162. The strategy of the private contingency fee attorneys to select an industry and go after it through tort litigation - as opposed to through legislation - is an end-run around representative government. See Victor E. Schwartz et al., Tort Reform Past, Present and Future: Solving Old Problems and Dealing With "New Style" Litigation, 27 Wm. Mitchell L. Rev. 237, 258-59 (2000).

These "new style" cases give the state executive branch a new revenue source without having to raise taxes. These lawsuits also give government officials the chance to achieve an objective that the majority of the electorate, as represented by their legislators, or regulators with statutory authority, may not support. As Clinton Administration Labor Secretary Robert Reich sagely observed, "The strategy may work, but at the cost of making our frail democracy even weaker. . . . This is faux legislation, which sacrifices democracy to the discretion of administration officials operating in secrecy." Robert B. Reich, Don't Democrats Believe in Democracy?, Wall St. J., Jan. 12, 2000, at A22.

In addition to offending the democratic process, contingency fee agreements by the state pose a danger to the business and legal environment in Alabama. They encourage lawsuits against "deep pocket" corporate defendants that are often viewed as unpopular by the public, making it difficult for the defendants to receive a fair trial. This is particularly true when what is essentially private litigation is backed by the State's moral authority and seal of approval. Thus, the Court should view the fraud claims in these cases with skepticism, given these public policy considerations and the questionable motivation of such litigation.

II. THE MANUFACTURER DEFENDANTS' REPORTING OF LIST PRICES CANNOT POSSIBLY CONSTITUTE FRAUD

Despite the plethora of government reports and studies confirming the common understanding of industry pricing practices, Alabama now claims it was ignorant of them all and somehow deceived into believing that the AWP and/or WAC prices reported by the defendants represented the actual, discounted price paid by pharmacies or wholesalers. The State's contention does not hold water.

A. **Elements of Fraud**

The State's fraudulent misrepresentation claim requires that it show: (1) the pharmaceutical manufacturer Appellants made a false representation; (2) the misrepresentation involved a material fact; (3) the State reasonably relied on that misrepresentation; and (4) the State suffered damages as a proximate cause of the misrepresentation. See AmerUS Life Ins. Co. v. Smith, No. 1061535, 2008 WL 4277861, at *6 (Ala. Sept. 19, 2008).

Likewise, a fraudulent suppression claim rests on the suppression of a material fact, rather than an affirmative misrepresentation, that induced the reasonable reliance and proximately caused the damage. See Ex parte Alfa Mut. Fire Ins. Co., 742 So. 2d 1237, 1240 (Ala. 1999) (citing Booker v. United Am. Ins. Co., 700 So. 2d 1333, 1338 (Ala. 1997)). "Where the record indicates that the information alleged to have been suppressed was in fact disclosed, and there are no special circumstances affecting the plaintiff's capacity to comprehend, the plaintiff cannot recover for suppression." Id. at 1243 (citing Robinson v. JMIC Life Ins. Co., 697 So. 2d 461 (Ala. 1997)).

As shown below, publicly available and authoritative sources from the federal government and others have for years clearly and repeatedly stated that AWPs and WACs are list prices that exclude discounts. The Alabama Medicaid Agency has been -- or at the very least should have been -- well aware for years that AWPs were higher than the actual acquisition costs paid by pharmacies for drugs and did not reflect averages of actual transaction prices. Similarly, the evidence shows that the State knew -- or at the very least should have known -- for years that reported WACs were undiscounted list prices to wholesalers. The undisputed evidence therefore overwhelmingly defeats the State's fraud claim.

B. Reporting of "List" Prices Has Long Been Standard Industry Practice, Accepted by Federal and State Regulators, and Well Known to the State of Alabama

Under Alabama law, a determination of fraud requires a finding that the defendant intentionally misrepresented a material fact, see Ray v. Montgomery, 399 So. 2d 230, 232 (Ala. 1980), and a determination of suppression requires a finding that the defendant intentionally suppressed material facts that were not reasonably available to the plaintiff. See Armstrong Bus. Servs., Inc. v. AmSouth

Bank, 817 So. 2d 655, 679 (Ala. 2001). The State proved neither claim here. Indeed, given the level of government knowledge of the challenged practices, the question is not close. Even if the State had made its case, it did not show the clear and convincing evidence of highly reprehensible conduct required to sustain an award of punitive damages. See Ala. Code § 6-11-20(a), (b)(1) (requiring clear and convincing evidence of an "intentional misrepresentation, deceit, or concealment . . ., which was gross, oppressive, or malicious and committed with the intention on the part of the defendant of thereby depriving a person or entity of property or legal rights or otherwise causing injury").

The evidence adduced in these cases falls far short of what is required for a finding of fraud or suppression, let alone punitive damages.

1. The Practice of List Price Reporting

As in many industries, the prices charged for a pharmaceutical product vary depending upon a host of factors, including the point in the distribution chain where the product is being sold (e.g., manufacturer-to-wholesaler or wholesaler-to-retailer) and the customer type

(e.g. wholesaler, pharmacist or hospital). In addition, as in many industries, discounts and rebates (of various amounts) from listed prices can sometimes be obtained, again depending upon a variety of factors such as customer type, prompt payment, competition and sales volume. Any estimate of the average fully discounted price actually paid for a drug either at the wholesale level (where discounts for "brand name" drugs are typically quite small) or the retail level (where there is tremendous variation in the level of discounts and rebates available both from wholesalers and manufacturers), is dependent on which sales to which customers at which point in the distribution chain are considered, what time period is considered, and how discounts and earned rebates are accounted for.

For decades it has been standard practice in the pharmaceutical industry for manufacturers to report to commercial pricing compendia such as First DataBank either AWP or WAC. It has been widely recognized that these two list prices -- which are reported only periodically for each drug -- do not include the discounts and rebates available to many purchasers.

In fact, a purchaser's actual price is often expressed in the industry as a percentage of one of the two key list price benchmarks. For example, a wholesaler may buy drugs from a manufacturer at WAC-3%, while a pharmacist may buy drugs from a wholesaler at AWP-15% (which can also be expressed as WAC+6.25%).

State Medicaid agencies are given discretion by federal regulators to set reimbursement rates for brand-name and generic drugs so that their reimbursements to pharmacies that dispense drugs to Medicaid patients accomplish the competing policy goals of cost containment, ensuring that Medicaid patients will have the same access to drugs as non-Medicaid patients, and administrative convenience. In order to strike the right balance between these goals, almost every state sets its Medicaid reimbursement rates by using either the reported AWP minus some percentage or the reported WAC plus some percentage (or both).

Since 1991, Alabama's Medicaid program has reimbursed pharmacists who dispense brand name drugs (like those involved in these cases) at either WAC+9.2% or AWP-10% (plus a dispensing fee). In addition, as in all other states, after reimbursing pharmacists who dispense drugs,

Alabama Medicaid receives a rebate. This rebate is often substantial and is paid to the State directly from the drug's manufacturer pursuant to a rebate agreement designed to ensure that the Medicaid program gets the benefit of the best discount available to large commercial insurers.

In this case, the State ignores the well-known practice of list price reporting upon which its Medicaid reimbursement system has been based for years (and which it is still using), and alleges that the defendants intentionally and fraudulently misled the Medicaid agency into believing that reported AWPs and WACs were not list prices at all, but were actual prices at which wholesalers and retail pharmacies purchase drugs. The State alleges that this deception supposedly resulted in AWP-based and WAC-based reimbursement formulas that caused the State to reimburse pharmacies more than they intended.[3] There was overwhelming evidence introduced at the trials of these

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[3] In light of the State's unsupported contention that Alabama Medicaid thought AWPs were amounts that pharmacies actually paid for drugs on average, the State's use of AWP minus 10% as a reimbursement formula leads to the absurd conclusion that for years Alabama actually intended to reimburse its pharmacies at 10% less than what pharmacies paid on average.

cases, however, that AWPs and WACs were well known, understood and accepted throughout the pharmaceutical industry and by Medicaid officials as undiscounted list prices. That leaves but one conclusion: there was no fraud here.

2. AWPs Were Widely and Repeatedly Explained in Government Reports as Undiscounted List Prices to Pharmacies that Did Not Reflect Actual Pharmacy Acquisition Costs

For decades, government reports and public studies on pharmacy reimbursement explained that AWP does not represent actual prices paid by pharmacies or other providers. For example, in 1980, the Comptroller General of the United States recognized, "State reimbursement limits were being based on published AWPs that reportedly exceeded by 15 to 18 percent the amount at which pharmacists could obtain drugs." Comptroller General of the United States, Programs to Control Prescription Drug Costs Under Medicaid and Medicare Could be Strengthened, HRD-81-36, at 30 (Dec. 31, 1980), at http://archive.gao.gov/f0202/114311.pdf. In addition, the Comptroller General referenced the position of the Department of Health and Human Services (HHS), published in

the Federal Register on July 31, 1975. In particular, HHS has understood for more than thirty years that "[a]verage wholesale price is not currently determined by surveying drug marketing transactions (i.e., by determining the actual price a pharmacist pays to a manufacturer or wholesaler for a particular drug product), and thus published wholesale prices often are not closely related to the drug prices actually charged to, and paid by, providers." Id.

The Department of Health and Human Services' Office of Inspector General (OIG) repeatedly recognized that AWPs were list prices that were higher than the acquisition costs of pharmacies. OIG's reports were publicly available and widely disseminated. For example, in 1984, the OIG sent a report to every state Medicaid agency explaining again that the term "AWP" means the "non-discounted list price," and that "[p]harmacies purchase drugs at prices that are discounted significantly below the AWP or list price." Dept. of Health & Human Servs., Office of Inspector General, Office of Audit, Changes to the Medicaid Prescription Drug Program Could Save Millions, No. 06-40216, at 3 (1984). The 1984 OIG report was very specific

in its findings. The OIG found that pharmacy drug purchases were made at prices averaging almost 16% below AWP, with some at 42% below AWP. See id. at 4. In 1989, the OIG reaffirmed, "Our current review of drug purchase data shows that, on average, pharmacies buy drugs for 15.5 percent below AWP." Dept. of Health & Human Servs., Office of Inspector General, Office of Audit, Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program, No. A-06-89-00037, at 1, 6 (Oct. 3, 1989), at http://www.oig.hhs.gov/oas/reports/region6/A-06-89-00037.pdf.

OIG reports like these continued to be published throughout the 1990s and into the current decade. Consider the following examples:

> [I]n the past many States based the [Estimated Acquisition Cost (EAC)] upon the AWP, but [ ] a number of studies have shown that: "...there is a preponderance of evidence that demonstrates that such AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10-20 percent because they do not reflect discounts, premiums, special offers or incentives, etc."

Dept. of Health & Human Servs., Office of Inspector General, Medicare Payments for Nebulizer Drugs, No. OEI-03-94-00390 (Feb. 1996), at 7, available at

http://www.oig.hhs.gov/oei/reports/oei-03-94-00390.pdf (emphasis in original).

> We estimated that the invoice price for brand name drugs was a national average of 18.3 percent below AWP. . . . The estimate of the discount below AWP for brand name drugs is significantly greater than the discount allowed under current reimbursement policies in most States. . . . Based on our review, we have determined that there is a significant difference between pharmacy acquisition cost and AWP.

Dept. of Health & Human Servs., Office of Inspector General, Medicaid Pharmacy - Actual Acquisition Cost of Prescription Drug Products for Brand Name Drugs, No. A-06-96-00030, at 4-5 (Apr. 1997), available at http://www.oig.hhs.gov/oas/reports/region6/69600030.pdf.

> We estimated that nationally, the invoice price for brand name drugs was an average of 21.84 percent below AWP. The estimate combined all pharmacy categories except non-traditional pharmacies and was based on the comparison to AWP of 16,204 invoice prices received from 216 pharmacies in the 8-State sample. . . . The results of the 1994 review showed that the discount below AWP was 18.30 percent while the results of this review show that the discount below AWP had increased to 21.84 percent. This shows that the discount below AWP had increased over 19 percent since the last review.

Dept. of Health & Human Servs., Office of Inspector General, Medicaid Pharmacy - Actual Acquisition Cost of Brand Name Prescription Drug Products, No. A-06-00-00023,

at 3, 5-6 (Aug. 2001), available at http://www.oig.hhs.gov/oas/reports/region6/60000023.pdf.

> As part of our expanded analyses, we developed an estimate of the average discount below AWP for tier - one type drugs (single source innovator drugs) at which pharmacies were able to purchase these drugs. We estimated that pharmacies purchased single source innovator drugs at a discount of 17.2 percent below AWP. . . . Our previous estimate (included in report A-06-00-00023) [August 2001 report], which included innovator multiple source drugs, was 21.8 percent below AWP. . . .

Dept. of Health & Human Servs., Office of Inspector General, Medicaid Pharmacy - Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products, No. A-06-02-00041, at 5 (Sept. 2002), available at http://www.oig.hhs.gov/oas/reports/region6/60200041.pdf.

> Of the 17 States reporting reimbursement rate changes as key to cost containment, 5 have refined their estimated acquisition cost formulas to better reflect the complexity of the pharmaceutical marketplace. . . . The tiered reimbursement formulas incorporate larger discounts for generic drugs, which is consistent with previous OIG findings that AWP overstates generic drugs to a greater degree than brand name drugs. Specifically, OIG found that, on average, AWP overstated pharmacy acquisition costs for brand name drugs by 22 percent and overstated acquisition costs for generic drugs by 66 percent.

Dept. of Health & Human Servs., Office of Inspector General, State Strategies to Contain Medicaid Drug Costs,

No. OEI-05-02-00680, at 8 (Oct. 2003), available at http://www.oig.hhs.gov/oei/reports/oei-05-02-00680.pdf.

Not only was the fact that AWPs were undiscounted list prices well-known to government regulators for decades, but the use of AWPs (minus a selected percentage) by state Medicaid agencies as a benchmark for Medicaid reimbursements was approved by the federal government time after time. The Centers for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration) provided consistent oversight of pharmacy reimbursement rates, which had to be submitted as part of state plans for Medicaid. See 42 C.F.R. § 518. In approving Alabama's state plans, the federal government necessarily found that AWP-10% provided a permissible estimate of pharmacy acquisition costs that, at the same time, adequately protected access to prescription drugs for Medicaid beneficiaries as required by law. See 42 U.S.C. § 1396a (a)(30)(A).

3. WACs Have Long Been Understood and Defined in Government and Other Reports as Undiscounted List Prices to Wholesalers

Like AWP, WAC has also been commonly understood for years to be a "list" price that does not include discounts.

The overwhelming evidence of this common understanding of WAC as an undiscounted list price to wholesalers comes from government reports (including Medicaid reports) and other public sources. For example:

- A 1997 treatise defined WAC as a term "used by some publishers of pricing data to denote the ex-factory charge, before discounts, to the wholesaler." Eugene Mick Kolassa, Elements of Pharmaceutical Pricing 33 (1997).

- The GAO defined WAC in 2000 as "the actual selling price charged by the manufacturer before discounts to the wholesaler." General Accounting Office, Prescription Drugs: Drug Company Programs Help Some People Who Lack Coverage, GAO-01-137, at 7 n.8 (Nov. 2000), at http://www.gao.gov/new.items/d01137.pdf.

- A U.S. General Accounting Office ("GAO") report, issued in 2001, defined WAC as a "list price a wholesaler pays to a manufacturer [that] does not include discounts that may affect the net price." General Accounting Office, Medicare: Payments for Covered Outpatient Drugs Exceed Providers' Costs, GAO-01-1118, at 23 (Sept. 2001), at http://www.gao.gov/new.items/d011118.pdf.

- In July 2001, the OIG issued a report about the Medicaid program that defined WAC as a "suggested list price[]" that "typically [is] not what is paid" because "[b]uyers negotiate lower prices through the inclusion of discounts, rebates, and free goods" and stated that "[p]ublicly listed WAC amounts may not reflect all available discounts." Dept. of Health & Human Servs., Office of Inspector General, Cost Containment of Medicaid HIV/AIDS Drug Expenditures, OEI-05-99-00611, at 5-6, 29 (July 2001), at http://www.oig.hhs.gov/oei/reports/oei-05-99-00611.pdf.

Moreover, many manufacturers, including both GlaxoSmithKline and Novartis, that report WACs to price reporting services like First DataBank have, for years, explicitly defined WAC in their pricing letters as an undiscounted list price.

Finally, in 2003, Congress codified the long-established definition of WAC as an undiscounted list price. In particular, Congress statutorily defined WAC as "the manufacturer's list price" for a drug "not including prompt pay or other discounts, rebates or reductions in price," and expressly applied that statutory definition of WAC to the Medicaid program. See Pub. L. No. 108-173, §§ 303(c)(1), 303(i)(4), 117 Stat. 2066, 2242, 2254 (2003) (codified at 42 U.S.C. §§ 1395w-3a(c)(6)(B), 1396r-8(b)(3)(A)(iii)(II)).

C. **The State Cannot Show Reliance**

Moreover, even if, despite these numerous government reports, the State believed that AWP and WAC included discounts, the State cannot show fraud because of the absence of reliance. Given that the State did not change, and has not changed, its course of conduct in relying on reported AWPs and WACs in reimbursing pharmacies since it

filed this lawsuit in January 2005, the State could not have relied on any alleged misrepresentation or suppression as a matter of Alabama law. See Exxon Mobil Corp. v. Alabama Dep't of Conservation & Natural Res., 986 So. 2d 1093, 1116 (Ala. 2007) ("Reliance requires that the misrepresentation actually induced the injured party to change its course of action.") (emphasis in original) (quoting Restatement (Second) of Torts § 537 (1977)); Hunt Petroleum Corp. v. State, 901 So. 2d 1, 9 (Ala. 2004) ("Without reliance, there can be no fraud."). This alone should require entry of judgment for the defendants on the State's fraudulent misrepresentation and suppression claims.

D. Pervasive Government Regulation and Knowledge of Medicaid Practices Should Preclude Liability

In this case, the evidence strongly shows that the federal and state governments, including Alabama's, well understood the practices at issue, i.e. that reported AWPs and WACs reflected undiscounted list prices. Moreover, states like Alabama based their Medicaid reimbursement rates on reported AWPs and WACs, and set those rates at levels designed to balance the competing policy goals of

cost containment and reimbursement to pharmacists at a rate that would ensure their participation in the Medicaid program (and thus Medicaid beneficiaries' access to prescription drugs). Alabama did so under the supervision of federal regulators who approved Alabama's reimbursement system with knowledge of the nature of AWPs and WACs and how they compared to actual pharmacy acquisition costs. And it did so knowing that Alabama Medicaid would also receive substantial rebates directly from manufacturers that were designed to ensure that Alabama Medicaid got the benefit of the largest discounts available to commercial insurers.

Yet now, years later, the State has hired private counsel on a contingency-fee basis to try to obtain staggering additional sums from pharmaceutical manufacturers. Even worse, the State has sought punitive damages from the manufacturers and, in the case of AstraZeneca, obtained a punitive damage award through a trial wrought with error. The State is attempting here to have this Court ignore the facts and the State's own past (and continuing) conscious and well-informed decisions

about pharmaceutical reimbursements in a bald attempt to reap a windfall.

When a practice complies with government standards or is licensed or otherwise approved by a state or federal agency, a business using it should not be subject to liability. See, e.g., Richard C. Ausness, The Case for a Strong Regulatory Compliance Defense, 55 Md. L. Rev. 1210, 1253-57 (1996) ("[A] regulatory compliance defense must fully protect manufacturers from liability when their products meet applicable federal design, testing, or labeling requirements."). Indeed, courts have accorded weight to government standards and approvals, finding that compliance is conclusive of liability. As just one example in Alabama, this Court has ruled that a school bus that is not equipped with seatbelts is not defective when the legislature has not required seatbelts. Dentson v. Eddins & Lee Bus Sales, Inc., 491 So. 2d 942, 944 (Ala. 1986). With respect to product liability, the American Law Institute recognizes that courts frequently cite compliance with regulations as a factor used to justify a directed verdict for a defendant. See Restatement Third, Torts: Product Liability § 7 cmt. e (1998).

As a matter of public policy, it is simply unfair and unjust to allow fraud claims to be upheld against businesses whose practices were understood and approved, formally or informally, by federal and state regulators.

The federal government's repeated approval of the use of AWP and WAC in Medicaid reimbursement formulas, knowing that both reflected list prices, should be given strong deference in tort litigation in consideration of institutional expertise and competence in making decisions about complex, policy-laden issues. In developing regulations in the health care area, government agencies make sensitive balancing decisions to ensure that the positives do not outweigh the negatives of a given regulatory system.

For example, in the case of pharmaceutical price reporting, requiring use of lower, fully-discounted prices as the benchmarks in Alabama's Medicaid reimbursement formulas would have made it more difficult (if not impossible) for pharmacies to cover their costs when dispensing drugs to Medicaid patients. Alabama Medicaid officials, or federal Medicaid regulators who had to approve Alabama's state plan for Medicaid reimbursements,

could have stepped in to prohibit use of AWPs or WACs, or could have required a different reimbursement rate, but they chose not to do so with clear knowledge that AWPs and WACs were list prices. There were many reasons for these decisions, but the consequences of any decision that resulted in a reimbursement rate that was higher than what the state now says it should have paid cannot fairly be borne by the pharmaceutical manufacturers (who did not even receive the reimbursements).

When the tort system determines liability, it does not have resources comparable to those at the disposal of regulators when they develop policy. A court is generally limited to considering the particular issue raised by the litigants before it. It is not typically in a position to consider the wider impact of its decisions, such as the risk-benefit and risk-risk tradeoffs carefully evaluated by regulatory agencies. Moreover, the tort system's decisions are imposed retroactively on a case-by-case basis, leaving the potential for conflicting rulings from different courts, and creating confusion and unpredictability for manufacturers, service providers, and employers.

Furthermore, imposing such liability creates tension and conflict between the judiciary and the public policy goals of the legislative branch. This occurs when a government agency finds that a product is safe or a practice is acceptable, yet a court finds that the same product is dangerous or the same practice is misleading. The same can occur in service industries where, for example, regulators find that a particular practice is in the public interest, but a local court disagrees and imposes damages on a provider for that very conduct. See Victor E. Schwartz et al., "That's Unfair!" Says Who - The Government or Litigant?: Consumer Protection Claims Involving Regulated Conduct, 47 Washburn L.J. 93 (2007).

If a corporation has complied with the law and manufactures a product or provides a service that meets the government's standards, then it is difficult, as a matter of public policy, to see why it should be held liable or punished. See Safeco Inc. Co. of Am. v. Burr, 127 S. Ct. 2201, 2215 (2007) (actions based upon an objectively reasonable interpretation of a statute are neither willful nor reckless). No matter how emotional the arguments might

be, it is not sound public policy to punish a company that has complied with the legal rules.

III. THE REPREHENSIBILITY REQUIRED FOR AN AWARD OF PUNITIVE DAMAGES IS CLEARLY ABSENT WHEN THE CONDUCT AT ISSUE WAS NOT FRAUDULENT AND WAS AT LEAST TACITLY APPROVED BY THE GOVERNMENT

Although the jury in the consolidated cases involving Novartis and GlaxoSmithKline found that the manufacturers' conduct did not warrant punitive damages, the AstraZeneca jury returned a $175 million punitive damage award (remitted to $120 million by the trial court).[4] This punitive damage award, rooted in conduct that was common industry practice for decades and well known to government regulators, does not reach the level of reprehensibility necessary to satisfy due process.

It is axiomatic that punitive damages cannot be imposed in a case in which there has been no fraudulent conduct. For the reasons set forth above, that is clearly the case here, and the Court need not even consider the additional reasons to vacate the punitive damages award against AstraZeneca set forth below if it determines, as the

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[4] Accordingly, this portion of the brief is offered regarding AstraZeneca v. State of Alabama.

evidence clearly requires, that AstraZeneca did not engage in fraudulent price reporting.

A. Punitive Damages: A Historical Overview

Punitive damages are not normal civil or tort law damages. They are not awarded to compensate for harm; that purpose is accomplished by compensatory damages, which provide compensation for both economic and noneconomic losses. Punitive damages are awarded when a "defendant consciously or deliberately engaged in oppression, fraud, wantonness, or malice with regard to the plaintiff." Ala. Code 6-11-20(a). A plaintiff "is not entitled to an award of punitive damages" and a defendant "may not be punished to such an extent that he is deprived of his rights." Fuller v. Preferred Risk Life Ins. Co., 577 So. 2d 878, 885 (Ala. 1991).

The modern Anglo-American doctrine of punitive damages dates back to two English cases, Huckle v. Money, 95 Eng. Rep. 768 (C.P. 1763), and Wilkes v. Wood, 98 Eng. Rep. 489 (C.P. 1763), which first used the term "exemplary damages" and expressed that "the punitive and deterrent purposes of damages awards could be separated from their compensatory function." D. Dorsey Ellis, Jr., Fairness and Efficiency

in the Law of Punitive Damages, 56 S. Cal. Rev. 1, 14 (1982); see also James B. Sales & Kenneth B. Cole, Jr., Punitive Damages: A Relic That Has Outlived Its Origins, 37 Vand. L. Rev. 1117 (1984). It was in these cases that English courts expressed for the first time that a "jury shall have it in their power to give damages for more than the injury received . . . as punishment to the guilty, to deter from any such proceeding in the future, and as proof of the detestation of the jury to the action itself." Wilkes, 98 Eng. Rep. at 498-99 (emphasis added).

These cases were followed by others approving punitive damages awards in a narrow category of torts involving conscious and intentional harm inflicted by one person on another, such as assault and battery, false imprisonment, and trespass. See Victor E. Schwartz et al., Reining in Punitive Damages "Run Wild": Proposals for Punitive Damages Reform By Courts and Legislatures, 65 Brook. L. Rev. 1003, 1006-07 (1999). Punitive damages were allowed in these cases to supplement the criminal law system, which in eighteenth century England "punished more severely for infractions involving property damage than for invasions of personal rights." James B. Sales, The Emergence of

Punitive Damages in Product Liability Actions: A Further Assault on The Citadel, 14 St. Mary's L.J. 351, 355 (1983). They serve as "private fines levied by civil juries to punish reprehensible conduct and to deter its future occurrence." Gertz v. Robert Welch, Inc., 481 U.S. 323, 350 (1974).

The doctrine promptly crossed the Atlantic to early America. See Mitchell v. Billingsley, 17 Ala. 391, 1850 WL 249, *2 (1850) ("The law in cases attended with circumstances of aggravation, allows the jury to give exemplary damages."); Louisville & N.R. Co. v. Hine, 25 So. 857, 859 (1899) (characterizing punitive damages as a "penalty or punishment to deter or prevent the party from again committing a similar offense"). As in England, punitive damages were limited to intentional tort cases. In general, punitive damages "merited scant attention," because they "were rarely assessed and likely to be small in amount." Ellis, 56 S. Cal. L. Rev. at 2. Typically, punitive damages awards only slightly exceeded compensatory damages awards, if at all.

Beginning in the late 1960s, courts began to allow punitive damages in cases that did not involve intentional

misconduct, such as in product liability actions. See Toole v. Richardson-Merrell, Inc., 251 Cal. App.2d 689 (1967) (holding for the first time that punitive damages were recoverable in a strict product liability action); Geohagan v. General Motors Corp., 279 So. 2d 436, 437-38 (Ala. 1973) (permitting punitive damages in wrongful death action arising out of allegedly defective motor mount). The simultaneous development of strict product liability and the advent of "mass tort" litigation raised the risk that a defendant could be subjected to repeated punishment for an alleged risk in a single product line. The "perfect storm" that was created by these dramatic changes in punitive damages and liability law began to impact the frequency and size of punitive awards.

For example, until 1976, there were only three reported appellate court decisions upholding awards of punitive damages in product liability cases, and in each case the awards were relatively modest. See Gillham v. Admiral Corp., 523 F.2d 102 (6th Cir. 1975), cert. denied, 424 U.S. 913 (1976) ($125,000 compensatory, $100,000 punitive); Toole, supra ($175,000 compensatory, $250,000 punitive); Moore v. Jewel Tea Co., 253 N.E.2d 636 (Ill. App. 1969)

($920,000 compensatory, $10,000 punitive), aff'd, 263 N.E.2d 103 (Ill. 1970).

Then, in the late 1970s and 1980s, the size of punitive damages awards "increased dramatically," George L. Priest, Punitive Damages and Enterprise Liability, 56 S. Cal. L. Rev. 123, 123 (1982), and "unprecedented numbers of punitive awards in product liability and other mass tort situations began to surface." John Calvin Jeffries, Jr., A Comment on The Constitutionality of Punitive Damages, 72 Va. L. Rev. 139, 142 (1986); E. Donald Elliott, Why Punitive Damages Don't Deter Corporate Misconduct Efficiently, 40 Ala. L. Rev. 1053, 1061 (1989) (noting a "general trend toward awarding punitive damages more frequently and in larger amounts in recent years."). One commentator observed, "Today, hardly a month goes by without a multi-million dollar punitive damages verdict in a product liability case." Malcolm Wheeler, A Proposal for Further Common Law Development of the Use of Punitive Damages in Modern Products Liability Litigation, 40 Ala. L. Rev. 919 (1989). By 1991, the United States Supreme Court expressed concern that punitive damages had "run wild." Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 18

(1991); see also TXO Prod. Corp. v. Alliance Res. Corp., 509 U.S. 443, 500 (1993) (O'Connor, J., dissenting) ("Recently, . . . the frequency and size of such awards have been skyrocketing" and "it appears that the upward trajectory continues unabated."). Between 1996 and 2001, the annual number of punitive damages awards exceeding $100 million doubled. See John Y. Gotanda, Punitive Damages: A Comparative Analysis, 42 Colum. J. Transn'l L. 391, 392 (2004).

B. Alabama's Reforms are Rooted in the Quasi-Criminal Nature of Punitive Damages

Over the past twenty-five years, many states, including Alabama, have responded by enacting various punitive damages reform laws. See Victor E. Schwartz et al., Reining in Punitive Damages "Run Wild": Proposals for Reform by Courts and Legislatures, 65 Brook. L. Rev. 1003 (2000).[5] These reforms are rooted in the origin of punitive damages as a quasi-criminal penalty and the principles of fairness understood in that context.

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[5] Louisiana, Massachusetts, Michigan, Nebraska, New Hampshire, and Washington do not recognize punitive damages.

For example, most states, either by court decision or legislation, have chosen to require plaintiffs to establish proof of punitive damages liability by "clear and convincing evidence." See id. at 1015. This middle-ground standard falls between the ordinary civil law "preponderance of the evidence" standard and the criminal law standard of "beyond a reasonable doubt." Alabama legislation enacted in 1987 requires "clear and convincing evidence that the defendant consciously or deliberately engaged in oppression, fraud, wantonness, or malice with regard to the plaintiff" to support a punitive damage claim. See Ala. Code § 6-11-20(a), (b)(4); see also Berry v. Fife, 590 So. 2d 884 (Ala. 1991) (closely defining "conscious" and "deliberate").

The Alabama Legislature was meticulous in defining the narrow circumstances in which a punitive damage award is appropriate in order to ensure such awards focused on the most reprehensible conduct. For instance, Alabama's punitive damages statute defines fraud as "[a]n intentional misrepresentation, deceit, or concealment of a material fact the concealing party had a duty to disclose, which was gross, oppressive, or malicious and committed with the

intention on the part of the defendant of thereby depriving a person or entity of property or legal rights or otherwise causing injury." Id. at § 6-11-20(b)(1). Malice is tightly circumscribed as "[t]he intentional doing of a wrongful act without just cause or excuse, either: a. With an intent to injure the person or property of another person or entity, or b. Under such circumstances that the law will imply an evil intent." Id. at § 6-11-20(b)(2). Wantonness is "[c]onduct which is carried on with a reckless or conscious disregard of the rights or safety of others." Id. at § 6-11-20(b)(3). Oppression is that which subjects a person "to cruel and unjust hardship in conscious disregard of that person's rights." Id. at § 6-11-20(b)(5).

States have also addressed the problem of runaway punitive damages by limiting the amount that can be imposed. This method reflects the importance of proportionality in consideration of the validity of criminal punishment. See Solem v. Helm, 463 U.S. 277, 284 (1983) ("The principle that a punishment should be proportionate to the crime is deeply rooted and frequently repeated in common-law jurisprudence."); Weems v. United

States, 217 U.S. 349, 366-67 (1910) (it is "a precept of the fundamental law" as well as "a precept of justice that punishment should be graduated and proportioned to the offense"). In an effort to provide proportionality, control the spiraling size of punitive damages, and eliminate outlier awards, the Alabama Legislature enacted statutory limits on the size of awards in 1987 and rewrote the statute in 1999. See Ala. Code § 6-11-21.

C. The U.S. Supreme Court and This Court Consider Reprehensibility The Most Significant Factor in Determining the Constitutionality of a Punitive Damage Award

Against this backdrop, the United States Supreme Court and this Court also began to impose increasingly strict limits on punitive damages. These legal controls include procedural due process requirements to guard against arbitrary awards and provide for meaningful judicial review, substantive due process restrictions on the amount of punitive awards, and Commerce Clause limitations on a state court's ability to consider activity outside its jurisdiction as a basis for punitive awards. Philip Morris USA v. Williams, 127 S. Ct. 1057 (2008); State Farm Mut. Auto. Ins. Co. v. Campbell, 538 U.S. 408, 416 (2003);

Cooper Indus., Inc. v. Leatherman Tool Group, Inc., 532 U.S. 424, 433 (2002); BMW of N. Am., Inc. v. Gore, 517 U.S. 560, 562 (1995); Honda Motor Co., Ltd. v. Oberg, 512 U.S. 415, 430 (1994); TXO Prod. Corp. v. Alliance Res. Corp., 509 U.S. 443, 456 (1993); Pacific Mut. Life Ins. Co. v. Haslip, 499 U.S. 1, 31 (1991).

1. Low Reprehensibility Cannot Support a Substantial Punitive Damage Award

In 1996, in a case arriving from this Court, the U.S. Supreme Court provided guidance as to determining whether a punitive damage award falls outside the limits of due process. In Gore, 517 U.S. 559 (1996), an Alabama jury returned $4,000 in compensatory damages, along with a $4 million punitive damage verdict, an amount reduced to $2 million by this Court. See id. at 567. The plaintiff, who purchased a new BMW sedan, claimed the car dealership acted fraudulently in failing to disclose that it had repainted his vehicle to repair minor pre-delivery damage. See id. Ultimately, the U.S. Supreme Court decided that the $2 million award still amounted to punishment exceeding Alabama's legitimate interests in protecting the rights of its citizens because of the low level of reprehensibility involved.

The U.S. Supreme Court emphasized in Gore that the "most important indicium of the reasonableness of a punitive damages award is the degree of reprehensibility of the defendant's conduct." Id. at 575. In finding the requisite reprehensibility absent to sustain the $2 million punitive damage award, the Court made a number of specific findings that are equally applicable to the case at bar.

First, it found no aggravating factors supporting a large punitive damage award. There, as here, the alleged harm was purely economic, and did not show indifference to or reckless disregard for the health and safety of others. See id. at 576.

Second, the Court considered evidence that the defendant's nondisclosure policy was explicitly permitted by the laws of roughly twenty-five states. See id. at 565. Conduct is not sufficiently reprehensible to sustain a large punitive damage award when "reasonable people may disagree about the value of a full disclosure requirement." Id. at 570. In this case, given the government's recognition for decades of the use of AWP as an undiscounted list price, and the State's knowledge of such use, it was perfectly reasonable for AstraZeneca (or any

other manufacturer) to believe that reporting AWPs that were list prices was not fraudulent.

Third, the U.S. Supreme Court found it significant that there was no evidence that the appellants acted in bad faith or persisted in a course of conduct once they were on notice of its illegality. See id. at 579. There, as here, the BMW-appellants' pre-lawsuit conduct had not been "adjudged unlawful on even one occasion, let alone on repeated occasions." Id.

Finally, the record in Gore disclosed "no deliberate false statements, acts of affirmative misconduct, or concealment of evidence of improper motive." Id. at 579. The Court recognized that "the omission of a material fact may be less reprehensible than a deliberate false statement, particularly when there is a good-faith basis for believing that no duty to disclose exists." Id. at 580. Here, AstraZeneca made no affirmative statements to the State whatsoever that suggested that AWP or WAC was a discounted price, and any lack of disclosure was due to a legitimate belief (based on public documents, including Medicaid reports) that there was widespread understanding of AWP as a list price. "[T]he absence of all [these

factors] renders any award suspect." Campbell, 538 U.S. at 419.

In Campbell, the U.S. Supreme Court struck down a $145 million punitive damage award stemming from the defendant's refusal to settle a case, where the plaintiff had received $1 million in compensatory damages. 538 U.S. at 418. The Court held that, even where compensatory damages are justified (which is not true here), punitive damages should only be awarded on top of them "if the defendant's culpability is so reprehensible as to warrant the imposition of further sanctions to achieve punishment or deterrence." Id. at 419 (citing Gore, 517 U.S. at 575).

2. This Court has Reserved Punitive Damages to Cases in Which There is a High Degree of Reprehensibility

Alabama law, similarly, provides seven factors to determine the excessiveness of a punitive damage award, including: (1) the reprehensibility of the defendant's conduct; (2) the defendant's financial position; (3) the plaintiff's litigation costs; (4) whether the defendant has been subject to criminal sanctions for similar conduct; and (5) other civil actions against the defendant arising out of similar conduct. See Shiv-Ram, Inc. v. McCaleb, 892 So.

2d 299, 317 (Ala. 2003) (applying Green Oil Co. v. Hornsby, 539 So. 2d 218, 223-24 (Ala. 1989) and Hammond v. City of Gadsden, 493 So. 2d 1374 (Ala. 1986)). Like the U.S. Supreme Court's constitutional inquiry, reprehensibility of the defendant's conduct is one of Alabama's most important indicium in determining the excessiveness of a punitive damages awards. See Ford Motor Co. v. Sperau, 708 So. 2d 111, 116 (Ala. 1997) (stating that the reprehensibility factor under state common law should be afforded greater weight).

As this Court explained in Employees Benefit Ass'n v. Grissett, 732 So. 2d 968, 980 (Ala. 1998), "assessment of the degree of the reprehensibility of the defendant's conduct is broader in a Hammond/Green Oil review than our assessment in a [Gore] review." Under this review, the reprehensibility of the defendant's conduct is determined by considering "'[t]he duration of this conduct, the degree of the defendant's awareness of any hazard which his conduct has caused or is likely to cause, and any concealment or 'cover-up' of that hazard, and the existence and frequency of similar past conduct.'" Green Oil, 539 So.

2d at 223 (quoting Aetna Life Ins. Co. v. Lavoie, 505 So. 2d 1050, 1062 (Ala. 1987) (Houston, J., concurring).

This Court has typically reserved punitive damages for cases where a high level of reprehensibility is a clearly established. This is not, for example, the case of an insurance agent who took advantage of an elderly woman by selling her a worthless insurance policy. See Life Ins. Co. of Ga. v. Johnson, 701 So.2d 524 (Ala. 1997). Rather, in the present case, the State, an sophisticated entity with significant resources at its disposal, had full knowledge of the price practices at issue at its fingertips.

As discussed above, AstraZeneca's conduct was not even fraudulent - let alone did it exhibit such signs of reprehensibility. AstraZeneca merely followed a longstanding industry reporting practice that was well-understood by Medicaid regulators, and made no attempt to cover up or conceal the reporting or content of its AWPs. The long duration and frequency of reporting prices in an industry-standard way -- even if (as is not the case here) there was something improper about the methodology used -- simply does not constitute behavior that can be punished by

imposition of a punitive damages award. This Court should reaffirm Alabama law's limitation on punitive damage to highly reprehensible conduct, and find that punitive damages are not available where, as here, the conduct at issue was closely regulated and fully understood by the government.

CONCLUSION

For these reasons, *amici* urge this Court to reverse the trial court below and render judgment in Appellants' favor because the Appellants' conduct does not constitute fraud as a matter of law. In any event, the Court should find that the $120 million punitive damages verdict against Appellant AstraZeneca is unwarranted and unconstitutional.

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