2009 WL 1867148 (Ala.) (Appellate Brief)
Supreme Court of Alabama.

ASTRAZENECA PHARMACEUTICALS LP and Astrazeneca LP, Appellants,
v.
STATE OF ALABAMA, Appellee.

Nos. 1071439, 1071440.
March 9, 2009.

On Appeal from the Circuit Court of Montgomery County, Alabama, CV-05-219.10 & .11

Brief of Appellee, State of Alabama

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ORAL ARGUMENT REQUESTED

*I *STATEMENT REGARDING ORAL ARGUMENT*

The State of Alabama (“State”) requests oral argument, as has AstraZeneca.

This case is vitally important to the State and the rest of the nation. AstraZeneca committed fraud against the State, and an appropriate judgment was justly entered. Seeking to undo that result, AstraZeneca asserts a laundry list of alleged errors, novel legal arguments and positions inapplicable to the facts. It has filed a lengthy appellants' brief, which required the State to file a lengthy brief of its own. However, it is crucial to maintain focus on the dispositive issues - (i) the evidence concerning AstraZeneca's conduct and the damage it caused, (ii) the disputed nature of the facts, and (iii) the appropriate standards of review.

This case is a straightforward fraud and suppression case which, in its essence, is not complex. The record, however, is long, and AstraZeneca's arguments are numerous. Oral argument will assist the Court in its analysis and to focus on the important issues. It will also provide the parties the opportunity to respond to any questions the Court may have, whether covered by the briefs or not.

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***ix** *STATEMENT OF JURISDICTION*

The State agrees with AstraZeneca's statement of jurisdiction.

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*XIX *QUICK REFERENCE TO TERMS USED IN BRIEF*

Many different acronyms have been used throughout this case, which are also used in this brief. Although the terms are defined in the body of the brief, the following quick reference is provided for the Court's convenience:

"AMA"	-	Alabama Medicaid Agency
"AMP"	-	Average Manufacturer Price
"AWP"	-	Average Wholesale Price
"CMS"	-	Centers for Medicare and Medicaid Services
"EAC"	-	Estimated Acquisition Cost
"HCFA"	-	Health Care Financing Administration
"HHS"	-	Department of Health and Human Services
"OBRA '90"	-	Omnibus Budget Reconciliation Act of 1990
"OIG"	-	Office of Inspector General
"WAC"	-	Wholesale Acquisition Cost (also WHN, or Wholesale Net)

In addition, the following record references are used:

C.	-	Clerk's Record on Appeal
R.	-	Reporter's Transcript
S.	-	Supplemental Clerk's Record on Appeal
PX	-	Plaintiff's Exhibit

DX - Defendants' Exhibit

1** ***STATEMENT OF THE CASE

I. NATURE OF THE CASE

This case concerns long-term deliberate pricing fraud perpetrated by Appellants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (collectively "AstraZeneca") [1] upon the State of Alabama Medicaid Agency ("AMA"). AstraZeneca reported false and inflated drug prices, which it knew would be used by AMA to reimburse pharmacists for AstraZeneca drugs dispensed to AMA beneficiaries. AstraZeneca's fraudulent price reporting caused AMA to overpay for prescription drugs by millions of dollars.

II. COURSE OF PROCEEDINGS AND DISPOSITION BELOW

The State filed this case against AstraZeneca and other pharmaceutical companies on January 26, 2005, alleging fraudulent misrepresentation, suppression, and other causes of action. Supplemental Clerk's Record ("S.") 55-99; *see also* S.390-460 (Second Amended Complaint). After a severance, the State proceeded to trial against AstraZeneca on February 11, 2008. At the end of the two-week trial, the jury returned a verdict in favor of the State, finding ***2** AstraZeneca liable for misrepresentation and suppression and awarding compensatory damages of $40 million and punitive damages of $175 million. The trial court entered judgment on the verdict.

AstraZeneca filed post-judgment motions seeking judgment as a matter of law, a new trial, and a vacatur or remittitur of the punitive damages award. S.7442-7501. The trial court partially granted AstraZeneca's motion for remittitur, reducing the punitive damages award to three times the compensatory award, or $120 million, in accordance with Alabama's statutory cap. Ala. Code § 6-11-21(a). S.8016-23. The court denied all other requested post-judgment relief. S.8016-23. AstraZeneca filed its notice of appeal on July 22, 2008. Clerk's Record ("C") 1155-68.

STATEMENT OF THE ISSUES

1. Whether the trial court correctly concluded, based on the evidence viewed in the light most favorable to the State, that the State presented substantial evidence supporting its claims of fraudulent misrepresentation, suppression, and resulting damages against AstraZeneca, warranting submission of those claims to the jury.

***3** 2. Whether the trial court, based upon the evidence viewed in the light most favorable to the State, could reasonably have concluded that the jury could properly assess punitive damages against AstraZeneca.

3. Whether the punitive damages award, after reduction by the trial court to three times the compensatory damages award, exceeds permissible law limits.

4. Whether the trial court correctly refused to overturn the longstanding common law doctrine - *nullum tempus occurrit reipublicae* - which shields the State from application of the statute of limitations in this case.

5. Whether the trial court correctly concluded that the State's common law fraud claims were not preempted by federal law.

6. Whether the trial court abused its discretion by refusing to grant a new trial regarding the following evidentiary issues:

a. Admission of pattern and practice and party admission evidence;

b. Refusal to require the State to disclose communications protected by the attorney-client privilege and work product doctrine;

***4** c. Exclusion of irrelevant, speculative, and cumulative evidence concerning profits and losses of individual pharmacies; and

d. Exclusion of irrelevant, speculative, and hearsay evidence from pharmacy lobbyists.

7. Whether, considering the entirety of the charge to the jury, the trial court committed reversible error by refusing to grant a new trial on AstraZeneca's requested reasonable reliance jury instruction and its objection to the court's charge that federal funding does not offset damages.

8. Whether the trial court abused its discretion by refusing to strike for cause venire members employed by the State of Alabama.

STATEMENT OF FACTS

I. THE MEDICAID SYSTEM

Medicaid is a program jointly financed by the state and federal governments that provides health care to low income individuals. DX 339 (R.1412), at p. 7; *see* R.1727. Unlike Medicare, Medicaid is a state-administered program. DX 339 (R.1412), at p. 7. The State pays all the bills and pursues all of the recoveries. R.1727-29.

***5** II. ALABAMA'S MEDICAID PROGRAM

Medicaid started in Alabama in 1970. DX 339 (R.1412), at p. 7. Today, the AMA manages healthcare services for nearly one million Alabamians. R.1299. AMA serves Alabama's children, pregnant women, elderly and disabled citizens, who qualify on an income-level basis. R.1299-1300. Pharmacy services comprise 15% of AMA's annual budget and are only one of the many services provided to AMA beneficiaries. R.1300-03.

AMA is a financially strapped agency, and works hard to manage costs. R.1301, 1327-29. AMA compares very well in management to other state Medicaid agencies and has one of the most aggressive pharmacy management programs in the nation. R.1306-08. AMA would not knowingly overpay for prescription drugs. R.1295-96, 1308.

In the 1970s and 1980s, AMA's pharmacy program was extremely small and controlled, both in the number of drugs covered and in spending. *See* R.1304, 1476-77. AMA had a limited formulary, covering only a handful of drugs it selected. R.1304, 1476-77.

AMA's pharmacy program changed dramatically in 1991 as a result of Medicaid-related legislation passed by Congress ***6** in the Omnibus Budget Reconciliation Act of 1990 (“OBRA '90”). R.1303-04, 1477. Unlike private health plans, which may cover only certain drugs, AMA is required under OBRA '90 to reimburse pharmacies for any drugs distributed to Medicaid beneficiaries so long as the drugs' manufacturer has signed a federal rebate agreement with the Centers for Medicare and Medicaid Services (“CMS”). R.1304, 1310. AMA cannot exclude a drug manufacturer from its pharmacy program, regardless of the manufacturer's conduct, if the manufacturer has a signed agreement with CMS. R.1304.

Today, AMA reimburses pharmacies for over 60,000 drug products, in contrast to the handful of drugs it covered prior to OBRA '90. R.1304. From 1991 through 2004, AMA paid over $3 billion for prescription drugs to pharmacies. R.1303, 1572. In 1991, AMA paid $51 million; in 2004, AMA paid $531 million. R.1303, 1572. For AstraZeneca drugs alone, AMA paid over $174.7 million from 1991 through 2004. R.1572-73, 1072. In 1991, AMA paid $1.3 million for AstraZeneca drugs; in 2004, AMA paid over $24 million for AstraZeneca drugs, an increase of 18 times. R.1572-73.

***7 III. ALABAMA MEDICAID'S PHARMACY REIMBURSEMENT METHODOLOGY**

AMA's prescription drug program is subject to certain federal regulations. R.1310. For brand name drugs (the only drugs at issue for AstraZeneca), AMA must pay pharmacies the lower of (1) the Estimated Acquisition Cost ("EAC") plus a reasonable dispensing fee; or (2) the provider's usual and customary charge to the general public for the drug.[2] 42 C.F.R. § 447.512 (formerly 42 C.F.R. § 447.331); PX 1348 (R.1311); R.1311; *see also* DX 993 (R.1388), at page 3, ¶ 4(c). EAC means *the agency's best estimate of the price generally and currently paid by providers for a drug* marketed and sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.502 (formerly 42 C.F.R. § 447.301) (emphasis added); PX 1347 (R.1314); R.1312.

To determine EAC, AMA used a two-pronged formula: wholesale acquisition cost ("WAC") + 9.2% or average ***8** wholesale price ("AWP") - 10%.[3] R.1319-20. AMA's reimbursement formula has been accepted and approved by the federal government every year since 1991 and is posted on CMS's website for public view.[4] R.1320-21, 1491; PX 936 (R.1321).

AMA contracted with First DataBank to provide AMA with electronic pricing data for all covered drugs on a biweekly basis. R.1172-73; *see, e.g.*, PX 1121 (R.1520). First DataBank is a nationally recognized compendium service that provides price information to 49 State Medicaid agencies and numerous other customers, including many drug manufacturers.[5] R.1173-74, 1501-03; PX 1120 (R.1520), at ALMED-820998-821004. AMA relied on the truth and completeness of the WAC and AWP prices published by First DataBank to reimburse pharmacies. R.1323.

***9 IV. ASTRAZENECA VOLUNTARILY PARTICIPATED IN ALABAMA'S MEDICAID PROGRAM AND ACCEPTED AMA'S FORMULA.**

Medicaid is a significant and profitable segment of AstraZeneca's business, representing 17.3% of AstraZeneca's gross sales (which totaled $1.9 billion in 2000) and 14.7% of its gross margin ($818 million in 2000).[6] R.770-72; PX 937 (R.850), at AZ0454876. AstraZeneca voluntarily participated in the Medicaid program so that its drugs would be dispensed to Medicaid patients; in turn, AstraZeneca realized greater revenues and profits.[7] R.772-73.

As a Medicaid participant, **AstraZeneca** admitted it had a duty to be familiar with federal and state laws, rules, and regulations governing Medicaid. R.773-74. **AstraZeneca** knew AMA used WAC and AWP in its reimbursement formula to estimate acquisition cost. R.838-39, 1003, 1059. **AstraZeneca** admitted it owed AMA a duty to be honest and truthful. R.774. By electing to participate in the Alabama Medicaid program, **AstraZeneca** accepted AMA's ***10** reimbursement formula. R.772-73, 1321; *see also* PX 939 (R.1135) (National Pharmaceutical Council, of which **AstraZeneca** is a member, listing the AMA formula as "AWP - 10%, WAC + 9.2%").

V. ASTRAZENECA REPORTED PRICES TO FIRST DATABANK INTENDING FOR AMA TO USE THOSE PRICES TO REIMBURSE PHARMACIES.

Recognizing that current drug prices are needed and used by state Medicaid agencies, **AstraZeneca** voluntarily reported prices for its drugs to First DataBank for publication. R.774-78, 785-86, 791-92 (**AstraZeneca** intended for First DataBank to publish its prices); *see* PX 947 (R.850); PX 37 (R.1220). Prior to 2002, **AstraZeneca** reported AWPs and WACs to First DataBank. R.776-78. From 2002 forward, upon advice of legal counsel, **AstraZeneca** reported only WAC prices to First DataBank.

R.776-78; *see also* R.1536-37 (an OIG investigation of **AstraZeneca** raised its concern about providing AWP). Even then, **AstraZeneca** knew that AWP was used as one of the bases for third-party reimbursement and that First DataBank would continue publishing AWP for **AstraZeneca** drugs by applying either a 20% or 25% markup to the WAC prices reported by **AstraZeneca**. R.778-79, 792-93, 1067-68; PX 947 (R.850). (That is, even from 2002 on, the AWP published for ***11** **AstraZeneca's** drugs was directly dependent on **AstraZeneca's** reported WAC.) *See* R.792-93.

AstraZeneca knew that reported WACs and AWPs (whether directly or indirectly furnished by **AstraZeneca**) would be used and relied on by state Medicaid programs to estimate acquisition cost in reimbursing pharmacies. R.793, 966-67, 969-70, 1002. **AstraZeneca** admitted that it was responsible for the integrity of data, including WAC and AWP, it generated for government reimbursement purposes. R.979-80.

VI. DEFINITION OF AVERAGE WHOLESALE PRICE ("AWP")

First DataBank's published documents defined AWP as the "average price which a wholesaler would charge a pharmacy for a particular product," a price which is based in market reality. PX 941 (R.850); PX 942 (R.850); R.779-81, 1506-07. **AstraZeneca** itself defined AWP as "[t]he composite wholesale price charged on a specific commodity that is assigned by the drug manufacturer and is listed in either the *Red Book* or *Blue Book*.[8] AWP is often used by third party payers as a basis for reimbursement," again reflecting a price anchored in market reality. PX 944 (R.850), at p. 18; R.781-83. The National Pharmaceutical ***12** Council's definition of AWP was exactly the same as **AstraZeneca's**, which **AstraZeneca's** corporate representative agreed reflected market reality and the prices wholesalers charged their customers. PX 946 (R.850), at 30; R.783-85.

These definitions were consistent with AMA's understanding of AWP, which (taken for its plain meaning) was a true average of wholesale prices paid by pharmacy retailers to wholesalers for a particular drug. R.1167-68; (State's expert testifying that AWP is an average of actual prices paid); R.1322 (AMA Commissioner testifying that AWP is "the price that the pharmacist pays the wholesaler."). However, contrary to the definition of AWP and AMA's expectation, **AstraZeneca**, by its own admission, did not report a true average price that pharmacists pay for drugs. R.1167-68, 1219; *see* R.814-15.

VII. DEFINITION OF WHOLESALE ACQUISITION COST ("WAC")

WAC is the net price wholesalers pay to purchase drugs from manufacturers, after rebates, chargebacks, and discounts. R.1168-70 (State's expert testifying that WAC is "the price that the wholesaler actually buys the drug for," including any discounts); R.1322, 1461-62 (AMA Commissioner testifying WAC is "the actual price paid by ***13** the wholesaler" to the drug manufacturer); *see also* PX 40 (R.1189)(**AstraZeneca** 2002 memo stating "WAC or Wholesale Acquisition Cost reflects the price wholesalers pay to the manufacturer.").

Contrary to **AstraZeneca's** post-litigation contention, WAC is not a list price, but a price actually paid by wholesalers to manufacturers, including all discounts, chargebacks,' rebates, and other price concessions. R.1168-70, 1215-16; *see also* PX 1482 (R.1551) (First DataBank reporting WAC as "WHN" or wholesale *net*); PX 1520 (R.1212), at 4 (1993 report to HCFA[9] defining WAC as "[t]he wholesaler's net payment made to purchase a drug product from the manufacturer, net of purchasing allowances and discounts.").

AstraZeneca's reported WAC, however, was not a true price because it did not include rebates, discounts, and chargebacks and did not reflect the actual price wholesalers paid **AstraZeneca** for its drugs. R.1168-70, 1219-20.

***14 VIII. OIG COMPLIANCE GUIDANCE TO PHARMACEUTICAL MANUFACTURERS**

In 2003, the Office of Inspector General ("OIG") for the Department of Health and Human Services ("HHS") published a Compliance Program Guidance for Pharmaceutical Manufacturers. PX 973 (R.850). **AstraZeneca's** corporate compliance department received and reviewed the guidance in detail. R.949. **AstraZeneca** knew about this notice because there had been fraud and abuse in the health care system, particularly among drug manufacturers. R.950. The OIG guidance did not create any new law, but merely stated existing law. R.961-62.

In the guidance directed to pharmaceutical manufacturers, OIG identified as a specific risk area the integrity of data used to establish or determine government reimbursement. PX 973 (R.850). The report stated as follows:

Many federal and state health care programs establish or ultimately determine reimbursement rates for pharmaceuticals, either prospectively or retrospectively, using price and sales data directly or indirectly furnished by pharmaceutical manufacturers. *The government sets reimbursement with the expectation that the data provided are complete and accurate. The knowing submission of false, fraudulent, or misleading information is actionable*. . . . Manufacturers may also be liable ***15** for civil money penalties under various laws, rules and regulations. . . .

Id. at 23733-34 (emphasis added). These guidelines were consistent with both AMA's expectation and **AstraZeneca's** admitted duty to provide honest and truthful prices. R.773-74, 1309-10.

Under the heading "Integrity of Data Used to Establish or Determine Government Reimbursement," the guidance directs manufacturers to report net prices, stating as follows:

Where appropriate, manufacturers' reported prices should accurately take into account price reductions, cash discounts, free goods contingent on a purchase agreement, rebates, up-front payments, coupons, goods in kind, free or reduced-price services, grants, or other price concessions or similar benefits offered to some or all purchasers.

PX 973 (R.850), at 23733-34 (emphasis added). This provision required WACs and AWPs to be real, net prices. R.1208-09.

AstraZeneca agreed that this provision was consistent with its obligation to report accurate prices, but conceded that the WAC and AWP prices it reported did not include ***16** discounts and did not reflect prices actually paid. [10] R.826-27, 832-34, 838, 840; *see also* R.1210. **AstraZeneca** did not tell AMA about the discounts off of WAC it provided to wholesalers, which were substantial. R.1065-66, 1185.

IX. AMA RELIED ON ASTRAZENECA'S REPORTED PRICES TO REIMBURSE PHARMACIES.

AMA relied on the truth and completeness of the WAC and AWP prices for **AstraZeneca** drugs reported through First DataBank to reimburse pharmacy providers. R.1309, 1323, 1556-57. In order for First DataBank to provide AMA with accurate drug pricing, it first had to receive accurate price reports from manufacturers. R.1504-05. **AstraZeneca** knew what its published prices were and approved them. *See* R.791-92, 1509.

AstraZeneca never told AMA that its published WAC prices were greater than the net prices paid by ***17** wholesalers. R.839-40, 1065-66. **AstraZeneca** never told AMA that its published AWP prices were greater than the true marketplace prices paid to wholesalers for its drugs. R.840. **AstraZeneca's** drug prices were not transparent, and it would be very difficult for anyone to determine the prices actually charged or paid. R.1159-60.

AMA could not access **AstraZeneca's** true transactional prices; AMA had no contract with **AstraZeneca**, and it had no authority to audit **AstraZeneca's** books. R.1163-64, 1308-09. AMA had no ability to negotiate prices with **AstraZeneca**, and **AstraZeneca** established and reported its prices without input from AMA. R.1203-04.

X. THE SPREAD

The "spread" is the difference between the amount that a provider receives as reimbursement from Medicaid and the amount the provider paid for the drug. R.1039-40; PX 973 (R.850), at 23736. When a pharmacy is reimbursed for the drug cost at an amount higher than what it paid for the drug, the pharmacy profits. *See* R.1036-40. The higher the spread, the higher the provider's profit.

Under the Medicaid system, however, reimbursement of drug cost is not designed for pharmacy profit, as evidenced ***18** by the regulation that state Medicaid agencies pay EAC. PX 1348 (R.1311). Any "profit" is covered by the dispensing fee component, which is paid in addition to the drug cost reimbursement (or EAC). [11] R.1269-71. Pharmacies voluntarily participate in Medicaid, knowing and accepting the federal regulations and AMA's reimbursement formula; no pharmacy is forced to participate. R.1779.

Because pharmaceutical manufacturers control not only the prices at which they sell a product to their customers, but also the amount those customers are reimbursed for drug cost under the Medicaid program (as a result of the manufacturer's reported prices), manufacturers control the "spread." *See* PX 973 (R.850), at 23736. Manipulation of the spread is illegal, as **AstraZeneca** was forced to admit at trial. *Id*. at 23737; R.837-38, 957-59. Any spread between reported prices and true prices results in AMA considerably overpaying pharmacies. R.1164-65.

XI. ASTRAZENECA'S HISTORY OF ILLEGALLY MARKETING THE SPREAD

AstraZeneca knowingly disregarded the law and engaged in a pattern and practice of pricing misconduct. ***19** **AstraZeneca** actively promoted the spread, knowing government payers would not "catch on" to the practice for years. *See* R.805-07.

AstraZeneca's pricing misconduct has been the subject of several investigations and a criminal conviction. **AstraZeneca** has been subpoenaed by various congressional committees and investigated by the OIG concerning its sales, marketing, and pricing practices related to AWP. R.763-64. In June 2003, **AstraZeneca** pled guilty to violating federal law in connection with its sales and marketing practices for the drug Zoladex. R.765-66; *see* PX 940 (R.850), at 15-16 (federal district court accepting guilty plea of **AstraZeneca** and describing conviction of "a serious crime"). As part of the guilty plea, **AstraZeneca** was fined $64 million and placed on probation. PX 940 (R.850), at 18-20. **AstraZeneca's** focus on marketing the spread was not limited to Zoladex, but was part of its corporate philosophy. R.1192; *see also* PX 966 (R.850).

In early 2002, **AstraZeneca** learned that First DataBank was increasing the markup between reported WAC and AWP from 20% to 25% for some of **AstraZeneca's** products. R.796-97; PX 40 (R.1189). **AstraZeneca** did not object to the ***20** increase, even though **AstraZeneca** knew that wholesaler markups to retailers averaged only 2-3%. R.802, 1538-39; *see also* R.815-16 (**AstraZeneca's** corporate designee testified that going back to 1993, the wholesaler markup has never been as large as 20%). **AstraZeneca** prepared a secret "white paper" analyzing the impact of the change and acknowledged that "a higher spread translates into higher reimbursement to retailers." R.797-98; PX 961 (R.850), at AZ0565612; PX 962 (R.850), at AZ0461109; *see also* PX 949 (R.850), at AZ0463136 ("By increasing the AWP spread that Astra currently assigns to its products, retail pharmacies will enjoy increased pharmacy margins.").

Increasing markup by 5% means that Medicaid programs pay 5% more for a drug. R.798; PX 961 (R.850), at AZ0565612. **AstraZeneca** knew the 5% increase would significantly disadvantage the state Medicaid programs, but made no effort to notify state Medicaid programs, including AMA, of the change. R.799-800, 810-12; PX 963 (R.850), at AZ0447849 ("Larger spreads such as 25% are pharmacy friendly while . . . government . . . unfriendly."). Instead, **AstraZeneca** sat back and expected government payers to "catch on" to the markup within a couple of years ***21** and then ratchet down reimbursement levels. R.805-07; PX 963 (R.850), at AZ0447849. **AstraZeneca** expected state Medicaid programs to pay the additional 5% for its

drugs over the first couple of years, which would result in Medicaid paying an additional $95 million over one year, or $190 million over two years. R.807-11.

Even before 2002, **AstraZeneca** reported AWPs for some of its drugs at a 25% markup above WAC. **AstraZeneca** devised the 25% wholesaler markup "to leverage the book of retail pharmacy contracts." PX 966 (R.850), at AZ0447822. **AstraZeneca** knew that by increasing the markup between AWP and WAC, "pharmacies could make more profit per transaction at no additional cost to the company." *Id.* "This was an attractive benefit that [**AstraZeneca's**] Customer Account Teams could sell to retail chains when discussing the overall benefits of [their] contract offer" and could be used "to drive market share." *Id.;* R.816-19.

High level **AstraZeneca** employees encouraged marketing the spread. R.954-56. **AstraZeneca** routinely measured profit to retailers based on its reported prices, even breaking down profit by payer segment, specifically cash ***22** payers, *Medicaid*, and other third party payers. PX 967 (R.850), at AZ0454790.

AstraZeneca also marketed the spread by encouraging brand conversion, i.e., a pharmacy converting a patient's prescription to an **AstraZeneca** drug, resulting in a greater profit for the pharmacy. **AstraZeneca** recognized this opportunity for larger market share and encouraged brand conversion by pharmacies by promoting a higher spread. R.822-23, 1045-48; PX 970 (R.850), at p. 39; PX 971 (R.850), at AZ0451158, AZ0451179-80. [12]

XII. THE STATE WAS DAMAGED AS A RESULT OF ASTRAZENECA'S CONDUCT.

Through detailed data analysis, the State's damages expert, Ed Sauls, concluded that AMA used **AstraZeneca's** prices reported to First DataBank to reimburse pharmacies. R.1548, 1576-80. Comparing the prices paid by AMA to real ***23** marketplace prices for **AstraZeneca** drugs, [13] Sauls concluded to a reasonable certainty that **AstraZeneca's** reported prices were significantly higher than true marketplace prices and that, as a result, AMA paid too much in pharmacy reimbursements for **AstraZeneca** drugs. R.1547, 1569, 1571.

In calculating the damages sustained by AMA, Sauls compared what AMA actually paid for **AstraZeneca** drugs to the amount AMA should have paid for **AstraZeneca** drugs. R.1571, 1580-82. Sauls testified that over the claims period, AMA paid $174 million in reimbursement for **AstraZeneca** drugs, but should have paid $146 million, for damages totaling $28,796,664.66. R.1566-67; PX 1237A (R.1592). Adding 6% simple interest per year from the date of each transaction to the time of trial, compensatory damages totaled $40,398,447.39. R.1567-68. **AstraZeneca** presented no alternative damages calculation. R.2110.

***24 XIII. FEDERAL REBATES PAID BY ASTRAZENECA UNDER OBRA '90 DO NOT OFFSET AGAINST AMA'S OVERPAYMENTS.**

Federally mandated quarterly rebates paid by **AstraZeneca** to AMA are completely separate and unrelated to the reimbursement AMA pays to pharmacies for prescription drugs. R.1085, 1165-67, 1195-96, 1331, 1721-23. **AstraZeneca** was required to pay quarterly rebates to AMA as part of its agreement with the federal government under OBRA '90 and as a condition of participating in the Medicaid program. R.1073, 1165-66, 1104. The federal rebate is calculated on a basis *other* than WAC and AWP. [14] R.1065, 1084-85. The rebate paid by **AstraZeneca** remains unchanged regardless of the fraud committed by **AstraZeneca**. R.1086; *see also* R.1114, 1331, 1723. Federal rebates do not compensate AMA for any overpayment AMA has made on **AstraZeneca** drugs. R.1332-33; *see also* R.1584 (federal rebates are not relevant in calculating damages and should not be considered).

*25 *STATEMENT OF THE STANDARDS OF REVIEW*

On the question of whether the State presented sufficient evidence to support the submission of its fraud and related damages claims to the jury, the trial court was correct to deny AstraZeneea's motion for judgment as a matter of law unless this Court finds that there was a complete absence of proof by the State on a material issue or that **AstraZeneca** has established that there are no controverted questions of fact on which reasonable people could differ. *See Liberty Nat'l Life Ins. Co. v. Daugherty*, 840 So. 2d 152, 156 (Ala. 2002). "[T]his Court must accept as true the evidence most favorable to the plaintiff, and must indulge such reasonable inferences as the jury was free to draw from that evidence." *Cackowski v. Wal-Mart Stores, Inc.*, 767 So. 2d 319, 326 (Ala. 2000); *see also Ocean Cruise Lines, Inc. v. Abeta Travel Serv., Inc.*, 562 So. 2d 205, 209 (Ala. 1990)(directed verdict "should be denied if there is any conflict in the evidence for the jury to decide").

On the question of whether the evidence warranted submitting the issue of punitive damages to the jury, the standard of review is the same as the trial court's: ***26** whether there was evidence of such quality and weight that a jury of reasonable and fair-minded persons could find by clear and convincing evidence that the defendant consciously or deliberately engaged in fraud. *Ex parte Norwood Hodges Motor Co., Inc.*, 680 So. 2d 245, 249 (Ala. 1996). As to the amount of punitive damages, the standard of review is also the same as the trial court's. The guideposts are established in *BMW v. Gore* and the factors set out in *Hammond/ Green Oil*. *Akins Funeral Home, Inc. v. Miller*, 878 So. 2d 267, 270-71 (Ala. 2003).

The standard of review on evidentiary matters is abuse of discretion. *Jimmy Day Plumbing & Heating, Inc. v. Smith*, 964 So. 2d 1, 7 (Ala. 2007). "The mere showing of error is not sufficient to warrant a reversal; it must appear that the appellant was prejudiced by that error." *City of Birmingham v. Moore*, 631 So. 2d 972, 973-74 (Ala. 1994).

On the question of whether a new trial is required based upon the trial court's failure to give certain requested jury charges or the giving of allegedly erroneous jury charges, the Court must "look to the entirety of the trial court's charge" and only order reversal when "the ***27** error is considered to be prejudicial." *King v. W.A. Brown & Sons, Inc.*, 585 So. 2d 10, 12 (Ala. 1991).

On the question of whether a new trial is required because the trial court refused to strike for cause venire members who were employed by the State, the standard of review is abuse of discretion. "A trial judge is given broad discretion in regard to sustaining or denying a challenge for cause. His decision is therefore entitled to great weight. . . ." *Kumar v. Lewis*, 561 So. 2d 1082, 1085 (Ala. 1990).

SUMMARY OF THE ARGUMENT

In the interest of justice, the judgment in favor of the State should be affirmed in its entirety. **AstraZeneca** committed a callous, egregious fraud against Alabama's Medicaid program which should not go unchecked or unpunished. **AstraZeneca** knowingly gamed the system for its own corporate profit, victimizing Alabama's neediest citizens in the process. The jury, confirmed by the trial court, found clear evidence of intentional fraudulent conduct, reasonable reliance and damages, all of which were disputed issues of fact. This Court is in no position to ***28** undo the hard work and sound judgment of the trier of fact on these issues of fact.

The starting point for prescription drug reimbursement by Medicaid is the federal regulation, fully known to **AstraZeneca**, which requires Alabama Medicaid to pay its "best estimate of the price generally and currently paid by providers for a drug marketed or sold by a particular manufacturer." 42 C.F.R. § 447.502. (formerly 42 C.F.R. § 447.301). The regulation prohibits Medicaid from negotiating prices with the sellers of the drugs, and de *facto* requires Medicaid to use an outside data source to determine the prices "generally and currently paid" by pharmacists.

AstraZeneca reported its WAC and AWP prices to First DataBank -- the industry's data source -- knowing and intending that those prices would be used by Alabama Medicaid to pay reimbursements.

AstraZeneca defrauded Alabama Medicaid by reporting prices which far exceeded actual wholesale and retail prices paid for its drugs. It knew AMA had to rely on the First DataBank. **AstraZeneca** benefitted by selling more drugs and increasing its market share. (The evidence was ***29** undisputed that manufacturers such as **AstraZeneca** receive $.78 out of every dollar generated by the sale or reimbursement of their drugs.)

AstraZeneca concealed from AMA the true prices of its drugs, which it could have reported had it chosen to do so. The OIG's guidelines, which were issued in 2003 to curb rampant fraud and abuse, reiterated that Medicaid sets reimbursements "with the expectation that the data provided [by **AstraZeneca**] are complete and accurate." PX 973 (R.850), at 23733. Fully discounted prices are to be reported. Even First DataBank, during the entire period at issue, defined the prices reported by **AstraZeneca** as prices *paid*. **AstraZeneca** had a legal duty to report actual prices paid, not false prices unrelated to real payment. As stated in the federal guidelines, "[t]he knowing submission [by manufacturers] of false, fraudulent, or misleading information is actionable." PX 973 (R.850), at 23733.

AstraZeneca argues that the State should have caught its fraud earlier. It argues that federal reports, based on extremely narrow surveys, found that some pharmacists were purchasing unspecified drugs at less than AWP. But not one of those reports involved **AstraZeneca** or its drugs. ***30** Not one of those reports surveyed Alabama pharmacists. Not one of those reports referred to WAC prices by any particular manufacturer, much less **AstraZeneca**.[15] Indeed, not one of those reports gave the State any notice whatsoever of **AstraZeneca's** fraud on the Alabama Medicaid program.

AstraZeneca next attempts to wrap itself within the blanket of *Exxon/Hunt*. Yet this case could not be any more different from *Exxon/Hunt*, and the holdings in those two cases do not apply to the facts of this case. Here the State, unlike in *Exxon/Hunt*, had *no contract* with **AstraZeneca**. Here the State, unlike *Exxon/Hunt*, had no right to examine, inspect or audit the internal economic records of the defendant. Here the State, unlike in *Exxon/Hunt*, had no actual knowledge of the real marketplace prices. This is undisputed. *Exxon/Hunt* involved a private contractual arrangement; this case involves massive economic fraud against a public health program.

***31** The statute of limitations does not run against the State unless the statute itself, by its express terms, affirmatively states that it applies to the State. That is not the case here because the general statute of limitations governing common law fraud contains no provision that it applies to the State or that the State is bound. **AstraZeneca** is asking the Court to change the law retrospectively, which cannot be done, and to overturn the long-settled *nullum tempus* doctrine. However, there is no legal basis to apply the statute of limitations to the State in this case, and there are a multitude of legal and policy reasons why the law should not be changed even prospectively.

Finally, **AstraZeneca's** other points are addressed in the Argument section below and require no comment in this summary except to say they are without merit. They include contentions concerning federal preemption, damages, admission of pattern and practice evidence, exclusion of irrelevant evidence, exclusion of privileged communications, and jury charges, all of which should be rejected. Regarding damages, the State's compensatory damages were proven to a reasonable certainty using the ***32** State's own reimbursement methodology which was approved by the federal government for the entirety of the State's claims period. **AstraZeneca** put on no evidence of an alternative damages figure. Given the egregiousness of **AstraZeneca's** conduct, the punitive damages were well-supported and comport with all legal standards.

ARGUMENT

Prologue

The very existence of appellate standards of review -- such as substantial evidence or abuse of discretion -- drives home the point that this Court is, in most instances, a reviewing court, not a deciding court. The jury decided the facts, hotly contested. That decision is to be given the utmost deference and should not be reversed or limited except under the strongest of circumstances. [16]

The jury in this case saw and heard **AstraZeneca** senior management testify that **AstraZeneca** deliberately increased the spread for its own profit knowing that government payers, like Medicaid, would not "catch on" for years. R.807. The jury in this case saw **AstraZeneca** internal ***33** documents stating that **AstraZeneca** deliberately set out to increase the spread on its drugs to "government unfriendly" levels in order to "drive [its own] market share." PX 963 (R.850); PX 966 (R.850).

The jury in this case saw and heard **AstraZeneca's** former pricing strategist describe **AstraZeneca's** pricing conduct as "unethical" and "sleazy." R.897-98, 902. They saw and heard him testify that **AstraZeneca** attempted to avoid detection from government investigations into this conduct by the following strategy: "If you got a dog . . . barking and running around you, the last thing you want to do is try and kick it. It's already excited and angry. So they wanted to lay low, like not kicking the dog." R.896.

The jury observed these witnesses, their credibility and demeanor, and weighed the evidence. The jury observed first-hand the power of the State's evidence and the culpability of **AstraZeneca's** conduct. By design, this Court will never have that opportunity. That is why the standard of *review* is so important.

***34 I. THE STATE PRESENTED SUBSTANTIAL EVIDENCE SUPPORTING ITS MISREPRESENTATION AND SUPPRESSION CLAIMS AGAINST ASTRAZENECA, WARRANTING SUBMISSION OF THOSE CLAIMS TO THE JURY.**

The State presented overwhelming evidence that **AstraZeneca** knowingly reported WAC and AWP prices for its drugs that were inflated and untruthful, causing AMA to overpay by millions of dollars. This Court's responsibility is to determine whether there was "a complete absence of proof on a material issue" or whether "there are no controverted questions of fact on which reasonable people could differ," while viewing the evidence in the light most favorable to the State. *Liberty Nat'l Life Ins. Co.*, 840 So. 2d at 156.

A. AstraZeneca Reported False WACs and AWPs (Misrepresentation).

Substantial evidence was presented that **AstraZeneca** misrepresented its drug prices by reporting false and inflated prices that were used by AMA to reimburse pharmacies. This was a fact question for the jury which was decided in favor of the State. [17]

***35 1. WAC is a net price paid.**

WAC is the price paid by wholesalers to manufacturers for drugs. **AstraZeneca's** reported WACs did not do so, they do not represent a true price. R.1168-70, 1219-20. **AstraZeneca's** reported WAC prices did not include discounts, rebates, chargebacks, prompt-pay discounts, or other price concessions that reflect the actual price paid for drugs. R.1168-70. **AstraZeneca** concedes that the WAC prices it reported were not net prices paid, but argues that this does not make its WACs "false." R.838; 968-69. Instead, **AstraZeneca** argues that WAC is defined within the industry and by federal law as an undiscounted list price. Both of those arguments are incorrect. And in any event, what WAC was understood to mean was a disputed factual question decided by the jury in favor of the State.

a. The plain meaning of WAC is actual cost or price paid.

The definition of WAC as the price paid by wholesalers to manufacturers, including all discounts, is supported by the plain meaning of its words. The dictionary meanings of ***36** the constituent parts are straightforward. [18] Combining all the terms, "wholesale acquisition cost" plainly means "the price paid to acquire goods in quantity for resale." *Massachusetts v. Mylan Labs.*, 2008 WL 5650859, at *14 (D. Mass. Dec. 23, 2008) (defining WAC in pharmaceutical pricing litigation by its plain meaning, as supported by the Medicaid regulatory context). "It does not mean a list price; it means the amount that goods actually cost." *Id*.

b. The federal regulation governing Medicaid reimbursement requires that WAC must be a price paid.

Federal regulations reinforce the plain meaning definition. Since the 1980s, WAC has been a part of AMA's federally approved reimbursement methodology with EAC defined as WAC + 9.2%. DX 993 (R.1388). By law, EAC is "the agency's best estimate of the *price generally and currently paid* by providers for a drug ... in the package size of drug most frequently purchased by providers." PX 1347 (R.1314); R.1312-14 (federal regulation requires AMA to reimburse pharmacies a price generally and currently ***37** paid, not on an undiscounted list or suggested price). Thus, WAC must be a price which can be used to estimate what pharmacies generally and currently pay for drugs. **AstraZeneca** knows this. R.793. Adding a percentage to WAC to account for the wholesalers' mark-up to a retailer (which is part of AMA's formula) results in an estimate of what pharmacies actually pay for drugs. If, on the other hand, WAC was intended to mean merely a list price - "a price set by manufacturers and listed at the top of invoices but almost never paid by wholesalers" - then WAC could not be utilized to accurately estimate what pharmacies generally and currently paid for drugs, rendering AMA's federally approved formula useless. *Massachusetts v. Mylan Labs.*, 2008 WL 5650859, at *14.

c. Related case authority says WAC is a discounted, net price paid.

Interpreting WAC as a list price leads to an absurd result. *See Laidlaw Transit, Inc. v. Ala. Educ. Ass'n*, 769 So. 2d 872, 882 (Ala. 2000) (interpretations which lead to absurd results should be avoided). Under **AstraZeneca's** post-lawsuit argument that WAC is a list price, AMA would be surrendering all control over its fiscal responsibility to a decision wholly dictated by the pharmaceutical ***38** industry. See *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d 277, 286 (D. Mass 2006). **AstraZeneca** could denominate any price as WAC even if it was not a real price paid by wholesalers, and AMA would then be forced to reimburse on the basis of that list price. The idea, however, that the agency "would deliberately condone a bribery scheme using public funds to enrich drug manufacturers and [others] is, to say the least, unusual." *In re Lupron Mktg. & Sales Practices Litig.*, 295 F. Supp. 2d 148, 163 (D. Mass. 2003). The suggestion that AMA "intend[ed] to give the pharmaceutical industry free reign *[sic]* over drug pricing" is "absurd." *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 286-87. "When the regulatory scheme is viewed as a whole, it is clear that WAC must mean the actual cost at which wholesalers acquired a drug." *Massachusetts v. Mylan Labs.*, 2008 WL 5650859, at *15.

Because **AstraZeneca** knew that AMA's EAC was the "agency's best estimate of the price generally and currently paid by providers" and that AMA used WAC to calculate EAC, a jury could certainly and reasonably conclude that **AstraZeneca** "knew or [was] deliberately ***39** ignorant of the fact that [it should not] report a mere list price, but [was] instead meant to report a price suitable for such estimation, that is, *a real price.*" *Id*. at *25.

d. AMA understood WAC to be a net price paid.

AMA's interpretation of WAC must be given substantial deference. *See Ex parte Bd. of Scn. Comm'rs of Mobile County*, 824 So. 2d 759, 761 (Ala. 2001). "It is well settled that an agency's interpretation of its own regulation must stand if it is reasonable,

even though it may not appear as reasonable as some other interpretation." *Id*. "An agency's interpretation of its own policy is controlling unless it is plainly erroneous." *Id*.

Consistent with its reimbursement requirements at actual cost, AMA understood WAC to be the actual price paid by wholesalers to manufacturers, net of all discounts. R.1322, 1461-62.

e. AstraZeneca's own records and industry-publications define WAC as a net price paid.

AstraZeneca insists that WAC is an "industry term" denoting nothing more than an undiscounted list price, but ***40** the evidence proves the contrary.[19] An internal **AstraZeneca** document defines WAC as the "price wholesalers pay to the manufacturer." PX 40 (R.1189). Numerous sources within the industry defined WAC as the price wholesalers actually pay for the drug. Significantly, First DataBank reported WACs under the heading "WHN," meaning *wholesale net*. PX 1482 (R.1551), at FDB-Alabama 060000.[20] "It is hard to see how a Wholesale Net Unit Price could be understood not to be *net* of 'rebates' and 'discounts.' " *Massachusetts v. Mylan Labs.*, 2008 WL 5650859, at *24. In a report to HCFA in 1993, WAC is also defined as a "wholesaler's *net* payment made to purchase a drug product from the manufacturer, net of purchasing allowances and discounts." PX 1520 (R.1212), at 4 (emphasis added); R.1215-16. The 2003 OIG Guidance likewise states that reported prices used for pharmacy reimbursement, such as WAC, should take into account discounts and other price reductions. R.1208-09; PX 973 (R.850), at 23733-34.

***41 f. The new Medicare definition of WAC is not applicable.**

AstraZeneca's repeated assertion that WAC is defined by federal Medicare law is incomplete, out of context, and intentionally misleading. **AstraZeneca** omits significant facts concerning that definition, including (1) that it was adopted as part of the *Medicare* Modernization Action ("MMA") of 2003; (2) that the definition did not become effective until January 2005, the same month the State filed this lawsuit and at the tail end of the State's claims period (1991-1Q 2005); (3) that it applies only to Medicare, not Medicaid; (4) that it applies only to physician-administered drugs, not the self-administered drugs which are at issue in this case; and (5) that, even in the Medicare context, it is of limited relevance because WAC is used only in rare circumstances where a drug is newly launched and has no sales history from which the manufacturer can calculate average sales price. R.1284-85, 1288. Indeed, **AstraZeneca's** counsel acknowledged during trial, in front of the jury, that "[o]f course, we don't know whether it applies to the Medicaid program or not." R.1285. In addition, the MMA definition of WAC was not admitted as an exhibit during trial, and **AstraZeneca** does ***42** not challenge that evidentiary ruling as error. R.1761-63. **AstraZeneca's** MMA argument is misleading and wrong. The jury had ample evidence to find that **AstraZeneca** lied to AMA about WACs.

2. AWP is a net price paid.

Like WAC, AWP is a price rooted in marketplace reality. AWP is the average price paid by pharmacies to wholesalers for drugs, net of all discounts, rebates, and other price concessions. R.1322, 1167-68; PX 941 (R.850); PX 942 (R.850); PX 944 (R.850), at p. 18; PX 946 (R.850), at p. 30. Because **AstraZeneca** reported an AWP that did not represent a true average price that pharmacists pay for drugs, **AstraZeneca** reported false AWPs. R.1167-68, 1219. **AstraZeneca's** argument that AWP is a sticker price based on a percentage markup having no market basis is belied by the evidence and does not defeat the State's claims as a matter of law. To the extent that "AWP" was a question of fact, the jury resolved this in the State's favor.

a. The plain meaning of AWP is the average of prices paid.

The definition of AWP as the average price paid by retailers to wholesalers, net of all discounts, is supported by the plain meaning of its words. The ***43** dictionary meanings of the words are straightforward.[21] Taken together, "average wholesale price" is a mathematical mean of the amount paid by retailers to wholesalers for a product.

b. The federal Medicaid regulations regarding reimbursement require AWP to be a true average of prices paid.

As with WAC, the plain meaning of AWP is supported by the Medicaid regulations defining EAC as a "price generally and currently paid by providers." PX 1347 (R.1314). Interpreting AWP as a "sticker price" that has no connection to market prices paid is inconsistent with the federal regulation governing Medicaid reimbursement. See *In* re *Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 288. In addition, leaving AWP to mean something other than an actual average price would, in effect, surrender Medicaid's fiscal responsibility to a decision wholly dictated by the pharmaceutical industry. ***44** *See id*. at 286. Interpreting AWP in the way **AstraZeneca** suggests would permit pharmaceutical manufacturers to funnel Medicaid funds to pharmacies by inflating AWPs, when the actual out-of-pocket costs of drugs were much lower. *See id*. at 286-87. This is an absurd result which must be avoided. *See Laidlaw Transit, Inc.*, 769 So. 2d at 882.

c. Case authority says AWP is a discounted, net price paid.

A federal court in Massachusetts has already held, based on the words' plain meaning and use in the Medicare context, that AWP is not a "reference price or benchmark," but instead means an average of actual prices in the marketplace, net of discounts and rebates. *In re Pharm. Indus. Average Wholesale Price Litig.*, 460 F. Supp. 2d at 284, 287-88. The court explained that "the policy here is to ensure that the government gets the benefit of rebates and discounts, by getting lower prices. Interpreting 'average wholesale price' as a retail sticker price that does not account for rebates and discounts would be inconsistent with the policy." *Id*. at 288.

***45 d. AMA understood AWP to be an average of prices paid.**

Consistent with its mandate to reimburse based on EAC, AMA understood AWP to be an actual average of prices paid by retailers to wholesalers, net of all discounts, chargebacks, and rebates. R.1322. AMA's own interpretation of AWP should be given substantial deference. *Ex parte Bd. of Sch. Comm'rs of Mobile County*, 824 So. 2d at 761. Further, AMA's understanding was a question of fact for the jury.

e. AstraZeneca's own records and industry publications defined AWP as an average of prices paid.

AstraZeneca's list price definition is contradicted by its own files and other industry sources. *See* discussion of First DataBank, **AstraZeneca**, and National Pharmaceutical Council definitions of AWP in the Statement of Facts, *supra* pp. 11-12.

B. AstraZeneca Breached Its Duty to Report Truthful and Accurate Prices (Concealment).

Substantial evidence was presented that **AstraZeneca** breached its duty to report truthful and accurate prices and that AMA detrimentally relied on the concealment by reimbursing based on false prices. This was a fact ***46** question for the jury which was decided in favor of the State.

1. AstraZeneca's duty arose from the particular circumstances.

Alabama law recognizes that a duty to disclose may arise from the particular circumstances of a case. *See* Ala. Code § 6-5-102. "[E]ach case must be individually examined," as "the words of the statute itself counsel flexibility" and "a rigid approach is

impossible[.]" *Lucas v. Hodges*, 589 So. 2d 154, 157 (Ala. 1991). Factors supporting the finding of a duty include: "(1) the relationship of the parties; (2) the relative knowledge of the parties; (3) the value of the particular facts; (4) the [plaintiff's] opportunity to ascertain the facts; (5) the customs of the trade; and (6) other relevant circumstances." *State Farm Fire & Cas. Co. v. Owen*, 729 So. 2d 834, 842-43 (Ala. 1998). Where a defendant has superior knowledge of the suppressed information and the injured party has been induced to take action that otherwise might not have been taken, the obligation to disclose is particularly compelling. *See Dominick v. Dixie Nat'l Life Ins. Co.*, 809 F.2d 1559, 1570 (11th Cir. 1987); *see also Lucas*, 589 So. 2d at 157 (duty to disclose often ***47** recognized where defendant has some particular knowledge not shared by plaintiff). In addition, inequitable access to material information is particularly relevant in determining that a duty to disclose exists among experienced business entities, effectively altering or nullifying the "arm's length transaction" doctrine. *Beirsdoerfer v. Hilb, Rogal and Hamilton Co.*, 953 So. 2d 1196, 1208 (Ala. 2006).

AMA was not privy to **AstraZeneca's** sales data and had to rely on the truthfulness of **AstraZeneca's** reported prices. R.1308-09, 1323. AMA had no contract with **AstraZeneca** and had no right to audit **AstraZeneca's** books. R.1308-09. Only **AstraZeneca** knew the true prices paid for its drugs, and it did not notify AMA about the discounts that its customers received. R.1065-66, 1308-09. Because **AstraZeneca** had superior knowledge of its drug prices and reported them with the knowledge and intent that AMA would rely on those prices for reimbursement, there can be no doubt that **AstraZeneca** owed AMA a duty to report truthful and accurate prices. *See North Mem'l Med. Ctr. v. Gomez*, 59 F.3d 735, 739 (8th Cir. 1995) (*citing Heckler v. Cmty. Health Servs.*, 467 U.S. 51, 64-65 (1984)); *Massachusetts v.* ***48** *Mylan Labs.*, 2008 WL 5650859, at *25; *Jackson Co. v. Faulkner*, 315 So. 2d 591, 600-01 (Ala. Civ. App. 1975)(where one voluntarily undertakes an obligation to speak, he is bound not only to state the truth but also not to suppress or conceal any facts within his knowledge which will materially qualify those stated; if he speaks at all, he must make a full and fair disclosure).

In addition, even though **AstraZeneca** reported prices to AMA through First DataBank rather than directly to AMA, the duty remained the same since **AstraZeneca** knew and intended for its prices to be published by First DataBank for use by AMA in reimbursing pharmacies. R.778-79, 792-93, 1002; *see Hines v. Riverside Chevrolet-Olds, Inc.*, 655 So. 2d 909, 920-21 (Ala. 1994), *overruled on other grounds*, *State Farm Fire & Cas. Co. v. Owen*, 729 So. 2d at 839 (concluding defendant manufacturer owed duty to purchasers of automobile who manufacturer expected or had reason to expect would be influenced by its decision to not disclose information about the repainting of damaged automobiles); *R.A. Barton v. Am. Red Cross*, 829 F. Supp. 1290, 1308 (M.D. Ala. 1993)(obligation to disclose material information can ***49** arise even when there is no "direct relationship with direct communications" between the parties).

2. AstraZeneca admitted it owed a duty to AMA.

AstraZeneca admitted it had a duty to familiarize itself with the requirements of each State's Medicaid program and to be honest and truthful with AMA. R.773-74, 793 (testimony of **AstraZeneca** vice president Roger Hyde). **AstraZeneca** reported prices to First DataBank, knowing that AMA would rely on the information. R.791-93. **AstraZeneca** was directly or indirectly responsible for ensuring accurate prices on which AMA relies for pharmacy reimbursement of **AstraZeneca** drugs. R.1059.

3. The OIG guidelines recognize a duty.

This duty was further supported by the OIG's Compliance Guidance to manufacturers, which provides that "[w]here appropriate, manufacturer's reported prices should accurately take into account price reductions, cash discounts, . . . or other price concessions . . . ." PX 973 (R.850), at 23733-34. Contrary to **AstraZeneca's** assertion, this reporting requirement did apply to WAC and AWP prices because that data is used for pharmacy reimbursement, and AMA "sets reimbursement with the ***50** expectation that the data provided are complete and accurate." *Id.* at 23733; R.1208-09; *see also* R.969-70 (admission by **AstraZeneca** that OIG Compliance Guidance applies to **AstraZeneca's** indirect reporting of prices to AMA through the price reporting service).

C. AMA Reasonably Relied upon AstraZeneca's Reporting of False Prices and Its Concealment of True Prices.

1. There is no question that AMA relied on AstraZeneca's reported prices.

The State's evidence is strong and unequivocal that (i) it used and relied on as true **AstraZeneca's** reported prices to reimburse pharmacists for **AstraZeneca's** drugs, (ii) it would have paid millions of dollars less had **AstraZeneca** reported true prices, and (iii) it detrimentally relied on **AstraZeneca's** price misrepresentations and concealment of true prices. See discussion *supra* pp. 16-23. Reliance is a fact question for the jury. *The Mall, Inc. v. Robbins*, 412 So. 2d 1197, 1200 (Ala. 1982). Where a plaintiff has been induced to make payment based on a defendant's misrepresentation, the plaintiff has relied on the misrepresentation. See, *e.g.*, *Billy Barnes Enters., Inc. v. Williams*, 982 So. 2d 494, 502 (Ala. 2007); *Shelton v. Duncan*, 385 So. 2d 1329, 1323-33 (Ala. Civ. App. 1980). ***51** Unless this Court finds a complete absence of proof on this issue (which would be impossible to conclude), the jury's verdict should stand.

2. The reasonableness of the State's reliance was a fact question for the jury.

The reasonableness of a party's reliance, particularly when the evidence is disputed, must be decided by the jury.[22] *See White v. State Farm Fire & Cas. Co.*, 953 So. 2d 340, 353 (Ala. 2006) (reversing summary judgment in fraud case where material questions of fact existed concerning whether plaintiff's reliance was reasonable); *Gilmore v. M & B Realty Co., L.L.C.*, 895 So. 2d 200, 210-11 (Ala. 2004)(same). This Court has readily acknowledged that even when a plaintiff has "actual knowledge of [a] discrepancy," that alone "does not translate to the broader proposition that, as a matter of law, the [plaintiff] should have been ***52** alerted to the need to investigate [.]" *Gilmore*, 895 So.2d at 210-211; *Ex parte Seabol*, 782 So. 2d 212, 216 (Ala. 2000) ("The question of when a party discovered or should have discovered the fraud is generally one for the jury.

The State submitted a wealth of evidence showing that it reasonably relied on the WACs and AWPs submitted by **AstraZeneca** and that -- in light of (i) the terms' plain meaning, (ii) the Medicaid regulation defining EAC, (iii) the First DataBank definitions, and (iv) the numerous publications defining WAC and AWP as real prices anchored to market reality -- such reliance was reasonable. Viewing the facts in the light most favorable to the State, and drawing all reasonable inferences in the State's favor, there was sufficient evidence for a jury to find that the State did not know of the falsity of **AstraZeneca's** reported WACs and AWPs, and that the State's reliance on **AstraZeneca's** reported prices was reasonable.

3. Insurance fraud cases are not analogous.

This case is not like a typical insurance fraud case in which an oral representation is directly contradicted by written terms in the parties' contract. For example, **AstraZeneca** cites *AmerUS Life Ins. Co. v. Smith*, in which ***53** this Court reversed a compensatory and punitive damages award, concluding that the plaintiff's reliance was not reasonable as a matter of law. 2008 WL 4277861, at *15 (Ala. Sept, 19, 2008). There, the plaintiff, a competent businessman, elected not to read the terms of his written insurance contract but relied on oral representations of the agent which conflicted with the contract's written terms. This Court concluded that the plaintiff's failure to read the contract and exercise ordinary diligence prevented his recovery for fraud.

Unlike that plaintiff in *AmerUS*, however, the State had no contract with **AstraZeneca** containing explicit written terms which directly contradicted oral representations made by **AstraZeneca**. AMA did not know **AstraZeneca's** true prices nor could it audit **AstraZeneca's** books. The facts of *AmerUS* (and other fraud cases in which a contract between the parties exists) are inapposite.

4. Documents pre-dating the claims period beginning in 1991 do not negate AMA's reasonable reliance.

The State's claims period against **AstraZeneca** begins in 1991, which corresponds with the implementation of OBRA '90 requiring AMA to reimburse for over 60,000 drug products as ***54** opposed to the handful previously covered. *See* R.1304. None of the documents pre-dating the claims period impute knowledge to the State that **AstraZeneca** reported false and inflated WACs and AWPs and concealed true prices from 1991 to the first quarter of 2005. They do not undermine AMA's reasonable reliance on prices reported between 1991 and 2005.

Exhibits introduced by **AstraZeneca** dated in the mid-1970s -- including a *proposed* rule from the Department of HEW, a letter from AMA's pharmaceutical services director, and the State Plan -- all document AMA's use of "actual acquisition cost" as its drug reimbursement basis. DX 1 (R.1589); DX 2 (R.1784); DX 12 (R.1419). These are irrelevant. The proposed rule mentioned that "[m]ost States use average wholesale price, Red Book data, Blue Book data, survey results or similar standard costs. Such standard prices are frequently in excess of actual acquisition costs to the retail pharmacists." DX 1 (R. 1589). The proposed rule required reimbursement on the basis of actual acquisition cost. *Id*. AMA did reimburse providers on the basis of actual acquisition cost at the ***55** time. R.1415-16; DX 2 (R.1784), at 1-2. [23] The proposed rule required no different action on the part of AMA, and, therefore, had no import with regard to its reimbursement formula for brand name drugs. [24] Moreover, none of these 1970s documents even mentions WAC.

The 1984 OIG report cited by **AstraZeneca** similarly makes no mention of WAC. *See* DX 12 (R.1419). As for AWP, the report recommends revising federal regulations to preclude the general use of AWP to determine EAC, but the HCFA administrator rejected that recommendation stating it "is premature" and "HCFA is not prepared to recommend any changes in the Federal regulations." DX 12 (R.1419), ***56** at p. 10,207-10,208. Even so, there is no evidence this document was ever received or reviewed by AMA, its recommendations are based on a survey of six states not including Alabama, the report made no mention of **AstraZeneca** or its drugs, and the report pre-dated the OBRA '90 legislation (which dramatically altered the AMA pharmacy program) by seven years.

In June 1985, HCFA Regional Administrator Richard Morris sent AMA Commissioner Faye Baggiano a letter stating that based on evidence obtained through surveys (not including Alabama), HCFA would not consider it acceptable for states to use published AWP as the states' EAC, unless AWP had been reduced significantly. DX 17 (R.1239). Although the letter stated that AWPs were inflated by an average of 15.96%, Morris testified that that inflation rate is not reflective of what might have occurred in Alabama. R.1485. Nevertheless, HCFA threatened to withhold federal financial participation if AMA did not adjust its EAC methodology to a recommended "wholesale acquisition price (WAP) [25] plus 5.01 percent" or a comparable methodology. DX 17 (R.1239). Commissioner Baggiano ***57** promptly responded to the directive, stating that AMA planned to implement the recommended methodology for EAC (WAP + 5.01%), effective October 1, 1985. PX 1172 (R.1496); *see also* DX 22 (R.1787). AMA's action corrected any perceived problem by HCFA regarding EAC and the use of AWP. [26] R.1490.

Effective October 29, 1987, the percentage markup on WAP (or WAC) was increased to 9.2% based on studies performed for AMA by the two primary wholesalers serving Alabama pharmacies. DX 44 (R.1791), at 2. Since then, AMA's reimbursement formula has consistently been approved by CMS, and AMA has never been held out of compliance with regard to its drug reimbursement formula. R.1350-51, 1491.

Commissioner Steckel also put in context a memo from 1987 that was addressed to her while she was employed at HCFA, which **AstraZeneca** suggests placed her on notice of ***58** AWP inflation. *See* DX 39 (R.1356). In 1987, two years prior to Steckel's return to Alabama to serve as Medicaid Commissioner (for her first term), she served as an assistant to the administrator of the Office of Legislation and Policy for both Medicare and Medicaid, with a primary focus on Medicare. R.1339, 1358. Steckel would have given the memo to her boss in preparation for a meeting and otherwise put it aside; she had no recollection of it. R.1358. The memo, not addressed or sent to AMA, does not give notice to AMA of anything.

Regarding WAC, none of the historical documents cited by **AstraZeneca** suggests that WAC is anything other than the price paid by wholesalers to manufacturers or that WAC is inflated. Indeed, an AMA internal memorandum from 1998 defines wholesale acquisition cost as the "price paid to the manufacturer/distributor by the wholesaler." DX 44, at 2 (R.1791).

***59 5. OIG reports issued during the claims period do not prove that AMA unreasonably relied on AstraZeneca's reported prices.**

None of the OIG reports cited by **AstraZeneca** refer to **AstraZeneca** or any of its drugs.[27] R.1477-78. The reports do not advise or place AMA on notice that **AstraZeneca** reported inflated drug prices or by how much. *Id*. And, regardless of the general information contained in the OIG reports, none of the reports absolve **AstraZeneca** of its duty to report true and accurate prices.

Specifically, there is no evidence that AMA received an April 1997 OIG Report cited by **AstraZeneca**, in which the OIG estimates actual acquisition cost to average 18.3% below AWP. DX 155A (R.1427). Even so, as Commissioner Steckel noted, this report is based on invoices from 315 pharmacies in an eleven-state survey, not including Alabama. R.1428. In addition, HCFA commented on this report, stating it would use the information in its review of state plans for reimbursement level appropriateness. ***60** R.1428; DX 155A (R.1427), at App. 3 p. 2. But HCFA/CMS has continually approved AMA's pharmacy reimbursement formula, both before and after this report was issued. R.1428. The report does not direct states to take any action, and the report does not mention **AstraZeneca** or any of its drugs.

There is also no evidence that AMA received an August 2001 OIG Report, in which **AstraZeneca** contends WAC is defined as a list price. DX 260A (R.1429). However, the report does *not* define WAC as a list price or otherwise define WAC at all. Instead, it merely notes that, based on a limited survey not including pharmacies in Alabama, that invoice prices were 1.81% below WAC for certain unspecified brand drugs. DX 260A (R.1429), at 5. The report does not mention **AstraZeneca** or any of its drugs.

6. Other documents did not negate reliance.

AstraZeneca cites a publication from First DataBank defining WAC as a list price. DX 563 (R.1529). This again is strongly misleading. That publication is undated, but the text of the document establishes that it was published sometime after *March 29, 2007*, two years after the State's lawsuit was filed. *See* DX 563 (R.1529), at p. 3 (stating that "[a]s of March 29, 2007, manufacturers report*ed* WAC or ***61** Direct Price for approximately 56% of all prescription drugs . . . products."). The publication also notes that WAC was "previously referred to as *Net* Wholesale Price," which was the First DataBank definition during the claims period at issue. DX 563 (R.1529), at p. 1. The document cited by **AstraZeneca** simply evidences a *change* by First DataBank of its WAC definition *after* litigation ensued, and it does not establish pre-suit notice to AMA of anything.

AstraZeneca's reference to two budgetary exercise documents likewise cannot be construed to establish the State had actual knowledge of **AstraZeneca's** fraud in reporting inflated WAC and AWP prices. *See* DX 108 (R.1457); DX 398 (R.1385). Those documents (dated November 1995 and November 2004, the latter less than two months. before this suit was filed) were part of AMA's annual budget review, which focused on across-the-board cost cutting measures and which did not consider whether those measures were even capable of being implemented. R.1384-87, 1475-76.

And finally, **AstraZeneca's** reference to an isolated excerpt from a 1992 federal Medicaid Manual simply regurgitates HCFA's 1985 directive which prompted AMA's ***62** action to change its reimbursement methodology in the 1980's. DX 76 (R.1366). The 1992 HCFA manual did not direct AMA, even by implication, to do anything differently from what it was already doing. AMA's reimbursement formula was at the time and remains today in compliance with federal regulations. R.1478-79.

7. AMA's reimbursement formula did not negate reliance.

AstraZeneca argues that because AMA used AWP - 10% in its reimbursement formula, rather than 100% of AWP, AMA could not have reasonably believed that AWP was an actual average of prices paid by retailers to wholesalers. The State presented substantial evidence, however, proving that it did in fact believe AWP was an average of prices paid by retailers to wholesalers, even though AMA included AWP - 10% as one component of its reimbursement methodology due to the federal government's directive in 1985. *See* R.1478-79. Thereafter, AMA did continue to reimburse pharmacists on the basis of 100% of AWP (with no 10% reduction) for certain drugs, which was also approved by the federal government. PX 1268 (R.1473).

In addition, AstraZeneca's own evidence revealed that AMA reimbursed 83% of the claims for AstraZeneca drugs on ***63** the basis of WAC + 9.2. AMA's formula certainly did not deduct anything from AstraZeneca's reported WAC price (instead, adding a percentage). Therefore, there can be no contention that WAC was understood by AMA to be something other than a fully discounted net price.

One federal court has concluded that the federal government's directive to the states to reimburse on a basis other than 100% of AWP may have been an effort to reduce cost to the program, while still expecting AWP to be a true average of wholesale prices. Examining the role of AWP in the Medicare context, the court explained:

> It is far more likely that by setting the Medicare reimbursement rate below the AWP, Congress took a tentative step towards using Medicare's purchasing power as a means of driving down the cost of prescription drugs to the Medicare program. "Average," after all, means that in a competitive market, some prices will be higher and some lower than the median. Congress might reasonably have wished to put Medicare on the lower rung of the equation.

In re Lupron Mktg. & Sales Practices Litig., 295 F. Supp. 2d 148, 163 (D. Mass. 2003).

Finally, both AstraZeneca and the pharmacists who were reimbursed accepted AMA's publicly-known formula when they elected to participate in Alabama's Medicaid program. R. 772-73, 778, 1003, 1778. It is disingenuous for ***64** AstraZeneca to argue now that the formula is unreasonable or that it somehow gave AstraZeneca a license to inflate its reported prices.

8. Average Manufacturer Price ("AMP"), which AMA did not even receive, did not negate AMA's reliance.

AstraZeneca argues that AMA could not have reasonably believed that WAC was anything other than a list price because the net price a wholesaler pays to a manufacturer is defined by a different term, average manufacturer price or "AMP," a number which AstraZeneca reports to CMS in connection with the federal rebate program. As AstraZeneca concedes, however, CMS was prevented from providing AMP data to AMA because that data is, by law, confidential. 42 U.S.C. § 1396r-8(b)(3)(A) and (D). Moreover, AstraZeneca did not provide any AMP data directly to AMA prior to 2004). In any event, AMA could not use AMP in its reimbursement formula because, like CMS, state agencies are prohibited by federal law from disclosing AMP. 42 U.S.C. § 1396r-8(b)(3)(A) and (D).

AstraZeneca did send AMP data to AMA in May 2004 for two drugs (Crestor and Nexium) reflecting one quarter (1Q 2004) in connection with a supplemental rebate offer, but ***65** did not submit AMP to AMA for any other drugs. R.1315-18. It would be impossible for AMA to reimburse pharmacies on an AMP price for two drugs received at one point in time (even if it were permitted to do so under federal law, which it is not). R.1316-18. AstraZeneca solidified that prohibition by instructing AMA that the AMP it provided "shall be held strictly confidential by the State." DX 2335 (R.1125), at ¶ 5.

D. AMA Detrimentally Relied upon AstraZeneca's False and Inflated Reported Prices and Its Failure to Report True Prices.

The evidence is clear that the State detrimentally relied upon **AstraZeneca's** misrepresentations and concealment of true prices. The input of honest and truthful prices results in accurate reimbursement calculations. The input of false and inflated prices, such as those reported by **AstraZeneca**, resulted in AMA paying excessive reimbursements. But for **AstraZeneca's** fraud, Alabama Medicaid would have paid millions of dollars less in pharmacy reimbursements. R.1332-34, 1583.

This Court has explained: " '[F]or a plaintiff to state a fraud claim, he must show that a misrepresentation induced him to act in a way that he would not otherwise ***66** have acted, that is, that he took a different course of action because of the misrepresentation.' " *Billy Barnes Enters., Inc.*, 982 So. 2d at 500.

The State proved that it did take a different course of action because of the misrepresentation by paying far more in reimbursements than it would have if **AstraZeneca** had reported true prices. Alabama law is clear that where a plaintiff is fraudulently induced to make payments it otherwise would not have made, the plaintiff has detrimentally relied on the misrepresentations. *See, e.g., id*. at 502 (payment is reliance); *Boswell v. Liberty Nat'l Life Ins. Co.*, 643 So. 2d 580, 581-82 (Ala. 1994) (payment of insurance premium is reliance); *Shelton v. Duncan*, 385 So. 2d 1329, 1332-33 (Ala. Civ. App. 1980) (obligation to pay is detrimental reliance).

In spite of this, **AstraZeneca** argues that AMA has not detrimentally relied because it did not change its reimbursement methodology *after* the lawsuit was filed. But the methodology was merely a mathematical formula dependent relies upon the manufacturer's reported prices. It is only when a manufacturer such as **AstraZeneca** submits false prices that the methodology is corrupted. Commissioner ***67** Steckel explained: "The methodology as it's designed works. If the information that's inputted by the drug manufacturer, in this case, **AstraZeneca**, is accurate, then our methodology works." R. 1332. Dr. Anderson, the State's expert witness, also testified as follows: "Q: Do you have an opinion as to whether or not that's a reasonable formula? A: I think if we were talking about fair prices, it would be a reasonable formula. It's also a formula that's very consistent to the other states, the other 49 Medicaid programs." R.1195.

E. The *Exxon* and *Hunt* Cases Are Inapplicable.

The points made in the State's Summary of the Argument section merit repeating:

> [T]his case could not be any more different from *Exxon/Hunt*, and the holdings in those two cases do not apply to the facts of this case. Here the State, unlike in *Exxon/Hunt*, had *no contract* with **AstraZeneca**. Here the State, unlike *Exxon/Hunt*, had no right to examine, inspect or audit the internal economic records of the defendant. Here the State, unlike in *Exxon/Hunt*, had no actual knowledge of the real marketplace prices. This is undisputed. *Exxon/Hunt* involved a private contractual arrangement; this case involves massive economic fraud against a public health program.

See supra p. 30.

***68** The holding in *Exxon* turned the particular facts of that case, where (i) the Department of Conservation and Natural Resources ("DCNR") had a contractual right to audit Exxon's records and actually performed audits of the records; (ii) DCNR had actual knowledge of Exxon's method of calculation; (iii) DCNR received actual disclosure of Exxon's underlying internal data; (iv) Exxon did not misrepresent the volume of gas it was extracting; (v) there was "no evidence" that Exxon withheld information; and (vi) DCNR never accepted Exxon's calculations as correct. The *Exxon* facts are therefore the polar opposite of the facts in the State's case against **AstraZeneca**.

Exxon Mobil Corp. v. Alabama Dep't of Conservation, 986 So. 2d 1093 (Ala. 2007), involved a dispute concerning the calculation of royalty payments for natural gas extracted from state lands. The leases at issue required Exxon to submit information to DCNR concerning production and sales and maintain all supporting information concerning the reported

production and sales figures for at least two years. The leases further authorized DCNR to audit Exxon's records. *Id*. at 1115. Four years prior to the lawsuit, Exxon representatives voluntarily met with a DCNR analyst ***69** and explained Exxon's method of calculating the royalty payments. *Id*. A DCNR memorandum concerning the meeting "clearly shows that DCNR was fully aware that Exxon was interpreting the leases differently than was DCNR and that Exxon did not misrepresent itself as being in agreement with DCNR's interpretation [of the leases] or that Exxon intended to comply with DCNR's interpretation." *Id*.

The court noted that "[t]here is no evidence indicating that Exxon intentionally withheld information." *Id*. Additionally, "Exxon never inflated the costs it claimed the right to deduct, nor did it misrepresent the volume of gas it was extracting." *Id*. at 1131-32 (Lyons, J. concurring). DCNR exercised its audit power and performed an audit of the Exxon records. *Exxon*, 986 So. 2d at 1098. Three more years passed while DCNR "continued to accept payments after it was aware that Exxon was calculating royalties under a contrary interpretation of the terms of the leases." *Id*. at 1116. Not only did DCNR accept the payments with full knowledge of Exxon's method of calculation, DCNR accepted the payments without objection, without asserting breach of the leases, and without invoking contractual remedies available to the Department ***70** under the leases. *Id*. Reviewing the record, the court found that there was no evidence that DCNR had changed "its position in reliance" on Exxon's representations. *Id*. at 1115. Finding no evidence of any change in position, the Court held that there was no detrimental reliance and, therefore, could be no recovery for fraud. *Id*. at 1116.

Hunt Petroleum Corp. v. State, 901 So. 2d 1 (Ala. 2004), likewise involved a dispute concerning the calculation of royalty payments for natural gas extracted from state lands. The calculation of the royalty payments and Hunt's reporting of production and sales were governed by a lease agreement similar to those at issue in *Exxon*. As was the case in *Exxon*, the Court found that DCNR never accepted Hunt's calculations as correct. The Court explained: "It is clear from the time the State entered into the lease agreement with Hunt it intended to audit the royalty calculations." *Id*. at 6. The court held that because DCNR never accepted the calculations as correct, always intended to audit Hunt's records and to recalculate the royalty payments due, and did not show any other action DCNR would have taken but for Hunt's representations, there was no detrimental reliance. *Id*. at 7-9.

***71** The State's case against **AstraZeneca** bears no resemblance to either the *Exxon* or the *Hunt* case. First, in this case, AMA did not have access to **AstraZeneca's** confidential pricing information. Second, AMA did not have the right or power to audit **AstraZeneca's** records and independently verify the accuracy of **AstraZeneca's** reported price information. Third, at the time AMA paid inflated reimbursement payments from calculations based on **AstraZeneca's** reported prices, AMA did not know that **AstraZeneca** had reported false prices. Fourth, *Exxon/Hunt* addressed the flow of money *into* the State through a private contract. The present case addresses the flow of money *out of* the State under a program meant for public health and welfare. And finally, had AMA known **AstraZeneca** reported false prices in order to inflate the reimbursements, AMA would not have paid those prices. The facts of this case demand a result opposite to the holdings of *Exxon* and *Hunt*.

F. The State Proved Damages.

AstraZeneca did not offer an alternative damages calculation, and the State's damages, which were calculated to a reasonable degree of certainty, were sufficient for ***72** the jury to consider. R.1547, 2110; *Jamison, Money, Farmer & Co., P.C. v. Standeffer*, 678 So. 2d 1061, 1067 (Ala. 1996) (damages need not be proven to a mathematical certainty; rather plaintiff must "produce evidence tending to show the extent of damages as a matter of just and reasonable inference"); *Shelton v. Clements*, 834 So. 2d 775, 784 (Ala. Civ. App. 2002)("All that is required is that the evidence, with as much certainty as the situation permits, lay a foundation with which the trier of fact may make a fair and reasonable estimate of the amount of damages.").

II. THE STATE'S CLAIMS ARE NOT BARRED BY A TWO-YEAR STATUTE OF LIMITATIONS.

The statute of limitations did not run on the State's claims. In 1999, this Court explained: "*Nullum tempus occurrit reipublicae* ('no time runs against the State') is a common-law doctrine providing that time does not run, i.e., that a statute of limitations does not apply, against the sovereign." *Bd. of Sch. Comm'rs v. Architects Group, Inc.*, 752 So. 2d 489, 491 n.3 (Ala. 1999). "The

theory that no time runs against the State or commonwealth is generally followed in regard to ordinary statutes of limitations unless the State or commonwealth is expressly ***73** or by necessary implication included within the operation of the statute." *Id*. at 491; *see also State v. Bley*, 50 So. 263, 263 (Ala. 1909); *Adler v. Prestwood*, 24 So. 999, 1000 (Ala. 1899); *Doe ex. Dem. Kennedy's Ex'rs v. Townsley's Heirs*, 16 Ala. 239 (Ala. 1849).

AstraZeneca argues that the *nullum tempus* doctrine has been abrogated by Alabama law stating: "All civil actions must be commenced after the cause of action has accrued within the period prescribed in this article and not afterwards, unless otherwise specifically provided for in this code." Ala. Code § 6-2-30(a). **AstraZeneca** asserts that "[a]ll civil actions" must necessarily encompass the State's claims in this case. However, **AstraZeneca's** argument is incorrect and also fails to recognize this Court's continued acknowledgment of the *nullum tempus* doctrine even after the adoption of the 1975 Code.

Because sections 6-2-30(a) and 6-2-38(1) (two-year statute) make no reference to the State, the legislature obviously did not expressly bind the State to those statutes. The State is also not included within the operation of the statutes by necessary implication. It is the precise effect of the *nullum tempus* doctrine that the ***74** State does not fall within the scope of a limitations provision merely due to general language in a statute.

Courts have imposed a limitations period on the State only where the State is expressly named in the statute as being bound by, or subject to, a limitations period by necessary implication. For example, in *Doe ex Dem. State Land Co. v. Roe*, 51 So. 991 (Ala. 1910), the Court held section 2794 of Alabama Code 1896, imposing a twenty-year limitations period on actions at the suit of the *state* for the recovery of real or personal property, barred the State's claim. *Id*. at 991-92; *see also Cox v. Bd. of Trs. of Univ. of Ala.*, 49 So. 814, 819-820 (Ala. 1909) (same). In *State v. Acacia Mut. Life Ass'n*, 108 So. 756 (Ala. 1926), the Court held that section 8945 of Alabama Code 1923, imposing a five-year statute of limitations on all actions by the *State* for the recovery of amounts claimed for licenses, franchise taxes, or other taxes, barred an action to recovery penalties for the non-payment of taxes. *Id*. at 757-58.

AstraZeneca cites *State v. Estate of Crocker*, 83 So. 2d 261 (Ala. Ct. App. 1955), but even that case recognized the continued vitality of the *nullum tempus* doctrine. *Id*. at ***75** 262 ("The theory that no time runs against the state or commonwealth is generally followed . . ."). At issue in the case was Title 61, Section 211 of the Alabama Code (1940), providing that all claims against an estate must be presented within six months of the grant of letters testamentary. That code provision was a non-claim statute governing estates, not a general statute of limitations imposed on a cause of action. The court held that for the non-claim provision to promote the orderly administration of estates, "the statute must apply to all claims." *Id*. at 263. The general two-year statute of limitations for fraud, however, is not implicated by the holding.

AstraZeneca's reference to section 6-5-1(c) of the Alabama Code is also misplaced and inappropriate. The cases in annotation clearly provide that this code section is subject to, and does not limit, the State's sovereign immunity. *See, e.g.*, *White v. Ala. Insane Hosp.*, 35 So. 454 (1903). Since the *nullum tempus* doctrine is derived from the same historical and policy foundations as sovereign immunity, this code section likewise has no limiting effect on the operation of the doctrine.

***76** Because this Court in 1999 again recognized the existence of the *nullum tempus* doctrine, **AstraZeneca's** argument that the 1975 Code extinguished the doctrine is meritless. *See Bd of School Comm'rs v. Architects Group*, 752 So. 2d at 491 n.3. If the reference to "all civil cases" in section 6-2-30(a) had indeed burdened the State with all of the Code's limitations periods, then there would have remained no field of operation for the *nullum tempus* doctrine, and the Court's 1999 affirmation of the doctrine would have been a nullity. Neither the Code nor the commentary suggest that section 6-2-30 (a) should be given such effect.

Clearly, therefore, the two-year statute of limitations for fraud does not apply to the State in this case. However, even if the Court were to decide that it does (which would be a change in the law), the State is protected by the discovery rule for fraud. *See* Ala. Code § 6-2-3 ("In actions seeking relief on the ground of fraud where the statute has created a bar, the claim must not be considered as having accrued until the discovery by the aggrieved party of the fact constituting the fraud, after ***77** which he must have two years within which to prosecute his action.").

The question of when a party discovered the fraud sued upon is for the jury. *Gilmore v. M & B Realty Co., L.L.C.*, 895 So. 2d 200, 210 (Ala. 2004); *Ex parte Seabol*, 782 So. 2d 212, 216 (Ala. 2000). Because the jury returned a verdict in favor of the State on the claim of concealment and awarded damages for the period from 1991 through 1Q 2005, the jury has already decided the discovery issue in the State's favor. Therefore, even assuming the statute of limitations applies (which it does not), there is no need to remand the question to the trial court for further determination because the State has already won the issue.

Finally, even if this Court were to consider abandoning the *nullum tempus* doctrine after 178 years, it may do so only prospectively and without prejudice to the State's January 2005 complaint. A retrospective application of the statute of limitations to the State would violate fundamental principles of equity and due process, as well as Alabama's constitutional guarantee of access to the courts. *See Wilson v. Iseminger*, 185 U.S. 55, 62 (1902); Ala. Const. art. I § 13 ("That all courts shall be open; ***78** and that every person, for any injury done him, in his lands, goods, person or reputation, shall have a remedy by due process of law; and right and justice shall be administered without sale, denial or delay.").

Indeed, this Court has held that the Alabama Constitution prohibits the promulgation of a statute of limitations which extinguishes a claimant's rights without the opportunity to seek a remedy. *See, e.g.*, *Lankford v. Sullivan, Long & Hagerty, Corp.*, 416 So. 2d 996, 1004 (Ala. 1982). The United States Supreme Court agrees:

> It may be properly conceded that all statutes of limitation must proceed on the idea that the party has full opportunity afforded him to try his right in the courts. A statute could not bar the existing rights of claimants without affording this opportunity; if it should attempt to do so, it would not be a statute of limitations, but an unlawful attempt to extinguish rights arbitrarily, whatever might by the purport of its provisions. It is essential that such statutes allow a reasonable time after they take effect for commencement of suits upon existing causes of action ....

Wilson v. Iseminger, 185 U.S. 55, 62 (1902). Therefore, a change in the law applying the statute of limitations to the State could not constitutionally prejudice the State's claims in this case (or any other claim included within its 2005 complaint).

***79 III. THE STATE'S CLAIMS ARE NOT PREEMPTED BY FEDERAL LAW.**

AstraZeneca's contention that the State's fraud claims conflict with federal Medicaid rules and regulations and are, therefore, preempted has no legal merit. At the outset, **AstraZeneca's** argument that the State's claims are preempted by federal law has been squarely rejected by other courts. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 197-201 (D. Mass. 2004) (state law claims against pharmaceutical manufacturers for reporting false prescription drug prices not preempted by federal Medicaid rebate statute); *see also In re Pharm. Indus. Average Wholesale Price Litig.*, 263 F. Supp. 2d 172, 187-88 (D. Mass. 2003)(plaintiffs' claims that defendants fraudulently inflated AWPs in violation of various state consumer protection statutes held not preempted by Medicare Act).

The Court should similarly reject **AstraZeneca's** argument that the State's damages theory conflicts with AMA's federally approved reimbursement formula. The State's evidence demonstrated that its damages methodology *followed* AMA's reimbursement formula, which had been consistently approved by CMS, and that it was not in ***80** conflict with anything approved by CMS. Moreover, the State's damages methodology was just that - a methodology for calculating damages against **AstraZeneca** for its past fraudulent conduct. It has nothing to do with complying with federal regulations concerning the reimbursement of pharmacists in the post-lawsuit future.

The State has not "redefined AWP" in this lawsuit as suggested by **AstraZeneca**. Nor has the State tried to bypass CMS approval of its reimbursement formula or retroactively change its approved plan. **AstraZeneca's** preemption argument is simply an attack on the State's damages methodology, which the jury rejected.

Preemption is disfavored, and the presumption against federal preemption of a state law designed to foster public health has special force when it appears that two governments are pursuing "common purposes." *Pharm. Research & Mfrs. of Am. v. Walsh*, 538 U.S. 644, 666 (2003). The " 'strong medicine' " of federal preemption "is 'not casually to be dispensed . . . especially . . . when the federal statute creates a program, such as Medicaid, that utilizes cooperative federalism': 'Where coordinated state and federal efforts exist within a complementary ***81** administrative framework, and in the pursuit of common purposes, the case for federal preemption becomes a less persuasive one.' " *Pharm. Research & Mfrs. of Am. v. Concannon*, 249 F.3d 66, 75 (1st Cir. 2001) (citation omitted), *aff'd sub nom.*, 538 U.S. 644 (2003); *Wyeth v. Levine*, 2009 WL 529172, at *5, n.3 (U.S. March 4, 2009) (" 'Congress does not cavalierly pre-empt state-law causes of action.' ").

IV. ASTRAZENECA IS NOT ENTITLED TO A NEW TRIAL BASED ON JURY CHARGE, EVIDENTIARY, AND JURY POOL ARGUMENTS.

A. The Trial Court Properly Charged the Jury on Reliance.

AstraZeneca argues that the trial court abused its discretion by giving the pattern charges on fraud and reliance which had been specifically approved by this Court at the time of trial. However, the giving of the pattern charges was clearly not an abuse of discretion, particularly when viewed in light of the oral charge as a whole.

The trial court instructed the jury as follows:

> **AstraZeneca** denies making any false statement, and it asserts that the State knew or *reasonably should have known* throughout the period at issue that average wholesale price did not represent ***82** an average of actual transaction price . . . .

R.2317 (emphasis added).

> **AstraZeneca** also asserts . . . *the State could not have reasonably relied* upon those prices as being an average of all actual transaction prices.

R.2318 (emphasis added).

> To recover damages on this [fraud] claim, the State must prove to your reasonable satisfaction all of the following . . . that **AstraZeneca** intended for the State to rely on this reported WAC and AWP prices; that the State *relied* on **AstraZeneca** reported WAC and AWP prices; and that the State *acted in reliance* on **AstraZeneca** reported WAC and AWP prices and was harmed.

R.2318-19 (charging APJI 18.01, emphasis added).

> I charge you a plaintiff suing for fraud must have relied on the important fact by acting on the important fact. You must take into account the circumstances that existed at the time in deciding if the State relied on the important fact.

R.2322 (charging APJI 18.10).

The trial court also instructed the jury:

> If the State of Alabama, on the other hand, has not met its burden of proof, then your verdict should be for **AstraZeneca**.

R.2306.

> ***83** And you're going to tell - you're going to resolve the issues that exist between the State of Alabama and **AstraZeneca** Pharmaceutical Company.

R.2307.

The charges given substantially and fairly detail the claims made and the parties' position on those claims, including reasonable reliance, leaving the jury to "resolve the issues." R.2307; *see also* R.2316, 2318-19.

Ignoring the totality of the overall jury charge, **AstraZeneca** argues that the pattern charges were insufficient and that the trial court abused its discretion by refusing to issue certain proposed charges on reliance. However, "the law is clear that the refusal of a requested charge is not error where the trial court's oral charge 'substantially and fairly' covers the same principles as the requested charge." *Volkswagen of Am., Inc. v. Marinelli*, 628 So. 2d 378, 385 (Ala. 1993) (quoting Ala. R. Civ. P. 51).

"The trial court is vested with broad discretion in formulating its charge, and the jury charge must be considered as a whole." *Williams v. State*, 611 So. 2d 1119, 1123 (Ala. Crim. App. 1992); *see also Murray v. Ala. Power Co.*, 413 So. 2d 1109, 1113 (Ala. 1982) ("[A]n ***84** oral charge must be considered as a whole, and if the entire charge states the law correctly, then no reversible error has been committed even though when considered alone a single part of the charge might be considered erroneous.").

The Alabama Rules of Civil Procedure also provide:

> No judgment may be reversed or set aside, nor new trial granted in any civil or criminal case on the ground of misdirection of the jury, the giving or refusal of special charges . . . unless in the opinion of the court to which the appeal is taken or application is made, after an examination of the entire cause, it should appear that the error complained of has probably injuriously affected substantial rights of the parties.

Ala. R. Civ. P. 45.

The trial court issued the pattern charges on the elements of fraud. This Court has recommended the use of pattern jury instructions. See Order of the Supreme Court of Alabama Approving Use of Alabama Pattern Jury Instructions (April 19, 1973), *Alabama Pattern Jury-Instructions Civil* (2d ed. 1993) at p. xx ("The publication by the Alabama Pattern Jury Instructions Committee of Alabama Pattern Jury Instructions in Civil Cases and their use by the trial judges of this state are recommended . . . ***85** ."); *see also Wren v. Blackburn*, 304 So. 2d 187, 192-93 (Ala. 1974) (noting Court's general approval of pattern charges).

In addition, in the ten years from the date the Court re-imposed the reasonable reliance standard to the 2008 revisions to the pattern fraud charges (which were adopted *after* the **AstraZeneca** trial), the pattern fraud charges were issued in hundreds of trials all over the state. *During that time, there is not one appellate decision reported in the State in which the pattern fraud charges were challenged as incorrect or incomplete under existing law or in which the court concluded the pattern fraud charges were erroneously given, requiring a new trial on that basis.*

The cases cited by **AstraZeneca** do not establish that the issuance of the pattern charges in this case was error. **AstraZeneca** cites, for instance, *Prowell v. Children's Hospital of Alabama*, 949 So. 2d 117 (Ala. 2006), a case in which this Court held that the trial court's giving of a pattern charge stating that a physician was justified in accepting another physician's diagnosis

invaded the jury's province in determining whether the physician breached a ***86** standard of care. The Court did not rule that the pattern instruction was an incorrect statement of the law, but merely that given the particular circumstances, the instruction "was misleading and confusing" to the jury. *Id*. at 133-35.

Similarly, in *Cackowski v. Wal-Mart Stores, Inc.*, 767 So. 2d 319 (Ala. 2000), this Court did not hold the trial court in error for giving a pattern charge, but determined that the court's charge (only portions of which were based on a pattern charge) was erroneous because it did not make clear that each party was required to prove its case by substantial evidence "in the relatively rare situation . . . where contributory negligence is an issue in a medical-malpractice case." *Id*. at 330. In other words, the burden of proof charges given were inconsistent and unbalanced. *Id*. Neither of these cases, which are factually unique, supports a conclusion that the trial court's giving of pattern charges in this case was error.

In this case the trial court correctly instructed the jury with the pattern charges on the elements of fraud. The trial court's instructions to the jury, taken as a whole, substantially and fairly instructed the jury ***87** concerning reliance. There was no reversible error. *See Griggs v. Finley*, 565 So. 2d 154, 160 (Ala. 1990) ("When a trial court's oral charge is a correct statement of the law, there is no reversible error.").

AstraZeneca also argues that the trial court erred in refusing to give two additional proposed charges to the jury to the effect that the State is charged with knowledge of information contained in documents within the State's possession. *See* C.395, 396. Neither of these requested instructions was necessary because (i) they do not address an essential element of the State's claim or an affirmative defense of **AstraZeneca**; (ii) the charges are unbalanced as they attempt to emphasize certain pieces of evidence over others; (iii) there are no similar charges in the pattern instructions; and (iv) the trial court instructed the jury that it was to consider the evidence in the case which came from the witness stand and "the documents, tangible evidence that I have admitted into this trial," which included documents within the State's possession. R.2309. The trial court also charged the jury to take its "common sense" to the jury room. *Id*. Given these circumstances, the trial court certainly did not commit prejudicial and ***88** reversible error by refusing **AstraZeneca's** requested charges.

B. The Trial Court Did Not Abuse Its Discretion by Admitting Pattern and Practice Evidence.

The trial court did not abuse its discretion by admitting evidence of **AstraZeneca's** plea of guilty to criminal fraud violations concerning the drug Zoladex as pattern and practice evidence. This Court has explained: "We review the admissibility of 'pattern-or-practice' evidence on a fraud claim by an abuse-of-discretion standard." *Morris v. Laster*, 821 So. 2d 923, 926 (Ala. 2001).

1. Evidence of similar acts admissible

Evidence of other crimes, wrongs or acts may be admissible for matters "such as proof of motive, opportunity, intent, preparation, plan, knowledge, identity, or absence of mistake or accident[.]" Ala. R. Evid. 404(b); *see Life Ins. Co. of Ga. v. Smith*, 719 So. 2d 797, 808 (Ala. 1998) (internal citations, quotations, and emphasis omitted). Moreover, "[e]vidence of . . .. the routine practice of an organization ... is relevant to prove that the conduct of the organization on a particular ***89** occasion was in conformity with. . .the habit or routine practice." Ala. R. Evid. 406.

This Court has recognized the liberality of the rule:

> As previously noted, in fraud cases, where intent, knowledge, and scienter constitute essential elements of the offense, evidence of similar frauds and misrepresentations is admissible. In passing upon the admissibility of such collateral matters, *great latitude must be extended so as to allow the admission of any relevant evidence* bearing upon the ultimate issue of fraud. In this respect, questions of relevancy rest largely within the discretion of the trial court. Its ruling concerning the relevancy of pattern and practice evidence should not be disturbed on appeal unless the court's discretion has been abused.

Foremost Ins. Co. v. Parham, 693 So. 2d 409, 429 (Ala. 1997) (emphasis added).

Alabama courts have repeatedly allowed the introduction of evidence of similar fraudulent schemes. *See, e.g.*, *Morris v. Laster*, 821 So. 2d at 927-28 (evidence of misrepresentations to prior customers); *Sessions Co. Inc. v. Turner*, 493 So. 2d 1387, 1391 (Ala. 1986) (evidence of prior misrepresentations); *Potomac Leasing Co. v. Bulger*, 531 So. 2d 307, 309-11 (Ala. 1988) (evidence of fraud concerning other transactions); *Valentine v. World Omni Leasing, Inc.*, 601 So. 2d 1006, 1008-09 (Ala. Civ. App. 1992) (holding that trial court committed reversible error ***90** by *not* admitting evidence of fraud concerning prior lease agreements).

AstraZeneca's criminal fraud conduct concerning Zoladex was substantially similar and contemporaneous to the acts at issue in this case, and such evidence was admissible to show **AstraZeneca's** knowledge, intent, notice, lack of mistake and common fraudulent plan and scheme. The trial court clearly instructed the jury that the State made no claim for damages regarding Zoladex, but that the evidence concerning Zoladex was admitted for the "sole purpose" of showing "a pattern and practice. . . and to show notice, intent, and lack of mistake. . . ." R.2332-33.

2. AstraZeneca's Zoladex scheme and guilty plea

In 2003, **AstraZeneca** entered a plea of guilty to conspiring to violate the Prescription Drug Marketing Act in violation of 18 U.S.C. § 371, which criminalizes a conspiracy "to commit any offense against the United States, or to defraud the United States."

At the plea hearing, **AstraZeneca's** vice president and general counsel entered the plea on behalf of the company stipulating that certain **AstraZeneca** employees provided the drug Zoladex to physicians knowing that the physicians ***91** would prescribe and administer the drug and seek reimbursement in violation of federal law. [28] PX 940 (R.850).

AstraZeneca and the United States entered into a Memorandum of Plea Agreement which was accepted by the court. S.6054-61. The Memorandum of Plea Agreement incorporated a civil settlement between **AstraZeneca** and the United States which was enforceable through the criminal plea. *Id*. Performance of the civil settlement was imposed as a condition of Defendant's criminal probation. *Id*.

The Settlement Agreement, which was incorporated into Defendant's criminal guilty plea, provided:
The United States . . . contends that Zeneca's Return-to-Practice program consisted of inflating the Average Wholesale Price ("AWP") used by Medicare and others for reimbursement of the drug, deeply discounting the price paid by physicians to Zeneca for the drug ("the discounted price"), and ***92** marketing the spread between the AWP and the discounted price to physicians as additional profit to be returned to the physician's practice from Medicare reimbursements for Zoladex. The United States further contends that Zeneca falsely advised physicians that the discounted price could not and should not be reported to Medicare.

(iv) The United States contends that Zeneca engaged in a marketing scheme where it set an AWP for Zoladex at levels far higher than the majority of its physician customers actually paid for the drug when purchasing from Zeneca. As a result, the United States contends that Zeneca's customers received reimbursement from Medicare and state Medicaid programs and others at levels substantially higher than the physicians' actual costs or the wholesaler's average price.

S. 5414. [29]

As shown, **AstraZeneca's** criminal plea regarding Zoladex related to AWP and spread allegations substantially similar to and contemporaneous with the allegations made by the State in this case. The trial court therefore properly admitted the pattern and practice evidence regarding Zoladex, which also constituted a party admission.

***93 C. The Trial Court Acted within Its Discretion by Excluding Certain Evidence during Trial which It Deemed Irrelevant, Immaterial, Privileged, or Otherwise Inadmissible.**

It is not this Court's role to micromanage the evidentiary rulings of a trial court. The trial court "has *great discretion* in determining whether evidence . . . is relevant and whether it should be admitted or excluded." *Van Voorst v. Fed. Express Corp.*, 2008 WL 4447590, at *5 (Ala. Oct. 3, 2008). **AstraZeneca** fails to satisfy the high burden establishing abuse of discretion in connection with the trial court's exclusion of evidence that it determined was irrelevant, speculative, privileged and otherwise inadmissible.

1. The trial court properly excluded the 2002 Attorney General "investigation" file materials and communications as privileged.

AstraZeneca repeatedly attempted prior to and during trial to require the State to produce documents that, by **AstraZeneca's** own description, are clearly protected by the attorney-client privilege.[30] *See, e.g.*, R.395-96, 501-05, ***94** 638-42, 841-45, 881-87, 1014-17, 1334-37, 1402-03, 1447-53, 1702. During trial, the special masters and trial judge reviewed the Attorney General materials *in camera*, including a memo prepared by Professor Mike DeBow, who served as a Special Assistant Attorney General to Attorney General Bill Pryor in 2002.[31] R.881-85, 1334-36. The court ruled that, with the exception of four documents, the materials in the Attorney General's file were privileged. R.881-82. The court also ruled that the DeBow memo was privileged.[32] R.1335. These rulings are without error, and the trial court did not abuse its discretion in reviewing the subject documents *in camera* and in preventing their production and exclusion from evidence upon determining that they were privileged. *See* Ala. R. Evid. 502(b)(5) (the ***95** attorney-client privilege cloaks communications between attorneys representing the same client).

The State did not impliedly waive the attorney-client privilege by filing this case. "A party does not lose the privilege to protect attorney client communications from disclosure in discovery when his or her state of mind is put in issue in the action." *Rhone-Poulenc Rorer Inc. v. Home Indem. Co.*, 32 F.3d 851, 864 (3d Cir. 1994); *see also In re Divine Tower Int'l Corp.*, 2007 WL 1108457, at *2 (S.D. Ohio April 10, 2007). Fraud claims are common, "and it would substantially undercut the attorney-client privilege if the privilege were deemed waived in every case where a party made a claim of reasonable reliance upon the misrepresentation or omissions of the other party." *In re Divine Tower*, 2007 WL 1108457 at *2.

AstraZeneca's reliance on *Ex parte Meadowbrook Ins. Group, Inc.*, 987 So. 2d 540 (Ala. 2007), is misplaced. There, the defendants asserted "advice of counsel" in defense to a tort of outrage claim. *Id.* at 550-51. As a result, the attorney's actual advice itself became an issue. *Id.* In contrast, the State has not asserted advice of counsel as an affirmative defense in this case, nor has ***96** it voluntarily testified regarding portions of attorney-client communications or placed the relationship itself at issue. To suggest, as **AstraZeneca** does, that a privilege is waived any time there is a communication that may bear some relevance to the issue of reasonable reliance would be a gross expansion of a deliberately narrow implied waiver exception. The exception would swallow the rule and eradicate the privilege.

For these reasons, the trial court did not abuse its discretion in excluding privileged communications from evidence, and **AstraZeneca** is not entitled to a new trial on this basis.

2. The trial court did not abuse its discretion in excluding testimony from individual pharmacists and industry lobbyists because it was irrelevant, speculative, cumulative, and hearsay.

The State moved to exclude the testimony of three pharmacists and two pharmacy association lobbyists from whom **AstraZeneca** intended to elicit testimony concerning what "everyone knew" about AWP and WAC, the alleged impact on individual pharmacies of the State's damages methodology, and individual pharmacy profits and losses. S.6883-88, 6918-7029. The State demonstrated that the ***97** proffered pharmacist testimony was inadmissible because it constituted improper ultimate issue testimony, contained improper lay opinion and hearsay, was not based on personal knowledge, and was speculative and irrelevant. *See* S.6883-88; *see also* R.1716-17.

The State further explained that "this case is not about pharmacists. This case is about whether or not **AstraZeneca** reported true prices to Alabama Medicaid." R.1717. The trial court agreed, stating as follows:
Well, if I let pharmacists come in, you'll go out and round up everybody on Medicaid and bring them in here to testify, and that's just a balance. . .

I'm not going to allow the pharmacists because it's not about pharmacists. I'm not going to allow beneficiaries because it's not about beneficiaries.

R.1717. The trial court's exclusion of the pharmacist evidence was, therefore, fair and balanced and not an abuse of the court's discretion.

The trial court did not abuse its discretion in excluding the testimony of two pharmacy industry lobbyists, John Rector and Dale Masten, because their testimony was an inappropriate attempt by **AstraZeneca** to introduce what amounted to expert opinions through inadmissible lay witness testimony. S.6918-7029. Their testimony was also ***98** properly excluded because it contained conclusory and speculative statements that improperly embraced the ultimate issues to be decided by the jury, and was otherwise irrelevant and prejudicial. S.6918-7029; R.1707, *see also* R.1712-13. The trial court explained:

> Well, this case is not about . . . the pharmacy. . . . This case is not about folks who are on Medicaid, the recipient of Medicaid, who benefits from Medicaid. This case is not about pharmacists. This case is about whether or not **AstraZeneca** knowingly overpriced or didn't give the State of Alabama the correct price and - for reimbursement purposes. Now, that's all we're going to let into this trial.

R.1707-08; *see also* R.1709-10.

AstraZeneca was allowed to present evidence through its expert witnesses concerning individual pharmacy profits and losses, which was one topic for which **AstraZeneca** offered the individual pharmacist and lobbyist testimony. R.1935-37, 2082-90); DX 2399 (R.2090); DX 2400 (R.2090); DX 2401 (R.2090; DX 2402 (R.2090). Given the allowed presentation of evidence on this point, the individual pharmacist and lobbyist testimony would be cumulative, and if there was any error in the exclusion of their testimony (which there was not), it was harmless. *City of Gulf Shores v. Harbert Int'l*, 608 So. 2d 348, 354 (Ala. 1992).

***99 D. The Trial Court Did Not Abuse Its Discretion by Refusing to Strike for Cause State Employees (Who Did Not Work for Alabama Medicaid) from the Jury Venire.**

The trial court did not abuse its broad discretion in rejecting challenges for cause to state employees who were members of the jury venire. All state employees on the jury venire affirmed that their employment would not affect their ability to fairly hear and decide the case. R.577-78. Only two state employees were selected to serve on the jury and neither was employed with Alabama Medicaid. R.460, 462.

"To justify a challenge of a juror for cause there must be a statutory ground . . . or some matter which imports absolute bias or favor, and leaves nothing to the discretion of the trial court." *Nettles v. State*, 435 So. 2d 146, 149 (Ala. Crim. App. 1983). The appropriate test "is whether the juror can eliminate the influence of previous feelings and render a verdict according to the evidence and the law." *Ex parte Trawick*, 698 So. 2d 162, 168 (Ala. 1997). The trial court has "broad discretion in regard to sustaining or denying a challenge for cause, and his decision is therefore entitled to great weight and will not be interfered with unless it is clearly erroneous and ***100** equivalent to an abuse of discretion." *Roberts v. Hutchins*, 613 So. 2d 348, 350 (Ala. 1993).

AstraZeneca argues that state employees in the venire should have been stricken for cause. Alabama courts, however, have ruled that mere status as a state employee does not render a person ineligible to serve on a jury where the state is a party. *See, e.g.*, *Lowe v. State*, 384 So. 2d 1164, 1170 (Ala. Crim. App. 1980) ("[T]he imputation of bias simply by virtue of any governmental employment, without regard to any actual partiality growing out of the nature and circumstances of particular cases, rests on an assumption without any rational foundation."); *Brown v. State*, 74 So. 2d 273, 274 (Ala. Ct. App. 1954), *aff'd*, 74 So. 2d 277 (Ala. 1954) (state employee not subject to challenge for cause where state is party); *McAdory v. State*, 68 So. 2d 68, 69-70 (Ala. Ct. App. 1953) (state employee not subject to challenge for cause where state is party).

AstraZeneca's counsel examined the venire and was assured that state employment would not affect any juror's ability to render a fair and impartial verdict in the case. R.578. Finding no evidence of bias or prejudice, the trial ***101** court properly ruled that none of the jurors was subject to challenge for cause merely due to their state employment. R.607. **AstraZeneca's** arguments concerning state employees in the jury venire are without merit.

V. ASTRAZENECA'S CHALLENGE OF THE STATE'S COMPENSATORY DAMAGES METHODOLOGY LACKS MERIT.

The State presented substantial evidence of damages resulting from its use of **AstraZeneca's** false and inflated reports prices. The State's damages methodology is consistent with Alabama law concerning the measure of compensatory damages a victim of fraud may recover: that is, "an amount which would place the defrauded person in the position he would occupy if the representations had been true." *Liberty Nat'l Life Ins. Co. v. Sanders*, 792 So. 2d 1069, 1075 (Ala. 2000). The State's compensatory damages were calculated to a reasonable degree of certainty by an experienced accountant whom the court accepted as a damages expert.[33] R.1544-47. **AstraZeneca** did not present any alternative damages theory or calculation. R.2110. Instead, **AstraZeneca** cross-examined the State's damages expert and offered its own damages expert to criticize the ***102** State's calculations. *See, e.g.*, R.1596-1683, 2068-69. There is no legal basis for this Court to reverse the jury's compensatory damages award, which was supported by the evidence. Any factual or credibility dispute was properly left for the jury, which decided those issues in favor of the State. *Floyd v. Broughton*, 664 So. 2d 897, 899 (Ala. 1995).

A. The State's "Should Have Paid Price" Properly Incorporated AMA's Approved Reimbursement Methodology.

The State's damages reflect the difference between what it actually reimbursed paid pharmacies for **AstraZeneca's** drugs and what it should have paid pharmacies for **AstraZeneca's** drugs had true prices been reported. R.1571, 1581-83. To arrive at the "should have paid" price, the State's damages expert, Ed Sauls, applied the same AMA approved reimbursement methodology to Cardinal's sales data, which was a conservative estimate of true marketplace sales prices to pharmacies.[34] R.1569-71, 1581-82. In other ***103** words, Sauls compared the reimbursement price, 91% of reported AWP, to the "should have paid" price, 91% of true marketplace AWP.[35]

Applying AMA's reimbursement methodology to only one side of the damages equation, as **AstraZeneca** suggests, would have resulted in a lop-sided or uneven application of the reimbursement formula. R.1598-99, 1690. In fact, **AstraZeneca's** damages expert conceded that AMA's reimbursement formula would have been applied and used regardless of whether **AstraZeneca** was

reporting true or false prices. R.2132. Therefore, comparing the reimbursement price, which incorporates AMA's methodology, to a should-have-paid price, which also incorporates AMA's methodology, was the proper comparison for damages calculation purposes.

AstraZeneca's criticism of the State's damages methodology is without merit on all fronts. First, Sauls' use of Cardinal prices as a conservative source of true marketplace AWP was not disputed by **AstraZeneca** at trial. ***104** *See* R.1570-71. In fact, the evidence reflected that the Cardinal prices used by Sauls were, in some cases, actually higher than Cardinal's dead net prices, thereby keeping the damages lower. R.1570-71.

Second, the State's two-pronged formula -- WAC + 9.2% or AWP - 10% -- is designed to arrive at the same estimated acquisition cost (EAC) from two different directions. Sauls' methodology recognized this, and his approach was appropriate regardless of whether AMA reimbursed for **AstraZeneca's** drugs on the basis of AWP or WAC. The damages methodology was an EAC approach, consistent with the federal regulations governing Medicaid reimbursement.

Third, **AstraZeneca's** speculation about whether CMS would approve in the future a new AMA reimbursement formula (based on pharmacy access assessments) is entirely unrelated to the question of damages for past fraudulent conduct by **AstraZeneca**. The damages methodology used by the State's expert derived from the reimbursement process in place during the claims period of the lawsuit, which both **AstraZeneca** and the pharmacists accepted when they elected to participate in Alabama's Medicaid program.

***105 B. The Trial Court Properly Instructed the Jury That It May Not Offset Any Damages Award by Federal Funding Received by the State.**

Although it receives federal funding like many state agencies, AMA is totally responsible for operating the State's program. R.1727. All pharmacy reimbursements for **AstraZeneca** drugs are paid directly by AMA; payments are not made by the federal government. R.1727-28. Under federal regulations, the State is responsible for pursuing a claim against a third party when it believes it has been defrauded. R.1728-29; *see also* 42 U.S.C. §§ 1396a, 1396k. The State is charged with recovering *all monies paid*, regardless of the federal funding percentage. R.1728-29. It is not appropriate to offset the State's damages by the federal funding share. R.1730.

In order to place AMA in the position it would have been in had **AstraZeneca** reported true prices, the full overpayment is due AMA as compensatory damages, not just 30% of the overpayment. *See Buchanan v. Collier*, 555 So. 2d 134, 136 (Ala. 1989) ("Where a plaintiff has suffered damage due to fraudulent conduct of a defendant, the measure of damages is the amount required to place the ***106** plaintiff in the position he would have been in had the representations by the defendant been true."). [36]

The trial court instructed the jury on this point as follows:

> I charge you the State of Alabama, not the federal government, administers the Alabama Medicaid program in Alabama and reimburses the pharmacists for **AstraZeneca** prescription drugs. The fact that Medicaid is a program jointly funded by both state and federal governments has no bearing on the State's claim for damages in this case. If you determine that the State is entitled to damages, then you may not offset or reduce such damages by any federal funding by the Alabama Medicaid program.

R. 2331. The jury charge is supported by the evidence and is an accurate statement of law. The trial court did not abuse its discretion by giving this instruction.

The case cited by **AstraZeneca**, *Edwards v. Allied Home Mortgage Capital Corp.*, 962 So. 2d 194 (Ala. 2007), is ***107** easily distinguished as it involved the unique application of the check conversion statute, Ala. Code § 7-3-420, and does not apply to a jointly funded but solely state-administered program as Medicaid.

VI. THE $120 MILLION PUNITIVE DAMAGES JUDGMENT IS SUPPORTED BY CLEAR AND CONVINCING EVIDENCE AND APPLICABLE LAW.

A. The State Is Entitled to Punitive Damages.

1. Punitive damages may be awarded upon a finding of intent to defraud.

The State presented evidence at trial sufficient to support an award of punitive damages. Punitive damages may be awarded "in a tort action where it is proven by clear and convincing evidence that the defendant consciously or deliberately engaged in oppression, fraud, wantonness, or malice with regard to the plaintiff." Ala. Code § 6-11-20(a). Fraud is defined 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.

Ala. Code § 6-11-20(b)(1). This definition does not, as **AstraZeneca** contends, require a showing of fraud that is greater than intentional fraud. "The terms 'malicious' and ***108** 'oppressive,' . . . and the term 'gross,' . . . are subsumed within the definition of fraud in § 6-11-20(b)(1)." *McIver v. Bondy's Ford, Inc.*, 963 So. 2d 136, 144 (Ala. Civ. App. 2007) (quoting *Prudential Ballard Realty Co. v. Weatherly*, 792 So. 2d 1045, 1049 (Ala. 2000)). As this Court explained in *Weatherly:*

[I]t cannot seriously be argued that an intentional act of fraud committed for the purpose of "depriving a person or entity of property or legal rights or otherwise causing injury," is not a gross, malicious, or oppressive act, as those terms are defined in § 6-11-20. In short, *for the purposes of applying § 6-11-20(b)(1), the terms "gross," "malicious," and "oppressive" are redundant.*

792 So. 2d at 1049 (emphasis added); *see also German Auto, Inc. v. Tamburello*, 565 So. 2d 238, 240 (Ala. 1990) ("Punitive damages may be awarded if there is a finding of intent to deceive or defraud."); *Alabama Farm Bureau Mut. Cas. Ins. Co. v. Griffin*, 493 So. 2d 1379, 1384 (Ala. 1986) ("Once an intent to deceive has been established, it is difficult to understand that the fraud was not committed grossly.").

2. The State proved intentional fraud at trial.

The State presented evidence at trial of such quality and weight that a jury of reasonable and fair-minded ***109** persons could find by clear and convincing evidence that **AstraZeneca** consciously or deliberately engaged in fraud. *See Ex parte Norwood Hodges Motor Co., Inc.*, 680 So. 2d 245, 249-50 (Ala. 1996); *see also Shiv-Ram, Inc. v. McCaleb*, 892 So. 2d 299, 313-15 (Ala. 2003). The State proved by clear and convincing evidence that **AstraZeneca** engaged in a long-running scheme of intentional fraud. The State proved that **AstraZeneca** knowingly reported inflated AWP and WAC prices to First DataBank, while concealing true transactional prices, for the purpose of manipulating the "spread" between reported and actual prices. R.774-78, 796-98; 967-70; PX 40 (R.1189); *See* PX 961 (R.850). **AstraZeneca** knew that larger spreads between actual acquisition costs and reported prices meant greater reimbursement to providers and market share for itself. *See* PX 966 (R. 850); R.793, 967, 969-72, 1002. **AstraZeneca** intentionally manipulated its prices to induce customers to purchase its products, disadvantaging state Medicaid programs that **AstraZeneca** knew relied upon its reported prices for reimbursement. R.798, 805-11, 816-19, 893-96, 955-56, 1036-40.

***110 B. The Punitive Damages Award Complies with the Statutory Cap on Damages and Applicable Constitutional and Common Law Standards.**

1. The punitive damages award comports with alabama's statutory cap.

The punitive damages award entered in this case is consistent with the statutory cap on punitive damages, which limits an award of punitive damages to three times the amount of compensatory damages. Ala. Code § 6-11-21(a). The ratio of punitive damages to compensatory damages as remitted by the trial court is 3:1, which complies with the cap. S.8016-23.

2. Pre-judgment interest should be included.

It is appropriate for the measure of compensatory damages considered in evaluating the ratio of compensatory to punitive damages to include pre-judgment interest. The evidence presented by the State established, and the jury found, that the State incurred $40 million in compensatory damages, inclusive of losses and pre-judgment interest thereon.

"[P]rejudgment interest is allowable at the legal rate in noncontract cases where the damages can be ascertained by mere computation, or where the damages are complete at a given time so as to be capable of determination at such ***111** time in accordance with known standards of value." *Nelson v. AmSouth Bank, N.A.*, 622 So. 2d 894, 895 (Ala. 1993); *see also* Ala. Code § 8-8-1 (legal rate of interest 6%); *Hunt v. Ward*, 79 So. 2d 20, 25 (Ala. 1955) (6% pre-judgment interest applies to tort claim). Where the damages are ascertainable by mere computation, a plaintiff may recover pre-judgment interest for fraud claims. *See, e.g., Lapeyrouse Grain Corp. v. Tallant*, 439 So. 2d 105, 111-12 (Ala. 1983) (plaintiff entitled to prejudgment interest in action for fraud). The State's damages in this case were clearly ascertainable by mere computation, and the State was entitled to the recovery of pre-judgment interest.

Pre-judgment interest constitutes a portion of the State's compensatory damages. *See Milwaukee v. Cement Div., Nat'l Gypsum Co.*, 515 U.S. 189, 195 (1995) ("The essential rationale for awarding prejudgment interest is to ensure that an injured party is fully compensated for its loss."); *West Virginia v. United States*, 479 U.S. 305, 310-311 n.2 (1987) ("Prejudgment interest serves to compensate for the loss of use of money due as damages from the time the claim accrues until judgment is entered, thereby ***112** achieving full compensation for the injury those damages are intended to redress.").

3. Punitive damages serve legitimate state interests.

Punitive damages in this case serve the State's lawful and legitimate interest in punishing **AstraZeneca's** fraudulent conduct and in deterring its repetition. *See BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 568 (1996). The State may legitimately protect itself and "its citizens by prohibiting deceptive trade practices[.]" *Id*. at 568-69.

The states "have considerable flexibility in determining the level of punitive damages that they will allow in different classes of cases and in any particular case." *Id*. at 568. The United States Supreme Court has made clear that "[o]nly when an award can fairly be categorized as '*grossly excessive*' in relation to these interests [of punishment and deterrence] does it enter the zone of arbitrariness that violates the Due Process Clause of the Fourteenth Amendment." *Id*. (emphasis added).

AstraZeneca's argument that punitive damages in this case serve no legitimate retributive or deterrent purpose is baseless. Punitive damages should deter **AstraZeneca** from continuing to report false and inflated prices that it ***113** knows AMA must rely upon to reimburse pharmacies in the Medicaid program. **AstraZeneca's** attempt to disclaim any ability to report accurate WAC or AWP prices cannot stand and is contradicted by the evidence. **AstraZeneca** could easily report true WAC and AWP prices to AMA, and **AstraZeneca's** refusal to do so was rightly punished. *See In re Pharm. Indus. Average Wholesale Price Litig.*, 321 F. Supp. 2d 187, 200 (D. Mass. 2004) ("Even if state courts came up with varying definitions, at worst, manufacturers would simply have to make accounting adjustments to report and file state-specific . . . reports, which is overall not a heavy

burden. While the state law fraud claims may pose some impediments to a nationwide drug program, these obstacles are not significant.").

Punitive damages are also justified as retribution for perpetrating nearly fifteen years of fraud upon the State. As discussed above, federal law does not "plainly allow" **AstraZeneca** to report false and misleading prices while concealing true prices for the purpose of deceiving the State. **AstraZeneca's** contention that the State "understood and accepted for decades" that it was being defrauded was ***114** resoundingly rejected by the jury and should also be by this Court.

4. The punitive damages award does not exceed federal constitutional limits.

In *Gore*, the United States Supreme Court articulated three guideposts to aid state courts in evaluating whether punitive damages are so excessive as to violate the Due Process Clause of the United States Constitution: "the degree of reprehensibility [of defendant's actions]; the disparity between the harm or potential harm suffered [by plaintiff] and [plaintiff's] punitive damages award; and the difference between this remedy and the civil penalties authorized or imposed in comparable cases." 517 U.S. at 574-75. The Due Process Clause is not a mechanism for undercutting a jury's verdict; to the contrary, the constitutional analysis mandated is confined to the question of whether a punitive damages award is a "grossly excessive or arbitrary punishment []." *State Farm Mut. Auto Ins. Co. v. Campbell*, 538 U.S. 408, 416 (2003). The award in this case does not come close to violating that constitutional standard.

***115 a. AstraZeneca's behavior was reprehensible.**

AstraZeneca's conduct was reprehensible and justified the punitive damages awarded. The *Campbell* court analyzed reprehensibility as follows:

> We have instructed courts to determine the reprehensibility of a defendant by considering whether: the harm caused was physical as opposed to economic; the tortious conduct evinced an indifference to or a reckless disregard of the health or safety of others; the target of the conduct had financial vulnerability; the conduct involved repeated actions or was an isolated incident; and the harm was the result of intentional malice, trickery, or deceit, or mere accident.

538 U.S. at 419 (citing *Gore*, 517 U.S. at 576-77).

AstraZeneca would have this Court believe that there can be no punitive damages awarded in cases of purely economic harm, but the "infliction of economic injury, especially when done intentionally through affirmative acts of misconduct, or when the target is financially vulnerable, can warrant a substantial penalty." *Gore*, 517 U.S. at 576 (internal citations omitted).

AstraZeneca's argument that AMA is not financially vulnerable because it is well run and makes the best use possible of consistently limited and often insufficient funds is unconvincing. **AstraZeneca** essentially diverted ***116** funds away from the financially constrained State agency charged with providing health care services to the State's most vulnerable citizens, and these actions evinced a flagrant disregard for the health and safety of those affected by Medicaid's overpayment of millions of dollars for **AstraZeneca's** drugs. [37]

AstraZeneca's fraud had serious ramifications. As the trial court observed in its order on **AstraZeneca's** post-judgment motions, "the State established that [**AstraZeneca's**] wrongful conduct deprived the State of limited funds available for the State's Medicaid recipients." S.8019. Commissioner Steckel testified that lack of funding strongly impacted AMA and that **AstraZeneca's** fraud denied Alabama residents the benefits of much needed programs and services. R.1327-29.

Moreover, **AstraZeneca's** deceit spanned nearly fifteen years. *See* PX 1237A (R.1592). It continued after **AstraZeneca** was sanctioned for similar misconduct in the marketing of the drug Zoladex. *See* R.765, PX 940 (R.850). ***117** It continued, and even spiked,[38] after the OIG issued guidelines making clear that **AstraZeneca's** method of reporting falsely inflated prices was prohibited. R.831-34; PX 973 (R.850). The Gore Court stated that continued bad actions may merit stronger punishment:

Certainly, evidence that a defendant has repeatedly engaged in prohibited conduct while knowing or suspecting that it was unlawful would provide relevant support for an argument that strong medicine is required to cure the defendant's disrespect for the law. Our holdings that a recidivist may be punished more severely than a first offender recognize that repeated misconduct is more reprehensible than an individual instance of malfeasance.

517 U.S. at 576-77.

b. The 3:1 ratio is appropriate.

The ratio of punitive to compensatory damages is 3:1. This ratio is well within the accepted parameters found in applicable case law and raises no constitutional concerns. *See Harrelson v. R.J.*, 882 So. 2d 317, 324-25 (Ala. 2003) (upholding 5:1 ratio); *Mercy Med. v. Gray*, 864 So. 2d 354, 365 (Ala. Civ. App. 2002) (upholding 10.3:1 ratio); ***118** *Gold Kist, Inc. v. Hood*, 773 So. 2d 1031, 1038 (Ala. Civ. App. 1999) (upholding 19:1 ratio); *Bogle v. McClure*, 332 F.3d 1347, 1362 (11th Cir. 2003) (upholding 4:1 ratio).

There is no bright-line test establishing the acceptable ratio between punitive and compensatory damages (aside from the treble damages cap found in Alabama Code § 6-11-21(a)). The United States Supreme Court has consistently reaffirmed the fluidity of its due process analysis of punitive damages:

Once again, "we return to what we said ... in *Haslip:* 'We need not and indeed we cannot, draw a mathematical bright line between the constitutionally acceptable and the constitutionally unacceptable that would fit every case.' " ... In most cases, the ratio will be within a constitutionally acceptable range, and remittitur will not be justified on this basis. . . .

[W]e are not prepared to draw a bright line marking the limits of a constitutionally acceptable punitive damages award.

Gore, 517 U.S. at 582-83; *see also Campbell*, 538 U.S. at 425 ("We decline again to impose a bright-line ratio which a punitive damages award cannot exceed. . . . [T]here are no rigid benchmarks that a punitive damages award may not surpass[.]").

Contrary to what defendants argue, the *Campbell* Court did *not* hold that a 1:1 ratio is required where compensatory damages are substantial. Quite the opposite, the ***119** Court, in the context of discussing the very absence of any "rigid benchmarks," observed that "ratios greater than those . . . previously upheld may comport with due process. . . . [Conversely,] [w]hen compensatory damages are substantial, then a lesser ratio, *perhaps* only equal to compensatory damages, can reach the outermost limit of the due process guarantee." *Id*. (emphasis added). The Court promptly qualified this observation by reaffirming the individuality of each case: "The precise award in any case, of course, must be based upon the facts and circumstances of the defendant's conduct and the harm to the plaintiff." *Id*. at 425. Indeed, "the proper inquiry is 'whether there is a reasonable relationship between the punitive damages award and *the harm likely to result* from the defendant's conduct as well as the harm that actually has occurred.' " *Gore*, 517 U.S. at 581.

The *Gore* Court "referenced a long legislative history, dating back over 700 years and going forward to today, providing for sanctions of double, treble, or quadruple damages to deter and punish." *Campbell*, 538 U.S. at 425 (citing *Gore*, 517 U.S. at 581 and n.33). History has long affirmed the propriety of treble damages. Certainly, a ***120** ratio of 3:1 is at the lower end of the single-digit spectrum. *See id*.

c. Civil or criminal penalties for comparable misconduct

The comparable civil fine to be imposed against **AstraZeneca** for its conduct is $80 million, and the comparable criminal sanction is imprisonment of not more than twenty years or less than two years. *See* Ala. Code § 13A-5-11(a)(4) (fine for felony is "[a]ny amount not exceeding double the . . . loss to the victim") and Ala. Code §§ 13A-8-3 and 13A-5-6 (together defining theft of property in first degree and establishing criminal sanction for same). As the trial court found in its review, the punitive damages verdict in this case is comparable to the civil and criminal penalties potentially applicable under Alabama law. *See Gore*, 517 U.S. at 583 ("[A] reviewing court engaged in determining whether an award of punitive damages is excessive should 'accord substantial deference to legislative judgments concerning appropriate sanctions for the conduct at issue.' ") (quoting *Browning-Ferris Indus, of Vt., Inc. v. Kelco Disposal, Inc.*, 492 U.S. 257 (1989)); *see also* ***121** *Pac. Mut. Life Ins. Co. v. Haslip*, 499 U.S. 1, 23-24 (1991) (possible imprisonment relevant to due process analysis).

5. The Punitive Damages Award Is Due to be Affirmed Under *Hammond* and *Green Oil*.

In *Hammond v. City of Gadsden*, 493 So. 2d 1374 (Ala. 1986), and *Green Oil Co. v. Hornsby*, 539 So. 2d 218 (Ala. 1989), the Alabama Supreme Court articulated the common law factors to be evaluated in considering the propriety of a punitive damages award. The Court has directed that the following be considered in addition to the *Gore* factors:

> (1) the reprehensibility of [defendants'] conduct; (2) the relationship of the punitive-damages award to the harm that actually occurred, or is likely to occur, from [defendants'] conduct; (3) [defendants'] profit from its misconduct; (4) [defendants'] financial position; (5) the cost to [plaintiff] of the litigation; (6) whether [defendants have] been subject to criminal sanctions for similar conduct; and (7) other civil actions [defendants have] been involved in arising out of similar conduct.

Shiv-Ram, Inc., 892 So. 2d at 317; *see also AutoZone, Inc. v. Leonard*, 812 So. 2d 1179, 1187 (Ala. 2001). These factors were carefully considered by the trial court, and there is no basis for this Court to differ in its conclusion.

***122 a. Reprehensibility of AstraZeneca's conduct**

In its *Hammond/Green Oil* analysis, the Court is to consider "[t]he duration of the 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." *Shiv-Ram, Inc.*, 892 So. 2d at 317 (quoting *Green Oil*, 539 So. 2d at 223). For the reasons set forth above, **AstraZeneca's** conduct was thoroughly reprehensible and does not warrant any reduction of the punitive award.

b. Relationship of punitive award to harm incurred

As discussed above, the ratio of punitive to compensatory damages does not warrant any reduction of the award.

c. AstraZeneca's profit from misconduct

Punitive damages serve a retributive purpose. Thus, "[i]f the wrongful conduct was profitable to the defendant, the punitive damages should remove the profit and should be in excess of the profit, so that the defendant recognizes a loss." *Green Oil*, 539 So. 2d at 223 (internal citation and quotation omitted). In undertaking this analysis, Alabama ***123** courts have looked at whether the object of a defendant's misconduct was profit. *See, e.g.*, *Nat'l Ins. Ass'n v. Sockwell*, 829 So. 2d 111, 139 (Ala. 2002); *Mercy Med. v. Gray*, 864 So. 2d at 366. As shown at trial, **AstraZeneca** perpetrated the fraudulent scheme over the course of years for its own financial gain. *See, e.g.*, R.1560-61; DX 677 (R.1560-61) (evidence reflecting that for every dollar

of a prescription, 78 cents of that dollar stays with the manufacturer); R.893-96 (**AstraZeneca** used "return to practice" to increase its sales); PX 966 (R.850)(spread used to "drive market share"). **AstraZeneca's** fraudulent scheme for profit supports the existing punitive damages award without reduction.

d. AstraZeneca's financial position

AstraZeneca does not rely on its financial position as a ground for remittitur, and it expressly disclaimed any such reliance on its financial position as a ground to reduce the punitive award. C.738. In *Ex parte Vulcan Materials Co.*, 2008 WL 1838309 (Ala. April 25, 2008), this Court stated that where the defendant disclaims reliance on its financial position as a basis for a remittitur, "[t]hat disclaimer requires the trial court to weigh the ***124** relationship factor *against* a remittitur." *Id*. at *6 (emphasis added). **AstraZeneca** has thus admitted that payment of the full judgment will not have any material impact on its financial condition.

e. Cost of Litigation to the State

The State has incurred enormous litigation costs to obtain the verdict in this case, which weighs against reduction of the punitive damages award. In *Green Oil*, the Court directed trial courts to consider "[a]ll the costs of litigation . . . so as to encourage plaintiffs to bring wrongdoers to trial." 539 So. 2d at 223 (internal quotation omitted). The Court has noted the litigation-cost factor requires a court to "consider whether the punitive-damages award was sufficient to reward the plaintiff's counsel for assuming the risk of bringing the lawsuit and to encourage other victims of wrongdoing to come forward." *Orkin Exterminating Co., Inc. v. Jeter*, 832 So. 2d 25, 42 (Ala. 2001).

As the Court is well aware, this case has been vigorously contested at every step. **AstraZeneca** has twice removed this case to federal court. **AstraZeneca** also filed four separate petitions for writs of mandamus with this ***125** Court. There have been fifty depositions, and both sides have retained a number of expert witnesses. The case was complex and lengthy. It was tried to the jury for nine days and involved numerous witnesses, including several experts for either side. The magnitude of the State's litigation effort and costs in this case therefore support the jury's punitive damages award.

f. Other criminal sanctions or civil actions

AstraZeneca is not subject to any other criminal or civil sanctions arising from the conduct at issue in this case. Therefore, these factors do not suggest that the award should be reduced.

CONCLUSION

For the foregoing reasons, the judgment of the trial court should be affirmed.

Appendix not available.

Footnotes

1 AstraZeneca stipulated during trial that the two AstraZeneca corporations could be treated as one for all legal and practical purposes. R.1020-21.

2 "Usual and customary" charges (i.e., what a cash paying customer is charged by a pharmacy) are not an issue in this litigation, as virtually all of AMA's pharmacy payments are based on EAC. R.1311.

3 WAC (price paid by wholesaler to manufacturer) represents an earlier point in the distribution chain than AWP (price paid by retailer or pharmacy to wholesaler).

4 AMA's reimbursement formula falls within the norm of other States' methodologies. R.1164, 1194-95.

5 AMA did not have the ability or resources to collect internally updated prices for 60,000 drug products on a biweekly basis. *See* R.1323. Even if it had attempted to do so, there was no assurance that AMA would have received any more accurate pricing information than the data reported by drug manufacturers to First DataBank. R.1323.

6 Medicaid accounted for over 40% of sales for one AstraZeneca drug - Seroquel, which is used to treat mental health issues. R.1049-50; PX 938 (R.1026), at AZ0450380.

7 Approximately 75% to 80% of all prescription drug income stays with the drug manufacturer. R.1162-63, 1560--61.

8 Blue Book is another name for First DataBank's electronic database. Red Book is a hard copy pricing publication.

9 "HCFA" is the Health Care Financing Administration, which was renamed in 2001 to the Centers for Medicare and Medicaid Services ("CMS"). *See* R.1298.

10 **AstraZeneca** gave a number of discounts and other price adjustments to wholesalers, including 2% prompt pay discounts, 2% one-site shipment discounts, 1.4% inventory management discounts, market share discounts, new product discounts, and chargebacks. R.821-22, 826-29, 1061-64; PX 969 (R.850, at 4) (providing 15% market share discount off of WAC to Omnicare); R.1757-58 (2% prompt pay discount taken "all the time"). **AstraZeneca** did not include any of these discounts or price concessions in the WAC prices it reported to First DataBank, although that information was readily accessible to **AstraZeneca** on its separately maintained database, which reflected net prices paid for its drugs. R.824-27, 838, 1585-86.

11 The reasonableness of AMA's dispensing fee of $5.40 per prescription, which is one of the highest in the country, is not at issue. *See* PX 936 (R.1321).

12 **AstraZeneca** argued during trial that because it manufactures only single source drugs, it had no motive to market the spread to retail pharmacies. **AstraZeneca's** own documents refute that contention. *See* PX 949 (R.850), at AZ0463137-38 (detailing major pharmacy chains' policies to reward manufacturers that use a 25% markup for AWP by "[i]ntervening to switch patients from low markup to high markup products.")

13 For damages calculation purposes, price data from one of the national wholesalers, Cardinal Health, was used to determine real marketplace prices. Sauls' use of Cardinal data was a conservative approach, as there are discounts and incentives not reflected in the Cardinal data produced to the State during the course of this litigation. R.1569-71. **AstraZeneca** did not criticize the applicability or reliability of the Cardinal data. R.2112.

14 Federal rebates are calculated on the basis of Average Manufacturer Price ("AMP") and Best Price, which **AstraZeneca** reports to the federal government. 42 U.S.C. § 1396r-8(c). AMP and Best Price are confidential under federal law and may not be disclosed by the federal government. *See* 42 U.S.C. § 1396r-8(b)(3)(A) and (D).

15 Only one report mentions WAC at all. In that 2001 report there is one isolated reference to WAC, with the OIG concluding that based on a limited survey the estimated invoice price for certain brand drugs was 1.81% below WAC. DX 260A (R.1429), at 5. That report in no way constituted notice to AMA of the serious WAC fraud by **AstraZeneca**.

16 This same point was eloquently made by the Eleventh Circuit in its *Seigelman/Scrushy* opinion released on March 6, 2009, the first page of which is attached hereto as Exhibit A.

17 Because **AstraZeneca** knew and intended that AMA would use its reported prices, it makes no legal difference that **AstraZeneca** reported prices to AMA through First DataBank rather than directly to AMA. *See Thomas v. Halstead*, 605 So. 2d 1181, 1184-85 (Ala. 1992) (it is not necessary to prove that a misrepresentation was made directly to the person who claims to have been injured so long as the plaintiff falls within class of those contemplated by defendant to act upon his representations).

18 "Wholesale" is defined as "the sale of goods in quantity, as to retailers or jobbers, for resale." *Random House Webster's Unabridged Dictionary* (2d ed. 2001). "Acquisition" means "the act of acquiring or gaining possession." *Id*. "Cost" means "the price paid to acquire, produce, accomplish, or maintain anything." *Id*.

19 **AstraZeneca's** senior management witness was not familiar with the term "list price." R.826.

20 **AstraZeneca** cites testimony of a former First DataBank employee, Patricia Morgan, to suggest that AWP and WAC are list prices, but her testimony conflicts with First DataBank documents and other sources discussed herein.

21 "Average" is defined as "1: equaling an arithmetic mean[;] 2a: approximating or resembling an arithmetic mean specif. in being about midway between extremes: not out of the ordinary for members of the group under consideration." Webster's *Third New International Dictionary of the English language* (1993). "Wholesale" is defined as "of, relating to, or engaged in the sale of goods or commodities in quantity for resale." *Id*. "Price" is the "amount of money given or set as the amount to be given as a consideration for the sale of a specified thing." *Id*.

22 "Whether a plaintiff has reasonably relied on a defendant's misrepresentation is usually a question of fact." *McIver v. Bondy's Ford, Inc.*, 963 So. 2d 136, 142-43 (Ala. Civ. App. 2007). "The 'reasonable reliance' standard . . . allow[s] the factfinder . . . flexibility in determining the issue of reliance based on all of the circumstances surrounding a transaction, including the mental capacity, educational background, relative sophistication, and bargaining power of the parties." *Foremost Ins. Co. v. Parham*, 693 So. 2d 409, 421 (Ala. 1997).

23 Regarding AWP, the 1975 letter from AMA's pharmaceutical services director to the FDA says only that AMA has realized a savings by using actual acquisition cost as opposed to AWP. The letter says nothing about AWP being inflated or by how much.

24 **AstraZeneca** cites to a final adopted rule, 40 Fed. Reg. 32284 (July 31, 1975), but that rule was not offered or admitted at trial, and should not be considered by the Court. This Court "cannot put a trial court in error in regard to a matter that, according to the record, was neither presented to nor decided by it." *Ocean Cruise Lines, Inc. v. Abeta Travel Serv., Inc.*, 562 So. 2d 205, 209 (Ala. 1990); *O'Barr v. Feist*, 296 So. 2d 152, 158 (Ala. 1974). Moreover, the portions **AstraZeneca** cites from that rule regarding AWP are not from the rule itself, but are buried in paragraph 67 of the "General Comments." **AstraZeneca's** citation to this rule is misleading and should be stricken.

25 "WAP" is "WAC."

26 **AstraZeneca's** reference to the State's expert's testimony that it was as "clear as day" that AMA "was on notice that AWP was not an actual acquisition cost" after receiving the June 1985 letter from HCFA does not prove the State knew **AstraZeneca's** AWP was false and inflated. The State's expert was correctly referring to the fact that AWP is exactly what it says - an *average* of prices paid, not actual acquisition costs on a specific transactional level. Of course, this testimony does not suggest that AMA had any notice concerning **AstraZeneca's** false reporting and inflated prices from 1991 to 2005.

27 This Court should not consider two reports outside the record referenced by **AstraZeneca** in its brief -- one a Congressional Budget Office Report and the other an OIG Report dated 2001. *See* **AstraZeneca's** Brief, at p. 47, n.7 and p. 53, n.8. **AstraZeneca** did not offer these reports in the trial court, and **AstraZeneca's** reference to them should be stricken. *See* discussion *supra* p. 55, n.24.

28 In addition to its admissibility under Rule 404(b), **AstraZeneca's** guilty plea and stipulation as to the facts underlying the charge constituted a party admission. See Ala. R. Evid. 801(d)(2); Ala. R. Evid. 803(22) (providing for admissibility of judgment entered upon plea of guilty). "An unwithdrawn plea of guilty in a criminal action to a charge of doing an act, made by a person who is now a party to a civil action, is admissible against the person in the civil action if the doing of such act is relevant to the present civil litigation." *McElroy's Alabama Evidence* § 180.02(3); *see also Durham v. Farabee*, 481 So. 2d 885, 886 (Ala. 1985) (criminal conviction upon guilty plea was admissible in subsequent civil action).

29 The settlement agreement was presented to the trial court in pre-trial motion in limine proceedings, and it supports the trial court's conclusion that **AstraZeneca's** conduct concerning Zoladex was properly admissible as pattern and practice evidence.

30 **AstraZeneca** made a similar argument in its motion to supplement the record on appeal, which this Court denied on November 6, 2008. The State filed an opposition to **AstraZeneca's** motion to supplement on October 7, 2008, which contains a complete timeline and description of relevant pre-trial and trial events and applicable legal arguments, which the State incorporates herein.

31 **AstraZeneca** argued to the court that Attorney General Bill Pryor hired Professor Mike DeBow to conduct an internal investigation to determine whether the State had a meritorious claim regarding AWP and that DeBow prepared a written report in response. *See* R.395.

32 The alleged error is, at its heart, a discovery dispute rather than an evidentiary error at trial. **AstraZeneca** did not seek mandamus relief on the discovery ruling, but even if it had, the trial court did not abuse its discretion in determining the documents were protected from disclosure.

33 **AstraZeneca** did not challenge Sauls' qualifications as a damages expert.

34 The State's two-pronged methodology, WAC + 9.2% or AWP - 10%, is designed to arrive at approximately the same number. R.1614-15, 1770-71; *see also* R.2132-34. Even though Sauls calculated the "should have paid price" from a marketplace AWP price, i.e., the Cardinal data, the result is the same as if applying the State's WAC methodology. R.1646-47; *see also* R.2134-39; PX 1533 (R.2139)(demon-strating that ".91 x AWP" equals same number as "WAC x 1.092").

35 The Cardinal data was obtained by the State pursuant to subpoena during this litigation. It was not available to the State prior to the lawsuit.

36 The federal government has its own mechanisms for resolving federal financial participation issues directly with the State, which is of no concern in this case. **AstraZeneca** suggests that the State must prove that the federal government was defrauded in order to recover damages for the federal percentage of financial participation in the State program. **AstraZeneca** cites no case, statute, or regulation supporting this illogical contention, nor can it because there is none. *Greene v. Jefferson County Comm'n*, 2008 WL 4892051, at *6 (Ala. Nov. 14, 2008) ("Where an appellant fails to cite any authority we may affirm, for it is neither our duty nor function to perform all the legal research for an appellant.").

37 See examples of **AstraZeneca's** reprehensible conduct cited in the Prologue to the Argument section, *supra* p. 32-33.

38 The State's year-by-year damages calculation reflects a dramatic increase in damages in year 2003. PX 1237A (R.1592).

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