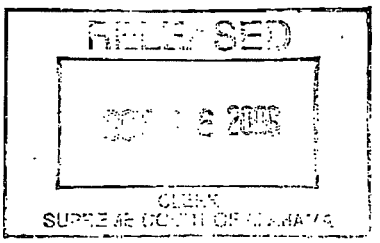

SUPREME COURT OF ALABAMA

OCTOBER TERM, 2009-2010

1071439

AstraZeneca LP and AstraZeneca Pharmaceuticals LP

v.

State of Alabama

1071440

AstraZeneca LP and AstraZeneca Pharmaceuticals LP

v.

State of Alabama

1071704

Smithkline Beecham Corporation d/b/a Glaxosmithkline

v.

State of Alabama

1071759

Novartis Pharmaceuticals Corporation

v.

State of Alabama

Appeals from Montgomery Circuit Court
(CV-05-219.10; CV-05-219.11; CV-05-219.68; and CV-05-219.52)

WOODALL, Justice.

AstraZeneca LP and AstraZeneca Pharmaceuticals LP (hereinafter referred to jointly as "AstraZeneca");[1] Smithkline Beecham Corporation d/b/a Glaxosmithkline ("GSK"); and Novartis Pharmaceuticals Corporation ("Novartis") appeal from judgments entered on jury verdicts in favor of the State

[1]AstraZeneca LP and AstraZeneca Pharmaceuticals LP have stipulated that they are to be regarded as one entity for purposes of trial and appeal.

of Alabama in actions alleging that AstraZeneca, GSK, and Novartis fraudulently inflated the prices of their prescription drugs for purposes of reimbursement by the Alabama Medicaid Agency ("the AMA"). We reverse the trial court's judgments and render judgments for AstraZeneca, GSK, and Novartis.

I. Factual and Procedural Background

This is the third time some aspect of this litigation has been before us. See Ex parte Novartis Pharmaceuticals Corp., 975 So. 2d 297 (Ala. 2007) ("Novartis I"), and Ex parte Novartis Pharmaceuticals Corp., 991 So. 2d 1263 (Ala. 2008) ("Novartis II"). These cases are exemplary of litigation currently pending in state and federal courts involving allegations that the nationwide pricing policies of pharmaceutical manufacturers caused states to over-reimburse providers of prescription drugs under the states' respective Medicaid programs.

"The Medicaid program was created in 1965, when Congress added Title XIX to the Social Security Act, 79 Stat. 343, as amended, 42 U.S.C. § 1396 et seq. ... [('the Medicaid Act')], for the purpose of providing federal financial assistance to

States that choose to reimburse certain costs of medical treatment for needy persons." Harris v. McRae, 448 U.S. 297, 301 (1980). "Although participation in the Medicaid program is entirely optional, once a State elects to participate, it must comply with the requirements of Title XIX." 448 U.S. at 301. Medicaid provides "joint federal and state funding of medical care for individuals who cannot afford to pay their own medical costs." Arkansas Dep't of Health & Human Servs. v. Ahlborn, 547 U.S. 268, 275 (2006). The "[f]ederal financial participation," 42 C.F.R. § 430.1, was, during the time relevant to this dispute, approximately 70% of the amount of the expense the AMA incurred under its Medicaid program.

At the federal level, Medicaid is administered by the Centers for Medicaid and Medicare Services ("the CMS"), formerly known as the Health Care Financing Administration. See Centers for Medicare & Medicaid Services; Statement of Organization, Functions and Delegations of Authority; Reorganization Order, 66 Fed. Reg. 35,437 (July 5, 2001); Statement of Organization, Functions, and Delegations of Authority, 49 Fed. Reg. 35,247 (Sept. 6, 1984); Reorganization Order, 42 Fed. Reg. 13,262 (Mar. 9, 1977). The CMS monitors

the states' compliance with federal law to, among other things, ensure that "payments [are] sufficient to enlist enough providers so that services under the [program] are available to recipients at least to the extent that those services are available to the general population." 42 C.F.R. § 447.204.[2] "Providers" are typically physicians and retail pharmacies that disburse prescription drugs to persons eligible for Medicaid benefits.

The AMA reimburses providers for drugs they dispense to eligible recipients. Reimbursement must, however, be made consistent with a methodology adopted with the approval of the CMS that takes economy into account. See 42 C.F.R. § 447.512 (formerly 42 C.F.R. § 447.331). For the brand-name drugs at issue in these appeals, reimbursement must not exceed, in the aggregate, the lesser of "(1) [the Estimated Acquisition Cost ('the EAC') of the drug] plus reasonable dispensing fees ...; or (2) [p]roviders' usual and customary charges to the general public." 42 C.F.R. § 447.512(b). EAC is defined as "the agency's best estimate of the price generally and currently

[2]According to the current commissioner of the AMA, "federal law requires [the State] ... to provide comparable access to services for a Medicaid recipient that [anyone] would receive in the private market."

paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size of drug most frequently purchased by providers." 42 C.F.R. § 447.502. In other words, Medicaid reimbursements may be made on the basis of what providers actually paid for each drug or on the basis of an estimated cost. Various reimbursement methodologies are employed by the various state Medicaid agencies to obtain the EAC for each drug disbursed under their Medicaid programs. The goal is to produce a payment rate sufficient to encourage providers to participate in the Medicaid program, while, at the same time, minimizing Medicaid costs.

Federal financial participation in the state Medicaid programs is made contingent upon a methodology that, in the view of the CMS, sufficiently addresses the somewhat competing objectives of adequate compensation and economy. However, the CMS has afforded the states flexibility in the formulas by which they attempt to arrive at the EAC. Formulation of these methodologies ordinarily involves the use of information supplied by pharmaceutical manufacturers to a national price compendium, such as First DataBank, Inc. ("DataBank"). DataBank defines itself as a "point of care database company

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whose purpose it is to provide custom drug [information] according to Medicaid specifications focused on providing accurate drug pricing."

Drug-pricing information is typically reported in the form of "wholesale acquisition cost" ("WAC") or in the form of both WAC and "average wholesale price" ("AWP"). Definitions for AWP and WAC have varied throughout the industry during the period relevant to this dispute. However, AWP was defined in DataBank, Monthly Interest (September 1991), as:

> "[A]n average price which a wholesaler would charge a pharmacy for a particular product. The operative word is average. AWP never means that every purchase of that product will be exactly at that price. There are many factors involved in pricing at the wholesale level which can modify the prices charged even among a group of customers from the same wholesaler. AWP was developed because there had to be some price which all parties could agree upon if machine processing was to be possible."

(Emphasis in original.)

In 1992, the Health and Human Services State Medicaid Manual ("the Medicaid manual") explained that "AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10-20 percent because they do not reflect discounts, premiums, special offers or incentives, etc." (Emphasis added.)

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In 1996, the Congressional Budget Office published CBO Papers: How the Medicaid Rebate on Prescription Drugs Affects Pricing in the Pharmaceutical Industry (1996). That publication stated, in pertinent part: "The average wholesale price (AWP) is the published (list) price that manufacturers suggest wholesalers charge their customers. Wholesalers usually charge pharmacists a price that is lower than the AWP, which is the price that is most widely available in published form." Id. at 20 (emphasis added).

A similar definition for AWP appeared in Novartis, Pharmacy Benefit Report: Facts & Figures (2000):

> "Average wholesale price (AWP) -- A published suggested wholesale price for a drug, based on the average cost of the drug to a pharmacy from a representative sample of drug wholesalers. There are many AWPs available within the industry. AWP is often used by pharmacies to price prescriptions. Health plans also use AWP -- usually discounted -- as the basis of reimbursement of covered medications."

(Emphasis added.)

WAC was specifically defined in the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, § 303, 117 Stat. 2066, 2242 (2003), codified at 42 U.S.C. § 1395w-3a(c)(6)(B), as follows:

> "The term 'wholesale acquisition cost' means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data."

(Emphasis added.) Public Law No. 108-173, § 303(i)(4)(B)(iii), amended the Medicaid Act to incorporate this definition of WAC into the Medicaid statutory scheme. See 42 U.S.C. § 1396r-8(b)(3)(A)(iii)(II). Not all such industry publications have defined WAC/AWP as "suggested" or "list" prices.

In the 1970s, the AMA merely reimbursed providers on the basis of their actual acquisition price. Indeed, in a letter to the "hearing clerk" of the United States Food and Drug Administration, dated February 13, 1975, Sam T. Hardin, then director of the AMA Pharmaceutical Services Medical Services Administration, objected to any proposed rule that would replace the AMA's actual-cost basis, then current, with a methodology based on AWP. More specifically, he stated: "Based on a study recently conducted for several of our top 200 drugs, a savings is being realized by use of actual cost

vs. AWP ...." Nevertheless, in the early 1980s, the AMA began reimbursing providers at a rate of 100% of AWP.[3]

In June 1985, however, Richard Morris, associate regional administrator of the Department of Health and Human Services ("the DHHS") sent a letter to then AMA Commissioner Faye Baggiano ("the Morris letter"), threatening to withdraw federal financial participation from the Alabama Medicaid program because of the AMA's use of 100% of AWP as the basis for reimbursement. The letter stated:

> "This is to inform you of corrective action being pursued by this office to secure compliance with Federal regulations regarding Medicaid prescription drug reimbursement and to request your assistance in implementing certain changes by October 1, 1985.
>
> "The Federal regulations at 42 CFR 447.331 [currently 42 C.F.R. § 447.512] provide that the State Agency may not pay more for prescribed drugs than the lower of ingredient cost plus a reasonable dispensing fee or the provider's usual and customary charge to the general public. Costs for certain multiple source drugs are subject to the lower of 'estimated acquisition cost' (EAC) or the 'maximum allowable cost' (MAC) limit as published in the Federal Register. For all other drugs, the allowable cost limit is the State Agency's best estimate of what price providers generally are paying based on the package size providers most frequently purchase -- 42 C.F.R. 447.332(c).

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[3]At all times relevant to this dispute, the AMA was receiving, pursuant to a contract with DataBank, drug-pricing information from DataBank.

"As early as 1975 the [DHHS] cautioned against the use of AWPs as estimates of drug ingredient costs by stating in the preamble to the final Federal Regulations that published wholesale prices are not closely related to prices actually paid by providers. This has been reiterated by the [DHHS] over the years to State Medicaid Agencies through policy issuances which have stated that the estimated acquisition cost (EAC) should be 'as close as feasible to the price generally and currently paid by providers.' In June 1984, the DHHS Office of Inspector General issued a Report to Congress and HCFA [currently the CMS] recommending action to reduce inflated Medicaid drug reimbursement. The IG's recommendations were based on a national review of State practices through intensive sample surveys in six States. The reviews consistently showed that Medicaid EACs were primarily based on published average wholesale prices (AWPs) which were inflated by an average of 15.96 percent. HCFA acceptance samples in Florida and Georgia confirmed the IG's findings.

"On the face of this substantial data, we convened a workgroup comprised of Region IV State Medicaid Consultant Pharmacists to develop a range of options to reduce the inflated levels of drug reimbursement caused by use of AWP as 'estimated acquisition cost' (EAC). The Alabama representative, Mr. Sam Hardin, was an active participant in the workshop and his contributions were appreciated. In two meetings during April and June 1985, State and Regional Office staff reached an agreement on the following methodology for obtaining the Estimated Acquisition Cost (EAC):

> "Obtain the Wholesale Acquisition [Cost] (WA[C]) for each drug in the State formulary and add 5.01 percent to that price. The product obtained will be the maximum allowable amount payable.

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"The methodology set forth above should produce a price that is 13.9 percent below AWP and result in an EAC adjusted to more realistically reflect actual cost in the package size providers buy most frequently.

"In the past, States which utilized the AWP as 'estimated acquisition cost' have not been found to be out of compliance with Federal regulations. Further, no sanctions or penalties have been applied. However, based on current conclusive evidence that the published AWP does not reflect the true cost of drug products we do not consider it acceptable for use as the State's EAC, unless the AWP has been reduced significantly to reflect a more accurate representation of the true estimated acquisition cost of a drug. As an alternative, HCFA will find acceptable either the methodology developed by the Region IV EAC workgroup or another methodology that would result in equivalent reductions.

"Based on our understanding of current Alabama practice, your current EAC methodology does not result in 'estimated acquisition cost' consistent with the intent of the regulations at 42 CFR 447.331-447.332. Therefore, it is our opinion that Alabama compliance with these Federal requirements is in question. Unless we receive evidence that Alabama has effected changes in the EAC determination methodology consistent with the principles previously described, effective no later than October 1, 1985, this issue will be reported to the HCFA Central Office on the compliance report for the quarter ending September 30, 1985. In addition, Federal financial participation (FFP) will not be available beyond September 30, 1985, in payments for prescribed drugs in excess of the amounts that would have been achieved had Alabama implemented the EAC methodology developed by the Region IV Drug Reimbursement Workgroup (i.e. wholesale acquisition [cost] (WA[C]) plus 5.01 percent), or a comparable

> methodology approved by the Health Care Financing Administration prior to implementation.
>
> "Please advise this office by July 8, 1985 of your time frame for implementing the new EAC. methodology. As always, we stand ready to be of assistance upon request."

(Emphasis added.)

Baggiano responded to the Morris letter on June 26, 1985. Her letter stated:

> "This is in response to your letter of June 18 concerning corrective action being pursued by your office to secure compliance with federal regulations with regard to Medicaid prescription drug reimbursement.
>
> "This Agency plans to pursue and implement the methodology for establishing the estimated acquisition cost (EAC) for drugs payable under the program (i.e., wholesale acquisition [cost] (WA[C]) plus 5.01%) to be effective October 1, 1985.
>
> "It is our opinion this change will place Alabama in compliance with the intent of the regulations at 42 C.F.R. 447.331-.332."

(Emphasis added.)

On September 6, 1985, the AMA sent "Provider Notice 85-18" to "all pharmacies and dispensing physicians participating in the Alabama Title XIX (Medicaid) Pharmaceutical Program," notifying providers of the change in reimbursement methodology. The notice stated, in pertinent part:

> "Through intensive sample surveys, the Department of Health and Human Services (HHS) has determined that published AWPs (average wholesale prices) are inflated and that AWP is not the [AMA's] 'best estimate of what price providers generally are paying for a drug.' The reviews consistently showed that Medicaid EACs were primarily based on published average wholesale prices. In order to comply with federal regulations, the methodology used to determine estimated acquisition cost will be changed effective October 1, 1985. The [AMA] will obtain the wholesale acquisition [cost] plus a percent to arrive at the estimated acquisition cost. This methodology will result in an EAC which more realistically reflects the actual cost in the package size providers buy most frequently."

(Emphasis added.)

Immediately afterward, the AMA conducted its own survey of wholesale drug companies to determine what providers were actually paying. On November 22, 1985, Baggiano sent Morris a letter reporting the results of this survey. In that letter, she also requested approval from the DHHS to increase the markup from WAC + 5.01% to WAC + 8.45%, based on the survey results. Specifically, the letter stated:

> "In accordance with federal regulations 42 CFR 447.332 [now 42 C.F.R. 447.512] effective October 1, 1985, the [AMA] adopted the price methodology for pharmacy programs as suggested by HCFA [now CMS] regional office (WA[C]) plus 5.01%) for reimbursement.
>
> "Studies have since been conducted, and an alternative methodology is being forwarded for your

> approval. Studies considered the top 100 most frequently prescribed drugs (600 entities) supplied to Alabama Medicaid recipients. The [AMA] will utilize the following methodology for obtaining estimated acquisition cost: obtain the wholesale acquisition [cost] (WA[C]) for each drug in the state formulary and add 8.45% to that price.
>
> "Studies were accomplished for Medicaid by the two primary wholesale drug companies (Walker Drug Company and Durr-Fillauer Medical, Inc.), serving 80% of Alabama pharmacies. Copies of these studies are attached for your review. The studies indicated that the average percentage markup on WA[C] that Alabama pharmacies are paying are 7.3% (Walker) and 7.6% (Durr-Fillauer). The average of these percentages is 7.45%. We are adding an additional 1% to compensate for higher cost paid by some pharmacists who are unable to take advantage of discounts. Discounts are offered only if they make timely payments (twice monthly) and/or if they are able to purchase in large volumes. With your approval, we plan to implement this program effective January 1, 1985 [sic].
>
> "Your consideration and approval of this alternative methodology is appreciated."

(Emphasis added.) On November 26, 1985, Morris replied to Baggiano, stating that the DHHS accepted her "proffered methodology and implementation date for implementing the [AMA's] best estimate of the price providers generally are paying for a drug(s)."

In March 1987, Carol Herrmann, then an official at CMS, received an internal memorandum regarding "Initiative on

Lowering Drug Acquisition Cost and the State of Alabama" ("the Initiative"). The memorandum stated, in pertinent part:

> "In approximately March 1985, under a HCFA [now CMS] PATROL Initiative, States were instructed (through HCFA Regional Offices) to obtain better estimations of acquisition costs on single source drugs. Most States were using average wholesale price (AWP) listings which are usually about 20 percent higher than acquisition costs. A few regions, including Atlanta, threatened States with noncompliance if they didn't change their policy by October 1, 1985, and revise their AWP listings."

(Emphasis added.)

In 1989, Carol Herrmann came to Alabama to serve as AMA commissioner. In that capacity, she sent a letter on February 26, 1992, to the associate regional administrator of the Health Care Financing Administration (now the CMS). The letter contained assurances that the AMA had reviewed "pricing for multiple source drugs" and had found Medicaid expenditures to be consistent with federal regulations. Attached to Commissioner Herrmann's letter was an excerpt from the Medicaid manual, stating, in pertinent part:

> "Estimated acquisition costs (EAC) mean the agency's best estimate of the price generally, and currently, paid by providers for a drug marketed or sold by a particular manufacturer or labeler in the package size most frequently purchased by providers. For example, in the past, many States based the EAC upon Average Wholesale Price (AWP) levels as contained in

> various commercially available publications. However, a number of studies have shown that in recent years the drug marketplace has changed and there is a preponderance of evidence that demonstrates that such AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10-20 percent because they do not reflect discounts, premiums, special offers or incentives, etc. Consequently, absent valid documentation to the contrary, a published AWP level as a State determination of EAC without a significant discount being applied is not an acceptable estimate of prices generally and currently paid by providers."

(Emphasis added.)

Meanwhile, on October 29, 1987, the AMA increased the markup used in its reimbursement methodology from WAC + 8.45% to WAC + 9.2%. This change resulted from surveys and analytical studies conducted by the AMA after 1985. However, beginning in approximately 1991, the AMA began supplementing its methodology with the use of a discounted AWP. Specifically, from 1991 through 2002, the AMA used AWP minus 10.2% (hereinafter "AWP - 10.2%") whenever the published AWP was more current than the published WAC. Since 2002, the AMA has used AWP - 10.2% whenever the discounted AWP formula yields a lower number than the marked-up WAC formula. In other words, since 1987, the AMA has -- with two exceptions -- reimbursed providers on the basis of either WAC + 9.2% or AWP

- 10.2%. The exceptions are (1) for physician-administered drugs and (2) for a "DEA [Drug Enforcement Administration] 2 (controlled substance)," for which, at least for a portion of the period from 1991 to 2005, the State allegedly reimbursed at 100% of AWP.[4]

As of September 2004, Alabama was one of six states using WAC and AWP formulas as alternate bases for reimbursement. Forty-one states used a CMS-approved, discounted AWP formula without WAC. However, the percentage that those states' plans discounted from the published AWP price varied considerably. For example, discounts applied in a number of states fell within the 10% to 12% range. By contrast, the Connecticut plan applied a 40% discount to the published AWP price on generic drugs, and Washington applied a 50% discount to a class of "multiple-source" drugs.

During the trial of the case against GSK and Novartis,[5] Dr. Gerard Anderson, the State's expert witness in the area of drug pricing, testified that "there is a mathematical

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[4]The use of 100% of AWP as a formula for reimbursement of physician-administered drugs was apparently discontinued in 1999.

[5]The claims against GSK and Novartis were consolidated for trial.

relationship between ... the WAC price and the AWP price," meaning that, "if the WAC price is not a true price, then, mathematically, the AWP cannot be a true price either." Also, in postjudgment responses filed in the trial court, the State explained that the AWP was calculated "by adding 20% or 25% to the reported WAC" and thus "bore a consistent, formulaic relationship to WAC." In fact, the State concedes that the WAC and AWP formulas are designed to -- and do -- yield roughly the same number.

This mathematical linkage between WAC and AWP was specifically addressed in an internal AMA memorandum dated November 28, 1995, regarding "suggested cost containment measures." The memorandum from Mary Finch, an official of the AMA, to the director of Medical Services for the AMA ("the Finch memo") stated, in pertinent part:

> "Because of the present budgetary situation of the [AMA], certain cost containment measures have been evaluated and are presented to you for further evaluation....
>
> "• Make adjustments in the current pricing methodology: Covered drugs are currently reimbursed at a rate of the wholesale acquisition cost (WAC) plus 9.2%. This is approximately equal to Average Wholesale Price (AWP) minus 10%. Because the accepted figure for the discount received by pharmacies

> receiving the AWP is 14%, there is room to decrease the percentage added to WAC.
>
> "WAC + 9.2% = AWP - 10%
> "WAC + 7.99% = AWP - 11%
> "WAC + 6.78% = AWP - 12%
> "WAC + 5.57% = AWP - 13%
> "WAC + 4.36% = AWP - 14%
>
> "If the percentage added to WAC is decreased to 4.36, approximately $5.6 million could be saved."

(Some emphasis added.) However, no changes were made to the AMA's reimbursement methodology of WAC + 9.2% or AWP - 10.2%, and those formulas are the formulas currently in use.

On January 26, 2005, the State sued 73 pharmaceutical manufacturers, including AstraZeneca, Novartis, and GSK. The complaint alleged (1) that the manufacturers fraudulently "provided or caused to be provided false and inflated AWP [and] WAC ... information for their drugs to ... DataBank"; (2) that the reported AWPs and WACs "greatly exceeded the actual prices at which [the manufacturers] sold their drugs to retailers (physicians, hospitals, and pharmacies) and wholesalers," because they did not include "undisclosed discounts, rebates, and other inducements which had the effect of lowering the actual wholesale or sales prices charged to their customers as compared to the reported prices"; (3) that

the manufacturers "knew that the false and deceptive inflation of AWP [and] WAC] ... for their drugs would cause [the AMA] to pay excessive amounts for these drugs"; and (4) that the AMA "reasonably relied on the false pricing data in setting prescription drug reimbursement rates and making payment based on said rates." The complaint contained claims of fraudulent misrepresentation, fraudulent suppression, and wantonness and sought compensatory and punitive damages for the period from January 1, 1991, through the first quarter of 2005.[6]

In Novartis I, we issued a writ of mandamus "direct[ing] the trial court to sever the claims against all [the pharmaceutical] companies." 975 So. 2d at 304 (emphasis added). Trial of the claims against AstraZeneca began on February 11, 2008. The claims against Novartis and GSK were presented in a consolidated trial that began on June 16, 2008.

AstraZeneca, Novartis, and GSK each filed timely motions for judgments as a matter of law ("JML"), placing in issue the sufficiency of the evidence as to the fraudulent-misrepresentation and fraudulent-suppression claims. In

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[6]Although the complaint also contained a claim of unjust enrichment, the State voluntarily withdrew that claim as to AstraZeneca, Novartis, and GSK.

particular, they challenged the sufficiency of the element of reliance. After those motions were denied, the juries in both trials returned verdicts in favor of the State.

The jury in AstraZeneca's trial returned a verdict against it on the claims of misrepresentation and fraudulent suppression, awarding $40,000,000 in compensatory damages and $175,000,000 punitive damages. The jury in the Novartis/GSK trial returned a verdict against Novartis and GSK on the claim of fraudulent misrepresentation only, awarding the State $33,257,694 in compensatory damages against Novartis and $80,989,539 against GSK. The juries found in favor of the defendants on the wantonness claims in both trials. The defendants renewed their JML motions postjudgment. Both motions were denied. In AstraZeneca's case, the trial court reduced the punitive-damages award to $120,000,000, leaving a judgment against AstraZeneca for $160,000,000. From those judgments, AstraZeneca, Novartis, and GSK appealed. Cases no. 1071439 and no. 1071440 represent AstraZeneca's appeal, case no. 1071704 represents GSK's appeal, and case no. 1071759 represents Novartis's appeal. Several amici curiae, including

the National Community Pharmacists Association ("the NCPA"),[7] filed briefs in support of both sides of the dispute. We consolidated these appeals for the consideration and resolution of an issue raised in the defendants' motions for a JML that is common to the parties and dispositive of these appeals: Whether the State presented substantial evidence that it reasonably relied on the published WAC and AWP prices for the pharmaceutical manufacturers' prescription drugs.

II. Discussion

The standard of review of a ruling on a JML motion is well settled:

> "'In reviewing a ruling on a motion for a JML, this Court views the evidence in the light most favorable to the nonmovant and entertains such reasonable inferences from that evidence as the jury would have been free to draw.' Daniels v. East Alabama Paving, Inc., 740 So. 2d 1033, 1037 (Ala. 1999). 'The denial of a defendant's motion for a JML is proper only when the plaintiff has presented substantial evidence to support each element of the plaintiff's claim.' Kmart Corp. v. Bassett, 769 So. 2d 282, 284 (Ala. 2000). '"Substantial evidence" is "evidence of such weight and quality that fair-minded persons in the exercise of impartial judgment can reasonably infer the existence of the fact sought to be proved."' Id. (quoting West v. Founders

[7]The NCPA claims to "represent[] the pharmacist owners, managers, and employees of more than 24,000 independent community pharmacies across the United States, including 598 in the State of Alabama." NCPA's brief, at 1.

> Life Assurance Co. of Florida, 547 So. 2d 870, 871 (Ala. 1989))."

Long v. Wade, 980 So. 2d 378, 383 (Ala. 2007).

> "'To establish the elements of fraudulent misrepresentation [the State] ha[s] to show: "(1) that the [pharmaceutical manufacturers'] representation was false, (2) that it concerned a material fact, (3) that [the State] relied on the false representation, and (4) that actual injury resulted from that reliance."' Consolidated Constr. Co. of Alabama v. Metal Bldg. Components, L.P., 961 So. 2d 820, 825 (Ala. 2007) (Bolin, J., concurring specially) (quoting Boswell v. Liberty Nat'l Life Ins. Co., 643 So. 2d 580, 581 (Ala. 1994)).
>
> "....
>
> "'The elements of a fraudulent-suppression claim are "'(1) a duty on the part of the defendant to disclose facts; (2) concealment or nondisclosure of material facts by the defendant; (3) inducement of the plaintiff to act; (4) action by the plaintiff to his or her injury.'"' McIver v. Bondy's Ford, Inc., 963 So. 2d 136, 143 (Ala. Civ. App. 2007) (quoting Freightliner, L.L.C. v. Whatley Contract Carriers, L.L.C., 932 So. 2d 883, 891 (Ala. 2005), quoting in turn Lambert v. Mail Handlers Benefit Plan, 682 So. 2d 61, 63 (Ala. 1996))."

Novartis II, 991 So. 2d at 1275-76.

Moreover, "[u]nder Foremost Insurance Co. v. Parham, 693 So. 2d 409 (Ala. 1997), a party alleging any form of fraud must present evidence of 'reasonable reliance' on the purported fraud." Hawk v. Roger Watts Ins. Agency, 989 So. 2d 584, 589 (Ala. Civ. App. 2008) (emphasis added). See Houston

County Health Care Auth. v. Williams, 961 So. 2d 795, 814 (Ala. 2006) ("a plaintiff in a suppression case must prove that [it] was induced to act by [its] reasonable reliance on the state of affairs as it appeared in the absence of the suppressed information").

The theory of the State's case is that, throughout the claim period -- 1991 to 2005 -- the AMA believed that the WAC and AWP published by DataBank represented actual prices and that it reimbursed providers on the basis of that belief. Specifically, the State argues that the AMA understood the AWP to be "a true average of wholesale prices paid by pharmacy retailers to wholesalers for a particular drug," and the WAC to be "the actual price paid by the wholesaler to the drug manufacturer." State's brief, at 12-13 (cases no. 1071439 and no. 1071440) (emphasis added). According to the State, the AMA did not know that the prices published by DataBank were merely "list prices," that is, that the prices "did not include discounts, rebates, chargebacks, prompt-pay discounts, or other price concessions that reflect the actual price paid for drugs." State's brief, at 35 (cases no. 1071439 and no. 1071440). The State says (1) that AstraZeneca, Novartis, and

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GSK published, or allowed to be published, WACs and AWPs that were not net prices in order to induce the State to overpay providers; (2) that the State was deceived by the publication of those prices; and (3) that it did overpay providers by millions of dollars in reliance on the inflated WACs and AWPs.[8] This theory "of a broad, systemic fraud" is asserted against all 73 defendants, which, according to the NCPA, comprise "virtually every pharmaceutical manufacturer under Medicaid." NCPA's brief, at 3.

Novartis, AstraZeneca, and GSK concede that the WAC and AWP prices published by DataBank were not net prices. They contend, however, that the industry -- and the AMA in particular -- was at all relevant times fully cognizant of the fact that the manufacturer's published drug prices were list prices, which excluded discounts, and that, as a matter of law, the State could not have reasonably relied on the

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[8]Pharmaceutical manufacturers profit under such a scheme, according to the State's theory, by "marketing the spread," which is the "difference between the amount that a provider ... receives as reimbursement from Medicaid and the amount the provider paid for the drug." State's brief, at 17 (case no. 1071759). According to the State, pharmacists tend to fill prescriptions using the drugs manufactured by competitor companies with the widest spread. See Novartis II, 991 So. 2d at 1268.

published prices. Consequently, according to Novartis, AstraZeneca, and GSK, they were entitled to a JML on the State's fraud claims. As Novartis states: "The State knew for decades that WAC and AWP did not represent actual, discounted transaction prices," Novartis's brief, at 65, yet the AMA has not changed its reimbursement methodology since learning of the alleged fraud. Novartis's brief, at 61. "[A]ccordingly, there was no reasonable reliance and no fraud." Novartis's brief, at 65. We agree.

"Knowledge may be established by circumstantial evidence even in the face of professions of ignorance." Liberty Nat'l Life Ins. Co. v. Weldon, 267 Ala. 171, 196, 100 So. 2d 696, 718 (1958). "To claim reliance upon a misrepresentation, the allegedly deceived party must have believed it to be true. If it appears that he was in fact so skeptical as to its truth that he placed no confidence in it, it cannot be viewed as a substantial cause of his conduct." Smith v. J.H. Berry Realty Co., 528 So. 2d 314, 316 (Ala. 1988) (emphasis added). "'If the plaintiff knew that the representations were false ..., he can not complain that he has been misled to his damage by the defendant's attempted deception. ... The idea of a person

knowing a representation to be false and at the same time "relying" thereon is a contradiction in terms.'" Shades Ridge Holding Co. v. Cobbs, Allen & Hall Mortgage Co., 390 So. 2d 601, 610-11 (Ala. 1980).

In Liberty National Life Insurance Co. v. Allen, 699 So. 2d 138, 141 (Ala. 1997), this Court summarized Smith as follows:

> "Smith, who was purchasing a house, asked the realty agent whether the house and the positioning of a fence complied with 'applicable regulations.' The agent told Smith that they did comply. Before the closing, Smith extensively investigated whether the house actually complied with the building code and zoning regulations. After Smith purchased the house, he learned that it did not comply with a zoning regulation. This Court stated:
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> > "'... The undisputed fact that Mr. Smith was unwilling to accept the statement of the defendant's agent without verification is evidence that he did not rely on it. Based on his own testimony, it is clear that Mr. Smith was unwilling to accept the statement of the defendant's agent regarding the applicable zoning regulations.'"

699 So. 2d at 141-42 (emphasis added). Consequently, the Court in Smith held that evidence of reliance was insufficient as a matter of law. Smith, 528 So. 2d at 316. See also Burroughs v. Jackson Nat'l Life Ins. Co., 618 So. 2d 1329,

1332 (Ala. 1993) ("'If the representee makes an investigation ... that is free and unhampered, and he learns the truth, or conditions are such that he must obtain the information he desires ... he is presumed to rely on his own investigation, and not on the representation.'" (quoting 37 Am. Jur. 2d Fraud and Deceit § 230 (1968)).

Similarly, "[r]eliance requires that the misrepresentation actually induced the injured party to change its course of action." Hunt Petroleum Corp. v. State, 901 So. 2d 1, 4 (Ala. 2004). Thus, where the plaintiff "'"would have adopted the same course irrespective of the misrepresentation and would have sustained the same degree of damages, anyway, it cannot be said that the misrepresentation caused any damage, and the defendant will not be liable therefor."'" Id. (quoting Shades Ridge Holding Co., 390 So. 2d at 611, quoting in turn Fowler V. Harper and Fleming James, Jr., The Law of Torts § 7.13 (1956)).

Applying these principles in Hunt Petroleum, we held there that the State had not presented substantial evidence that it relied, as an element of its fraud claim, on royalty reports filed by Hunt Petroleum Corporation ("Hunt"). The dispute in that case arose out of a contract between Hunt and

the State requiring Hunt to pay royalties, namely, "25% of the gross proceeds" from gas it extracted from wells drilled in Mobile Bay. 901 So. 2d at 2. "Hunt and the State dispute[d] the proper point in the extraction process at which the gas should have been valued, that is, the point at which 'gross proceeds' should have been calculated." Id. The State construed the term "'gross proceeds' ... to mean revenue 'at the tailgate,' net of transportation costs from the tailgate to a pipeline," while Hunt interpreted the term to mean "revenue not only net of the costs of transporting the gas from the tailgate to a pipeline for final sale, but also net of the transportation costs from the wellhead to the treatment plant and the costs of treating the gas." 901 So. 2d at 3. Every month, Hunt "reported royalties to the State based on the value of the gas produced 'at the wellhead.'" Id.

The State sued Hunt alleging fraud on the theory that each one of over 100 monthly royalty reports from late 1993 to August 1997 constituted a misrepresentation that "'net proceeds' were 'gross proceeds' under the lease agreement." 901 So. 2d at 3. A jury returned a verdict in favor of the State for $3,403,200 in compensatory damages and $20,000,000 in punitive damages. Id. Hunt appealed the denial of its

motion for a JML as to the fraud claim, arguing that "the State failed to establish that the State relied on the alleged misrepresentations made by Hunt." 901 So. 2d at 4.

This Court agreed with Hunt. It did so, because, despite the State's "bald assertion" to the contrary, the State had never assumed the royalty reports to be true. Instead, it was undisputed that the State had always intended to "audit the royalty calculations." 901 So. 2d at 6 (emphasis added). "If the State merely 'assumed' that the calculations were correct, there would have been no need for an audit." Id. Moreover, the State did not change its course of conduct after actually discovering the discrepancy. Specifically,

> "[t]he only evidence of the effect of the monthly royalty reports on the State's conduct after August 1997 when the State realized the reports were inaccurate is that the State 'adopted the same course,' that is, it accepted the checks and allowed Hunt to sell the gas exactly as ... the State [had done] with the reports it had 'assumed' were accurate."

901 So. 2d at 8. There was, therefore, as a matter of law, no reliance. See also Exxon Mobil Corp. v. Alabama Dep't of Conservation & Natural Res., 986 So. 2d 1093, 1115-16 (Ala. 2007) (there could be no reliance on alleged misrepresentations as a matter of law when the Department of

Conservation and Natural Resources did not "act[] on the alleged misrepresentations by changing its position" after learning that royalty payments were not being made consistent with its view of certain oil and gas leases).

The sine qua non of the State's fraud claims in these appeals is its assertion that it did not know that the published WACs and AWPs were merely suggested -- or list -- prices, exclusive of discounts and other incentives available to wholesalers and providers. This assertion is untenable in light of the correspondence and internal memoranda involved in the State's formulation of its reimbursement methodology.

As early as 1975, the AMA knew, through Director Sam Hardin, that the published AWPs were higher than the actual prices paid. Nevertheless, by 1985, the AMA was reimbursing providers at the higher rate. Significantly, in that same year, the AMA received a warning from the DHHS that the State stood to lose federal financial participation if the AMA continued to reimburse on the basis of an undiscounted AWP. The Morris letter clearly stated that published AWPs were being inflated by "an average of 15.96 percent." Morris demanded that the AMA formulate a methodology that discounted the published AWP "significantly to reflect a more accurate

representation of the true estimated acquisition cost of a drug." In AstraZeneca's trial, Dr. Gerard Anderson, the State's expert, testified that, based on Morris's letter, it was "clear as day that [the AMA was] on notice that AWP was not an actual acquisition cost." (Emphasis added.)

The Morris letter set in motion the process culminating in the AMA's current reimbursement methodology. First, then Commissioner Baggiano notified Morris of the AMA's intent to adopt a methodology based on WAC + 5.01%, which, according to the Finch memo, corresponded to a discount from AWP of approximately 13.5%. This intent was then communicated on September 6, 1985, to "all pharmacies ... participating in the Alabama Title XIX (Medicaid) Pharmaceutical Program" through Notice 85-18. In Notice 85-18, the AMA itself acknowledged that "published AWPs ... are inflated and ... [are] not the [AMA's] 'best estimate of what price providers generally are paying for a drug." (Emphasis added.)

The experience of Commissioner Herrmann provides further evidence of the AMA's actual knowledge of the true meaning of AWP. The Initiative she received in 1987 while she worked for the CMS informed her that the AWP listings used by "most states" were "usually about 20 percent higher than [actual]

acquisition costs." According to the State, however, the Initiative, because it was "not addressed or sent to the AMA, did not give AMA notice of anything." State's brief, at 49 (case no. 1071759). The State's position, in other words, is that any knowledge the future AMA Commissioner acquired in Washington, D.C., did not accompany her to Alabama. We reject this argument out of hand.

Moreover, in 1992, while Herrmann was actually serving as AMA Commissioner, she was acquainted with that portion of the Medicaid manual stating that "AWP levels overstate the prices that pharmacists actually pay for drug products by as much as 10-20% because they do not reflect discounts, premiums, special offers or incentives, etc." (Emphasis added.) Thus, by 1992 at the very latest, the AMA had actual knowledge of what the State now seeks to disavow, that is, that published AWPs were not net prices.

As for WAC, the mathematical linkage between AWP, which is the average quoted price paid by pharmacists to wholesalers, and WAC, the price quoted to wholesalers by manufacturers, was fully explored in the Finch memo. The Finch memo demonstrated that a higher AWP discount logically corresponded to -- and required -- a smaller WAC markup. That

the AMA understood this linkage is obvious from the undisputed evidence that the use of WAC + 9.2% and AWP - 10.2% was designed to, and did, yield roughly the same number. Otherwise stated, any alleged inflation or overstatement necessarily affected both WAC and AWP proportionately and required proportionate adjustments to both. Also, in 2003, WAC was specifically defined by the Medicare Prescription Drug Improvement and Modernization Act of 2003 as "the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price." (Emphasis added.)[9]

Moreover, the reimbursement value of WAC currently employed by the AMA was determined from surveys conducted by the AMA, itself, from 1985 to 1987. The 1985 survey was done for the AMA "by the two primary wholesale drug companies (Walker Drug Company and Durr-Fillauer Medical, Inc.) serving 80% of Alabama pharmacies." Based on that survey, the AMA

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[9]The State also relies on dictionary definitions of the words included in the terms WAC and AWP and argues that the "plain meaning" of the words supports its position. However, any relevance the "plain-meaning" rule might have had in this dispute is negated by the State's actual knowledge of a different meaning.

requested, and obtained, from the DHHS permission to increase the WAC markup from the 5.01% suggested by Morris to 8.45%. Subsequent surveys and analytical studies -- also conducted by the AMA -- resulted in the increase, on October 29, 1987, of the WAC markup from 8.45% to its current 9.2%. Thus, the AMA's understanding of the meaning of WAC derived, not from the manufacturers' misrepresentations or suppressions, but from its own studies and surveys. A party that reaches a conclusion regarding a state of facts on the basis of that party's own truly independent investigation cannot claim that it relied on an allegedly fraudulent misrepresentation. Burroughs, supra; Smith, supra.

Thus, the dissent, which focuses on the role of WAC in the State's formulation of its reimbursement methodology, is unpersuasive. At "the eye of [this] hurricane" is AWP, Grant Bagley, John Bentivoglio, and Rosemary Maxwell, Accurate Drug Price Reporting: a Modest Proposal 19 No. 11 Andrews Pharmaceutical Litig. Rep. 13 (January 2004), not WAC. This is so, because the State neither paid -- nor ever intended to pay -- WAC. Instead, it has, at times, paid a markup of WAC. This markup was derived, however, not from anything reported

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by the manufacturers, but from the AMA's own studies and surveys.

As noted by GSK:

> "[W]hile AMA has reimbursed pharmacists using a WAC-based formula since the mid-1980s, it has not done so in 'reliance' on a belief that WAC itself represents an actual transaction price; rather, it has done so because, whatever WAC represents, AMA has deemed WAC + 9.2% to be an appropriate measure by which to reimburse all Alabama pharmacists fairly, without regard to size or market power."

GSK's reply brief, at 25 (case no. 1071704) (emphasis in original).

Indeed, the WAC markup has been intended to approximate what the AMA has determined to be the appropriate discount of AWP. In light of the AMA's surveys and the manner in which the AMA ultimately arrived at its methodology, what the AMA thought about WAC is largely irrelevant. There is, as a matter of law, no basis on which the State can plausibly contend that it relied on WAC to determine what to pay providers.

Perhaps, however, the most irrefutable evidence of the State's actual understanding of WAC and AWP is the reimbursement methodology itself. The AMA uses WAC + 9.2% and AWP - 10.2% to arrive at EAC. State's brief, at 7-8 (cases

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no. 1071439 & no. 1071440). The State concedes that "EAC is not a 'list' price or an 'undiscounted price,' but is a 'price paid.'" State's brief, at 6 (case no. 1071704). Remarkably, the State has taken the position that AWP also means "an actual average price" paid. State's brief, at 43 (cases no. 1071439 & no. 1071440) (emphasis added). See also State's brief, at 39 ("AWP is the average price paid by pharmacies to wholesalers for drugs, net of all discounts and other price concessions") (case no. 1071704); State's brief, at 40 (AWP is "an actual average of prices paid by retailers to wholesalers") (case no. 1071759). If these assertions were true, then the State could merely reimburse on the basis of AWP - 0%, as it was doing in 1985.[10] The State, however, has not reimbursed providers on the basis of an undiscounted AWP since 1985 when the DHHS threatened to cut off federal funding on account of that practice. In truth, the State -- as do all the states -- takes a discount from AWP to compensate for the fact that AWP is not a net figure. The AWP discounts are

[10]These statements amount to a default to the position the State was taking in 1985, a position that occasioned the Morris letter.

meant to offset the discounts and other price concessions that are available to providers.

Aside from the fact that the State's current position flatly contradicts the DHSS mandate stated in the Morris letter, if, in fact, the AMA believed, as it now claims, that the published AWPs were, like EAC, prices actually paid, then, undisputedly, the State, by discounting the published AWPs by 10.2%, must have intended to reimburse its providers at an average of approximately 10% below their actual cost. The State points to the fact that it has continued to reimburse providers for the distribution of two classes of drugs at 100% of AWP as proof that it believed the published AWPs were actual acquisition costs for all drugs. However, these reimbursements actually prove the opposite. Specifically, in the GSK/Novartis trial, Finch testified for the State, as follows:

> "Q. [State's counsel]: In that methodology, does the State of Alabama use 100 percent of AWP for anything?
>
> "A. [Finch]: We do.
>
> "Q. Okay. Tell us about that.
>
> "A. Well, during the period that I talked about a moment ago in the late eighties when this directive came down from the federal

> government, we went through a process of determining how we could appropriately comply with the federal law that says we have to pay what's generally and currently being paid, our best estimate of what that is.
>
> "What we did is during that time conducted a couple of surveys of wholesalers, and we found that for drugs that are controlled drugs, the estimated acquisition cost for those drugs was actually AWP. Because we were under a federal directive to discount off of AWP, we corresponded back with the federal government, shared our findings with them, and they actually approved for us for that group of drugs -- those controlled drugs -- to continue to pay AWP and then to take a discount off of the other drugs, which is where our current formula is."

(Emphasis added.) The unmistakable inference from Finch's testimony is that, for all the "other drugs," the State knew that "the estimated acquisition cost ... was [not] actually AWP."

Although the trial judge disallowed the proffered testimony of pharmacists who would have provided evidence as to what the AMA actually knew, the NCPA states in its amicus brief that a practice of discounting by 10% an actual AWP "would cause pharmacies to lose money on every prescription they filled on behalf of a Medicaid recipient" and would "force many pharmacies to discontinue participation in the Medicaid program altogether." NCPA's brief, at 5-6. In other

words, reimbursing Alabama providers at approximately 90% of their actual cost would drive them from, and, perhaps, effectively terminate, Alabama's Medicaid program.

Because there is no evidence indicating or contention that the State intends to discontinue its Medicaid program, it must not have intended to discount the actual AWP by 10.2%. Indeed, testifying for the State in the trial of Novartis and GSK, Finch agreed that the AMA could not legally reimburse providers at 9% or 10% less than EAC, or true AWP. Thus, the State's argument that it believed the published AWPs to represent actual AWPs is simply untenable. On the contrary, it is clear beyond cavil that the reimbursement methodology adopted by the AMA is the product of a conscious and deliberate policy decision, which seeks to "balance (i) the amount [it] reimburse[s] pharmacies that dispense drugs to Medicaid patients, and (ii) the requirement -- established by federal law -- to set reimbursement sufficiently high to ensure participation in the Medicaid program by retail pharmacies." NCPA's brief, at 3.

Thus, we agree with AstraZeneca when it contends that this litigation is essentially an "attempt to use tort law to re-define [the AMA's] Medicaid reimbursement obligations."

AstraZeneca's brief, at 32. Such regulation by litigation raises, of course, serious questions of federal preemption and supremacy, none of which we address here. However, given the State's particularized knowledge of the challenged reporting practices, a claim of common-law fraud -- with its element of reasonable reliance -- is, like the proverbial "square peg in a round hole," particularly ill-suited for the task to which it was put in this dispute.

In short, the State determined for itself the appropriate reimbursement formulas based on its own surveys and calculations. It cannot, therefore, "claim reliance upon [the alleged] misrepresentation[s]." Smith, 528 So. 2d at 316. Although the State does not explain when, or how, it first began to take issue with the pharmaceutical manufacturers' methods of reporting, it is undisputed that the relevant reimbursement methodology has not changed since 1987. In other words, the State has never altered its course of conduct since taking issue with the reporting methods. See Hunt, 901 So. 2d at 8 (reasonable-reliance requirement was not met where the State did not change its course of conduct after discovering the alleged discrepancy). In Hunt, the State never assumed the royalty reports to be true, while in this

case, the State did not accept the published AWP reports as true, nor did it rely on the truthfulness of the published WAC reports. In Hunt, the State always intended to audit the royalty calculations, while here, the State always used the formula it deemed appropriate. Indeed, the State contends that it should not have to change its conduct but that the manufacturers should have to change their conduct by "report[ing] real prices paid." State's brief, at 68 (case no. 1071704).

III. Conclusion

In summary, this case is controlled by Hunt and the authority on which Hunt relied. The State failed to produce substantial evidence that it reasonably relied on the misrepresentations and/or fraudulent suppression it alleged AstraZeneca, GSK, and Novartis engaged in in these cases. Consequently, the trial court erred in denying the motions for a JML of AstraZeneca, Novartis, and GSK. The judgments in favor of the State are reversed, and judgments are hereby rendered in favor of AstraZeneca, Novartis, and GSK.

1071439 -- REVERSED AND JUDGMENT RENDERED.
1071440 -- REVERSED AND JUDGMENT RENDERED.
1071704 -- REVERSED AND JUDGMENT RENDERED.
1071759 -- REVERSED AND JUDGMENT RENDERED.

Lyons, Stuart, Smith, Bolin, and Shaw, JJ., concur.

Cobb, C.J., and Murdock, J., concur in the result.

Parker, J., dissents.