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SUPREME COURT OF ALABAMA

SPECIAL TERM, 2012

1081402

Sandoz, Inc.

v.

State of Alabama

Appeal from Montgomery Circuit Court
(CV-05-219.65)

PER CURIAM.

The defendant below, Sandoz, Inc. ("Sandoz"), appeals from a judgment entered on a jury verdict in favor of the plaintiff, the State of Alabama. The State alleged at trial that Sandoz, a manufacturer of generic pharmaceuticals,

purposely reported inflated pricing information for generic drugs in third-party publications and that the State, using those published prices, overpaid certain reimbursements to providers of prescription drugs made pursuant to the Medicaid program. The State thus sued Sandoz seeking damages under various theories of fraud.

Previously, in AstraZeneca LP v. State, 41 So. 3d 15 (Ala. 2009), the State unsuccessfully sued manufacturers of brand-name pharmaceuticals under the same theories. Alabama law requires that a party claiming to be the victim of fraud must have actually relied on the false information it received and that such reliance must have been reasonable. Because in this case, as in AstraZeneca, the State knew that the prices reported by Sandoz were not what the State claims they should have been, Alabama law does not allow the State to claim that its reliance on that information was reasonable. Further, the State's reimbursement decisions were not based on the allegedly false information provided by Sandoz; instead, its decisions were based on policy concerns and certain requirements of the federal Medicaid program. Thus, as was the case in AstraZeneca, the State's claims should not have

been submitted to the jury, and Sandoz is entitled to a judgment in its favor. Therefore, we reverse the trial court's judgment and render a judgment in favor of Sandoz.

Facts

This case is part 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." AstraZeneca, 41 So. 3d at 18. In AstraZeneca, we discussed the background of these cases as follows:

> "'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, 100 S. Ct. 2671, 65 L. Ed. 2d 784 (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, 100 S. Ct. 2671. 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, 126 S. Ct. 1752, 164 L. Ed. 2d 459 (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 [Alabama Medicaid Agency] 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 [('the HCFA')]. 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. 'Providers' are typically physicians and retail pharmacies that disburse prescription drugs to persons eligible for Medicaid benefits.
>
> "The [Alabama Medicaid Agency] 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."

AstraZeneca, 41 So. 3d at 18-19 (footnote omitted).

Providers -- usually pharmacies -- participating in the Medicaid program dispense prescription drugs to eligible persons. In turn, the Alabama Medicaid Agency ("the AMA") reimburses the providers for the dispensed drugs. There are

several methods for determining the price of drugs for purposes of calculating a reimbursement, and each state's method must be approved by the Centers for Medicare and Medicaid Services ("the CMS"). In the instant case, which involves generic drugs, the AMA used one of the following predetermined prices:

1. the estimated acquisition cost ("EAC") of the drug, plus a reasonable dispensing fee,

2. the mandated federal upper limit ("FUL"), or

3. the "maximum allowable cost" ("MAC").[1]

State's brief, at 5 (citing 42 C.F.R. § 447.512 (2010) (formerly 42 C.F.R. § 447.331)). Each of these reimbursement prices are discussed more specifically below.

A. EAC

The EAC is defined as "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 of drug most frequently purchased by providers." 42 C.F.R. § 447.502 (2010) (formerly 42 C.F.R. §

[1]Reimbursements could also be made based on the provider's "usual and customary charge" to the general public for the drug dispensed; however, that reimbursement method is not material in this case.

447.301). The determination of EACs was at the center of our discussion in AstraZeneca:

> "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 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')."

AstraZeneca, 41 So. 3d at 19 (emphasis added).

As we noted in AstraZeneca, "[d]efinitions for AWP and WAC have varied throughout the industry during the period relevant to this dispute." Id. In the case of generic drugs,

both WAC and AWP are set by the manufacturer of the generic drug and reported to First DataBank, Inc. ("DataBank"), which in turn publishes these prices in directories. The State's argument in the instant case, as it was in AstraZeneca, is that the WAC and AWP information reported to and published by DataBank is supposed to be the final, "net" prices that include any discounts or incentives that may have been afforded the wholesalers or providers. Sandoz, on the other hand, contends that WACs and AWPs are merely "list" prices; various purchasers of generic drugs might receive various discounts and rebates on these list prices that could lower the "net" prices they ultimately pay.

The State's expert witness defined AWP as "the price that the pharmacy acquires the drug from the wholesaler." The commissioner of the AMA, Carol Steckel,[2] testified that the AMA understood AWP as "the price that the pharmacist pays to acquire the drug from the wholesaler. ... [I]t is the actual price paid by that pharmacist for the drugs." This definition, the State contends, would include all discounts and would represent an average, final "net" price. However, the AMA

[2]Carol Steckel is also referred to in the record and in AstraZeneca as Carol Herrmann.

published no definition of AWP.

Sandoz's witness, on the other hand, testified that, in the case of generic drugs, Sandoz develops an AWP before the drug is even sold. Specifically, an AWP for a generic drug is set at between 10% to 15% below the AWP of the comparable brand-name drug. This is done so that DataBank will designate the drug as a "generic drug" for price-reporting purposes, which, according to Sandoz, is critical. This is a "list" price that, according to Sandoz, might not reflect the actual "net" price ultimately later paid.

As we noted in AstraZeneca:

> "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.'"

41 So. 3d at 19. DataBank also issued a definition of AWP as "that price paid by the pharmacy to the wholesaler."

The State's expert testified that a WAC was the wholesalers' "net payment made to purchase a drug product from the manufacturer net of purchasing allowances and discounts" and that the "net price includes discounts, rebates, charge-backs, all of the different discounts that the drug companies [give]." The State's expert further testified that, according to DataBank, WAC was an average price.[3] Commissioner Steckel testified, however, that WAC was an actual net price, not an average price.[4]

Sandoz's witness, on the other hand, testified that WAC did not include discounts, rebates, or other forms of price deductions and that it was the price wholesalers "paid for the drug." Specifically, according to Sandoz's witness, WAC was an invoice price the wholesalers paid, although it was often subject to a two percent "prompt-pay" discount. At that point, once purchased by the wholesaler, the drug left the

[3]The complaint also describes WAC as an "average" price paid by wholesalers to manufacturers.

[4]Testimony indicated that only one WAC was reported for each drug by the manufacturer, but that there are numerous wholesalers who pay different prices. It is unclear how the WAC could reflect one actual "net" price, and not an average price, as Commissioner Steckel maintained, when several wholesalers purchase the drug, unless all paid the same "net" price.

control of Sandoz. Sandoz maintained contracts with certain providers to lock in prices. If such a provider bought that drug from a wholesaler, the provider would pay the lesser, contracted-for price. The wholesaler in turn would apply to Sandoz for a "charge-back," whereby Sandoz would pay the wholesaler the difference between what it paid (the WAC minus any discounts) and the price for which it sold the drug to the provider. In other words, according to Sandoz, wholesalers actually paid WAC and later, depending on who bought the drugs from the wholesaler, might receive a charge-back, thus reducing the amount the wholesaler previously paid. Sandoz reported the initial price paid as WAC because the discounted "net" price was unknown at the time of the initial sale and would vary depending on the provider.

We noted in AstraZeneca that Congress has undertaken to define "WAC":

> "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)."

41 So. 3d at 20. We further noted, however, that "[n]ot all such industry publications have defined WAC/AWP as 'suggested' or 'list' prices." Id.

WACs and AWPs reported by DataBank were used by the AMA to calculate EAC and thus the amount to be reimbursed to providers that sold generic drugs to Medicaid patients (assuming EAC was the method used). In AstraZeneca, we traced the complex development of the AMA's EAC formulation as follows:

> "In the 1970s, the AMA merely reimbursed providers on the basis of their actual acquisition price. ... [I]n 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 ... "estimated acquisition cost" (EAC) ... 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).
>
> "'<u>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</u> 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 [the Health Care Financing Administration, 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.

"'The methodology set forth above should produce a price that is 13.9 percent below

AWP and resu1t 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 [currently 42 C.F.R. § 447.512]. 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.)

"... On November 22, 1985, Baggiano sent Morris a letter. ... [That letter] requested approval from the DHHS to increase the markup from WAC + 5.01% to WAC + 8.45% .... Specifically, the letter stated:

> "'In accordance with federal regulations 42 CFR [§] 447.332 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 [Steckel], 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 [Steckel] 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 [Steckel'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.
>
> _____
>
> "[3]At all times relevant to this dispute, the AMA was receiving, pursuant to a contract with DataBank, drug-pricing information from DataBank."

AstraZeneca, 41 So. 3d at 20-24 (alterations in AstraZeneca.) This evidence was also produced in the instant case. At the time of trial, the State continued to calculate EAC at WAC plus 9.2% or AWP minus 10.2%.

B. FUL

In 1987, the federal government created through regulation a program to set certain price limits on drugs offered through the Medicaid program as FUL--federal upper limit--prices. FULs are computed by the federal government as a price cap for state Medicaid agencies when reimbursing providers for certain drugs; FULs for generic drugs were set at 150% of the lowest reported AWP, WAC, or direct price. This figure was subject to an increase in order to ensure availability of the drug. According to Commissioner Steckel, from 1991 to 1997 the AMA reimbursed providers at the FUL price, if available, even if it was not the lowest price.

C. MACs

In 1997, the AMA instituted the "maximum allowable cost" ("MAC") program, which is similar to the FUL program instituted by the federal government. A memorandum entered into evidence at trial indicated that this program was implemented because the AMA "continued to find drastic differences in what the providers were able to obtain certain products for and what [the AMA was] paying." Additionally, the memorandum recognized that "overpayment" can occur when paying at the FUL rate. A MAC is developed if there are three or

more manufacturers for a particular generic drug; MAC is determined by ranking all available WAC prices for the drug and selecting the price at the 65th percentile.[5] MAC prices, like FUL prices, represent a ceiling or price cap.

Procedural History

On January 26, 2005, the State filed an action seeking damages against over 70 pharmaceutical manufacturers, including Sandoz.[6] In AstraZeneca, we described this action as follows:

> "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

[5]There is a dispute in the record as to whether the WAC prices used are unmodified or include a 9.2% addition to the WAC price.

[6]The initial complaint sought damages against 79 defendants; the State's amended complaint filed on January 11, 2006, sought damages against 73 defendants.

> 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."[7]

41 So. 3d at 25.

Sandoz answered the State's complaint and asserted a variety of affirmative defenses. The State's case against Sandoz went to trial, and, at the close of its case, the State withdrew its claims seeking damages for wantonness and unjust enrichment. Sandoz moved for a judgment as a matter of law ("JML") on the remaining claims, which the trial court denied. Sandoz again moved for a JML at the close of all the evidence, which motion the trial court also denied. The jury returned a verdict in favor of the State on its misrepresentation and suppression claims and awarded the State $28,443,572 in compensatory damages and $50,000,000 in punitive damages.

Discussion

In AstraZeneca, we noted that the State's central argument with respect to its fraud claim revolved around the

[7]In Ex parte Novartis Pharmaceuticals Corp., 975 So. 2d 297 (Ala. 2007), this Court had directed the trial court to sever the claims against each company.

assertion that the published WACs and AWPs were "net" prices and not suggested or list prices: "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." 41 So. 3d at 27. In the instant case, the State similarly contends that "Sandoz misrepresented its drug prices by reporting false and inflated prices ...." State's brief, at 43. Because the reported WAC and AWP prices where higher than what the State contends they should have been, according to the State, AMA's reimbursements to pharmacies and other providers were likewise inflated.[8]

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[8]The allegedly inflated reimbursements were not paid to Sandoz; rather, the pharmacies and other providers actually profited by receiving reimbursements at rates allegedly much higher than the actual purchase costs from wholesalers.

> "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."

AstraZeneca, 41 So. 3d at 27 n.8.

On appeal, Sandoz argues that the trial court erred in refusing to grant its motions for a JML; specifically, Sandoz contends that the State failed to present substantial evidence of fraud and suppression because, it says, the State did not, and could not, rely on the pricing information Sandoz provided to DataBank.

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

Long v. Wade, 980 So. 2d 378, 383 (Ala. 2007). In the context of a fraud case, we have stated:

> "[W]hether the evidence is sufficient to permit submission of disputed factual issues to a jury is a question of law for the court to decide. If the answer to the question is no, then the case should not be submitted to a jury. 'The question concerning the sufficiency of the evidence (i.e., whether it was of such "weight and quality" that the jurors could reasonably infer from it that [the plaintiff]

> had been defrauded) [is] a question of law and [is] therefore for the court to decide ....'"

Exxon Mobil Corp. v. Alabama Dep't of Conservation & Natural Res., 986 So. 2d 1093, 1100-01 (Ala. 2007) (quoting Phillips Colleges of Alabama, Inc. v. Lester, 622 So. 2d 308, 314 (Ala. 1993)).

In support of its misrepresentation claim, the State was required to present substantial evidence in support of the following:

> "In order to recover for fraud, the [State] needed to establish (1) that [Sandoz] made a false representation, (2) that the misrepresentation involved a material fact, (3) that the [State] relied on the misrepresentation, and (4) that the misrepresentation damaged the [State]. Liberty Nat'l Life Ins. Co. v. Ingram, 887 So. 2d 222, 227 (Ala. 2004)."

AmerUS Life Ins. Co. v. Smith, 5 So. 3d 1200, 1207 (Ala. 2008). To establish a claim of fraudulent suppression, the State must establish that: "(1) [Sandoz] had a duty to disclose an existing material fact; (2) [Sandoz] concealed or suppressed that material fact; (3) [Sandoz's] suppression induced the [State] to act or refrain from acting; and (4) the [State] suffered actual damage as a proximate result." Coilplus-Alabama, Inc. v. Vann, 53 So. 3d 898, 909 (Ala.

2010).

A plaintiff's purported reliance in an action alleging misrepresentation or suppression must be reasonable: "'[T]he right of reliance comes with a concomitant duty on the part of the plaintiffs to exercise some measure of precaution to safeguard their interests. In order to recover for misrepresentation, the plaintiffs' reliance must, therefore, have been reasonable under the circumstances.'" AmerUs Life Ins. Co., 5 So. 3d at 1207 (quoting Torres v. State Farm & Cas. Co., 438 So.2d 757, 759 (Ala. 1983)). See also Houston Cnty. Health Care Auth. v. Williams, 961 So. 2d 795, 814 (Ala. 2006) ("Additionally, 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 ...." (emphasis added)).

In AstraZeneca, this Court's holding focused on two fatal flaws in the State's fraud and suppression cases: (1) the State knew that the WACs and AWPs reported by the drug manufacturers were not "net" prices that included discounts and (2) the State did not rely on the prices reported. Both are pertinent in the instant case.

A. Knowledge

As we noted in AstraZeneca, a party cannot claim that it was deceived by a representation if it was sufficiently skeptical of it or knew the representation to be false.

> "'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) [(quoting Fowler V. Harper and Fleming James, Jr., The Law of Torts, § 7.13 (1956))]."

AstraZeneca, 41 So. 3d at 28. Further, plaintiffs alleging fraud cannot be said to have reasonably relied on alleged misrepresentations when they have been presented with information that would either alert them to any alleged fraud or would provoke inquiry that would uncover such alleged fraud. AmerUs Life Ins. Co., 5 So. 3d at 1216 (noting that language in documents received by the plaintiff "should have provoked inquiry or a simple investigation of the facts" and

that the plaintiff is "then charged with knowledge of all the information that the inquiry would have produced"). Alfa Life Ins. Corp. v. Green, 881 So. 2d 987, 992-93 (Ala. 2003) (holding that the plaintiffs had not shown reasonable reliance where they had been presented information that contradicted an insurance agent's representations); Liberty Nat'l Life Ins. Co. v. Ingram, 887 So. 2d 222, 229 (Ala. 2004); and Baker v. Metropolitan Life Ins. Co., 907 So. 2d 419, 423 (Ala. 2005) (holding that the plaintiff failed to produce substantial evidence of reasonable reliance because, "[i]n light of the conflict between [the defendant's] alleged misrepresentations and the documents presented to [the plaintiff] when he entered into the transaction in question, it cannot be said that [the plaintiff] reasonably relied on the [defendant's] representations").

We stated in AstraZeneca: "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." 41 So. 3d at 29. However, we held that such argument was "untenable in

light of the correspondence and internal memoranda involved in the State's formulation of its reimbursement methodology." Id. Specifically,

> "by 1985, the AMA was reimbursing providers at the [AWP] rate. Significantly, in that same year, the AMA received a warning from the DHHS [Department of Health and Human Services] 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....
>
> "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 [Steckel] 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 [Commissioner Steckel] 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."

AstraZeneca, 41 So. 3d at 29-30.[9]

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[9]The State argued at trial in the present case that AWPs were supposed to be actual net prices. As we noted in AstraZeneca:

> "If [this was] 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 [Department of Health and Human Services] 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 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 DHHS mandate stated

The evidence referenced above in AstraZeneca was also presented at the trial in this case, and the holding, as a matter of law, that the AMA had actual knowledge that AWPs were not "net" prices is equally applicable here.[10]

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

41 So. 3d at 31-32.

[10]On appeal, the State appears to contend that, if AWP was the basis for only 2% of the AMA's reimbursements, as testimony at trial suggested, "then there is no need to dwell herein on the meaning of AWP or whether Sandoz misrepresented or concealed its true AWP." State's brief, at 51. Sandoz contends that the State is abandoning AWPs as a basis to support the judgment in its favor. The record reveals a great deal of testimony, evidence, and argument regarding Sandoz's alleged fraudulent reporting of AWPs. This raises numerous issues regarding the prejudicial impact of what the State now says is immaterial evidence presented at trial, as well as the propriety of the State's damages calculation, which seems to rely exclusively on the difference between AWP and the actual "net" prices suggested by the State. In fact, the State appears to suggest that the damages award in this case may be recalculated by this Court or by the trial court on remand. State's brief, at 91-92. However, our resolution of this case pretermits discussion of these concerns.

In AstraZeneca, there was a mathematical link between AWPs and WACs; thus, the State's knowledge that AWPs did not equal "net" prices necessarily meant that the State also knew that WACs did not represent "net" prices. 41 So. 3d at 30. The State contends that in the present case, unlike in AstraZeneca, which involved brand-name drugs, there is no mathematical relationship between AWPs and WACs of generic drugs; thus, according to the State, any information regarding whether AWPs reflected "net" prices did not similarly alert the State to whether WACs reflected "net" prices:

> "In AstraZeneca, the Court concluded that AMA did not rely on the WAC prices reported by the manufacturers because WAC was mathematically tied to AWP and because AMA knew that AWP was inflated, deeming WAC irrelevant. ... However, a consistent mathematical relationship between WAC and AWP does not exist in the generic drug context. ... Therefore, the premise in AstraZeneca that WAC and AWP are mathematically tethered is inapplicable to Sandoz and not supported by the record. ... Consequently, any notice AMA may have had concerning AWP inflation could not have given AMA notice of similar WAC inflation ...."

State's brief, at 41.

Other evidence in the record, as discussed above, indicates that the AMA was aware--or should have been aware--that WAC data did not include discounts: the November 22,

1985, letter by Baggiano to Morris acknowledging that WACs were to be adjusted to compensate some pharmacists who were "unable to take advantage of discounts";[11] the 1998 memorandum discussing the creation of the MAC program, which indicated that providers were acquiring drugs at a drastically different price than the AMA was paying;[12] and a March 5, 2004, AMA research summary indicating that "WAC amounts may not reflect all available discounts."[13]

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[11]Justice Parker, in his dissent, restates his objection stated in his dissent in AstraZeneca regarding the effect of this letter. However, the majority in AstraZeneca rejected this analysis.

[12]In his dissent, Justice Parker suggests that this memorandum only reflects knowledge by the AMA that reimbursements to pharmacies were drastically higher than the actual prices the pharmacies were paying to wholesalers, but did not communicate any specific knowledge regarding the accuracy of WACs. However, these reimbursements were calculated based on WACs, specifically, 98% of the EACs were calculated using the WAC plus 9.2 percent formula. If the addition of 9.2 percent to wholesale WACs resulted in calculated reimbursement prices (EACs) "drastically" higher than the actual prices paid by pharmacies, then the AMA should have been aware that the actual wholesale prices were lower than the WAC price. In other words, if the AMA knew that reimbursements based on wholesale WAC prices were "drastically" too high, then it should have known that this meant that the WACs--the basis for those reimbursements--were also too high.

[13]We also note that other evidence in the record indicates that the federal government was aware that WACs did not include discounts and rebates. A Government Accounting Office

More important, however, is evidence indicating that the State was privy to other pricing information from Sandoz that directly indicated that WACs and AWPs did not include certain discounts or were not "net" prices. According to testimony at trial, the federal government uses a rebate program in which generic-drug manufacturers must rebate, directly to the states, a percentage of the "average manufacturer's price" ("AMP") for their drugs. The AMPs upon which the rebates are based are reported to the CMS and are intended to reflect the average amount paid to a pharmaceutical manufacturer by wholesalers for generic drugs, which prices must include certain discounts. Using the AMPs, the CMS calculates a "unit rebate amount," which is 11% of the AMP. That rebate amount is then sent to the various state Medicaid agencies.[14] The State's

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report from 1994 entered into evidence stated: "Some observers have criticized the use of the WAC as a measure of manufacturers' prices because it does not capture manufacturers' discounts and price reductions provided to certain buyers...." Similarly, a March 2002 report of the Department of Health and Human Services Office of Inspector General stated: "We estimated that the invoice price for generic drugs was a national average of 30.55 % below WAC. ... The results of our review show that WAC was not a true wholesale acquisition price and was significantly higher than the actual acquisition costs for generic drugs."

[14]It is to the manufacturer's advantage to include all discounts and rebates in the calculation of the AMP because

expert agreed that, with this formula in mind, a state Medicaid agency could calculate the reported AMP using the rebate amount and the quantity of the drugs the agency dispensed.

Although not required by law to do so, from 1991 to 1997 Sandoz voluntarily submitted certain AMP data to the AMA. On appeal, Sandoz contends that this information "would have, given a cursory review, put a reasonable state Medicaid agency on notice that those AMP prices, which were required by federal law to include discounts ... were lower than WACs and AWPs," thus alerting the AMA that WACs and AWPs did not include discounts and were not "net" prices. Sandoz's brief, at 51. In other words, Sandoz contends that the AMPs were the "net" prices the State contends were suppressed and kept from it; because the State had this information in hand, Sandoz argues, the State cannot prove that its purported reliance on any alleged misrepresentation was reasonable.

On appeal, the State contends that the AMP figures could not be used to alert the AMA that WACs and AWPs were not net prices because, by law, the AMA was not allowed to consult the

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the lower the price reported, the lower the amount the pharmaceutical manufacturer must rebate.

data for reimbursement purposes. Witnesses testified to, and the State cited in support of this argument, statutory authority prohibiting such data from being disclosed by certain governmental entities, as well as a letter from the CMS to a Texas agency noting that because AMP information is confidential, it could not be used to calculate EAC. None of this testimony, however, indicates that the AMA was forbidden from reviewing the AMP data it undisputedly received.

The State also contends that the AMP information was not in a form useful to the AMA for comparison purposes. At trial, Commissioner Steckel stated that AMPs were not "reliable." Specifically, she stated that AMPs were not readily comparable with AWP, WAC, FUL, or MAC figures because AMPs were quarterly figures based on different unit sizes.[15]

The State's arguments as to the incompatibility of AMP data for comparison purposes is belied by the fact that the AMA did in fact compare AMPs to WACs and AWPs and noted the difference. Specifically, in a document communicated to Commissioner Steckel in October 2004 by Mary Finch, the AMA's

[15]Commissioner Steckel testified that comparing the figures is "challenging" and "difficult." Other testimony indicated that "there was not a way for" the AMA to use the AMP information for comparison purposes.

director of Policy and Legislative Affairs, AMPs for certain drugs were compared to "Medicaid" prices[16] for those drugs. This document, on its face, places the "Medicaid prices" alongside the observably lesser AMP prices, and calculates the "projected savings" both per unit and for the quantity of units purchased in the previous year if an AMP-plus-10% formula is used instead of the "Medicaid prices." This document clearly demonstrates that AMP data could be compared to AWPs and WACs and, given that AMPs, by law, include certain discounts, would demonstrate that WACs[17] and AWPs do not include all discounts or were not the final, "net" prices ultimately paid for the drugs.[18]

As noted above, the question whether the evidence was sufficient for the jury to "reasonably infer" that the State "had been defrauded" is a "question of law." Exxon, 986 So.

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[16]Finch testified that the "Medicaid" prices represented AWP minus 10%, WAC, MAC, and FUL, and WAC plus 9.2% figures.

[17]Justice Parker, in his dissent, does not address whether the AMP data should have provoked inquiry by the AMA into whether WACs were "net" prices.

[18]Finch testified that this could not have been done with prior AMP information, but her explanation as to why this was the case was based on the premise that AMP prices were "meaningless in terms of reimbursement."

2d at 1100-01. The evidence in the instant case demonstrates that the State knew, or should have known, that the WACs and AWPs did not represent fully discounted net prices. Therefore, as in AstraZeneca, any reliance on the alleged misrepresentations was not reasonable: "'"If the [State] knew that the representations were false ..., [it] can not complain that [it] has been misled to [its] damage by [Sandoz'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."'" AstraZeneca, 41 So. 3d at 28 (quoting Shades Ridge Holding, 390 So. 2d at 610-11 (quoting in turn The Law of Torts, § 7.13)).

B. Reliance

Sandoz further argues that the State did not actually rely on the AWPs and WACs it reported. Specifically, Sandoz argues that the evidence at trial demonstrated that the AMA's reimbursement methodology was not enacted in response to Sandoz's representations, but instead was based on various policy decisions and the dictates of the federal government. Specifically, the AMA was required to develop a policy ensuring that pharmacies and other providers were reimbursed

enough money to ensure profitability and to keep their participation in the Medicaid program, and not simply to reimburse out-of-pocket expenses. This was our exact holding in AstraZeneca:

> "[I]t 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.'...
>
> "....
>
> "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[v. J.H. Berry Realty Co.,] 528 So. 2d [314,] at 316 [(Ala. 1988)]."

AstraZeneca, 41 So. 3d at 33.

The EAC reimbursement formulations in the present case, as we noted in AstraZeneca, were the result of "conscious and deliberate policy decision[s]." 41 So. 3d at 33. The decision in September 1985 to change from reimbursement on 100% AWP to WAC plus 5.01% was the result of a directive of the federal government, not in response to Sandoz's prices. The adjustment in October 1985 to a WAC-plus-8.45% EAC formula was the result

of studies conducted by the AMA based on what pharmacies were paying, including pharmacies that did not receive "discounts." Again in 1987 the EAC reimbursement formula was altered to a WAC-plus-9.2% figure based on the AMA's own studies. The State's witnesses confirmed that the AMA could have selected numerous other adjustments to the AWP and WAC figures, paying a percentage greater or lesser than each; however, the adjustments were the result of the AMA's own policy-making decisions, its own research, or the directives of the federal government, all in an effort to balance costs with the policy to set reimbursements high enough to ensure the participation of pharmacies and other providers in the Medicaid program. See AstraZeneca, 41 So. 3d at 31 ("[T]he 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."), and 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) (emphasis omitted))).

Most telling is that, even after discovering the purportedly fraudulent pricing by Sandoz, the AMA did not change its EAC formulas. In Hunt Petroleum Corp. v. State, 901 So. 2d 1 (Ala. 2004), this Court noted that reliance on an alleged misrepresentation must induce the allegedly defrauded party to act or to change its course of action:

> "Reliance requires that the misrepresentation actually induced the injured party to change its course of action. ...
>
> "This Court has explained what constitutes legal reliance in Alabama:
>
> > "'"To determine whether or not a misrepresentation was actually relied upon, whether it was a cause in fact of the damage, the sine qua non rule is often applied. If the plaintiff would not have acted on the transaction in question but for the misrepresentation, such misrepresentation was an actual cause of his loss. If he would have adopted the same course irrespective of the misrepresentation and would have sustained the same degree of damages anyway, it can not be said that the misrepresentation

> caused any damage, and the defendant will not be liable therefor."'
>
> "Shades Ridge Holding Co. v. Cobbs, Allen & Hall Mortgage Co., 390 So. 2d 601, 611 (Ala. 1980) (quoting Fowler V. Harper and Fleming James, Jr., The Law of Torts § 7.13 (1956))....
>
> "....
>
> "Although the terminology varies from state to state, the underlying principle is the same -- for 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 have acted, that is, that he took a different course of action because of the misrepresentation."

Hunt Petroleum, 901 So. 2d at 4-5 (emphasis added). In AstraZeneca, the fact that the State had not adjusted its reimbursement formulas after discovering the allegedly fraudulent reporting of AWPs and WACs was fatal to the State's case:

> "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)."

41 So. 3d at 33.

AstraZeneca's holding regarding the State's reliance on the prices reported to DataBank applies equally to the State's formulation of the same EAC reimbursements in the present case. The State "always used the formula it deemed appropriate," and its decisions were formed by its own study and actions or by the dictates of the federal government, not by reliance on Sandoz's price disclosures to DataBank.

In the context of reimbursements based on FULs and MACs, there is also no reliance. As to FULs, the record discloses that such figures were set exclusively by the federal government,[19] not by the AMA. The AMA "relied" on nothing but

[19]Although there was some testimony at trial implying that Sandoz's purported misrepresentations could have affected FUL prices, there is no allegation that the federal government was defrauded or that it even relied on Sandoz's price reports. Indeed, evidence presented at trial indicated that the federal government was aware that AWPs and WACs were not fully discounted prices, and 42 U.S.C. § 1395w-3a(c)(1)(B) confirmed this understanding.

the federal government when it reimbursed on the basis of FUL prices. Although the AMA was required to reimburse at the FUL rate if it was the lowest price available, according to Commissioner Steckel, from 1991 to 1997 the AMA reimbursed generic drugs at the FUL rate (if available for a particular drug) even if the AWP or WAC formulas required a lesser reimbursement. It can hardly be said that the State relied on AWPs and WACs as fully discounted "net" prices for purposes of paying the lowest reimbursements possible when the AMA paid on the basis of FUL prices even if those prices were not the lowest.[20] In the end, reimbursements made at the FUL rate by the AMA were in no way made in reliance on any purported misrepresentation by Sandoz.

Similarly, the reimbursements made pursuant to MAC were the result of the AMA's own decision-making process. The State's witness acknowledged that the decision to select a reimbursement rate at the 65th percentile of all available

[20]Justice Parker, in his dissent, nevertheless appears to conclude that reimbursements based on FULs were made by the AMA in reliance on Sandoz's representations regarding WACs, even though the AMA did not formulate the FUL prices, had no discretion to reject such prices when they were the lowest available price, and paid such prices (for a span of six years) even if they were not the lowest prices.

prices was a decision by the AMA.[21] A different percentile could have been selected, establishing a higher or lower price. Moreover, if MACs represent the 65th percentile of what the AMA believed was the "net" price wholesalers were paying (i.e., WACs), then the AMA knew it was making reimbursements to pharmacies and other providers for the remaining 35% at less than the price the wholesalers were actually paying. Like the State's arguments as to AWP, this would mean that the AMA was intentionally reimbursing some pharmacies and providers at a price it believed was below the "net" cost of what some wholesalers were paying in direct contravention of the policy to adequately compensate providers and to ensure their participation in the Medicaid program. See supra n.8. This negates the assertion that the AMA believed that WACs amounted to a final, "net" price.

Conclusion

Sandoz was entitled to a judgment as a matter of law;

[21]The record contains an internal AMA document proposing the MAC program; no rationale for the selection of the 65th percentile is given, other than that "[t]he 65th percentile is the price at which 65% of the products are available." Indeed, a memorandum in the record authored by Mary Finch suggests adjusting the MAC percentile to a different percentage to increase savings.

therefore, we reverse the judgment of the trial court and render a judgment in Sandoz's favor.

REVERSED AND JUDGMENT RENDERED.

Malone, C.J., and Woodall, Stuart, Bolin, Murdock, Shaw, and Wise, JJ., concur.

Parker, J., dissents.

PARKER, Justice (dissenting).

I respectfully dissent from the holding of the main opinion. I dissented in AstraZeneca LP v. State, 41 So. 3d 15 (Ala. 2009), based upon what I explained there was a mistaken view of the case and a mistaken interpretation of the evidence. Because both sides in this appeal present arguments directed to the substance of my dissent in AstraZeneca, it will help to restate the pertinent portions of that dissent:

> "I respectfully dissent from the holding of the main opinion. I do agree that the Alabama Medicaid Agency ('the AMA') cannot claim lack of knowledge that the average wholesale price ('AWP') was not a true average wholesale price paid, as evidenced by the fact that the AMA's reimbursement formula for pharmacies -- AWP-10% -- reduced the AWP. This formula is the product in large part of studies the AMA had [had] conducted in 1985 and 1987 by two large pharmaceutical wholesalers of the average prices paid by pharmacies for prescription drugs.
>
> "I dissent, however, from the holding in the main opinion that the AMA did not reasonably rely on the wholesale acquisition cost ('WAC') because the AMA also knew that the WAC was not a true price paid by wholesalers to the pharmaceutical manufacturers net of purchaser discounts. I do not believe that either the surveys performed by Alabama pharmaceutical wholesalers for the AMA or the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, emphasized in the main opinion, put the AMA on notice that the WAC was not a net price. There is no evidence indicating that the surveys examined the WAC, and there is no credible evidence that the 2003

Medicare Modernization Act affected the WAC for state Medicaid reimbursement.

"The 1985 and 1987 Surveys

"In a November 22, 1985, letter, then AMA Commissioner Faye Baggiano told regional director of the United States Department of Health and Human Services ('DHHS') Richard Morris about the results of surveys that had been performed for the AMA by two Alabama pharmaceutical wholesalers:

> "'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].'

"(Emphasis added.) As the Baggiano letter states, the AMA did not survey pharmaceutical wholesalers; the AMA had two pharmaceutical wholesalers survey pharmacies. These studies were by two pharmaceutical wholesalers, not of the wholesalers. The focus was the markup on the WAC paid by pharmacists; the focus was not the WAC itself.

"Another survey was conducted for the AMA in 1987 by the same two pharmaceutical wholesalers:

> "'Effective October 29, 1987, the percentage markup was increased to 9.2%. Analytical studies were once again accomplished for Medicaid by the two primary wholesale drug companies servicing Alabama pharmacies (Walker Drug Company and Durr-Fillauer Medical, Inc.). The studies indicated average percentage markups on WA[C] for Alabama pharmacies as 7.95% (Walker) and 8.45% (Durr-Fillauer). The average of these percentages is 8.2%. The additional 1% was again added to compensate for higher cost paid by pharmacists who are unable to take advantage of discounts offered.'

"(Emphasis added.)

"Thus, these two surveys, the one completed in 1985 and the one in 1987, did not study the prices the pharmaceutical wholesalers actually paid to the manufacturers -- the WAC; instead, they focused on the markup on the WAC that pharmacies were actually paying to the pharmaceutical wholesalers. These studies did not put the AMA on notice that the reported WAC was not a true net price.

"....

"The Effect of the WAC in These Cases

"The WAC was the primary basis for payment by the AMA in these cases: 83% of the claims for drugs manufactured by AstraZeneca were reimbursed based upon the WAC (State's brief, at 62-63); 85% of the claims for drugs manufactured by GSK were reimbursed based upon the WAC (State's brief, at 62); and 85% of the claims for drugs manufactured by Novartis were reimbursed based upon the WAC (State's brief, at 66). The AWP-10% formula was used for reimbursement less than 1% of the time for Novartis

> and less than 2% for GSK and about 8% for AstraZeneca. Therefore, the WAC was the predominant basis for the AMA payments in these cases.
>
> "This evidence is undisputed.
>
> "Conclusion
>
> "The AMA's own surveys put the AMA on notice that the AWP benchmark was not a true representation of the prices actually paid by pharmacies in Alabama for drugs purchased from pharmaceutical wholesalers. The AMA's reimbursement formula, which deducted 10% from the AWP, graphically codifies the AMA's understanding that the AWP was not a true representation of the price paid by pharmacies in Alabama.
>
> "In contrast, the mathematical relationship between the WAC and the AWP, the two surveys by Alabama pharmaceutical wholesalers of the markup on the WAC paid by pharmacies in Alabama, and the 2003 Medicare Modernization Act did not put the AMA on notice that the WAC was not a net figure. The AMA presented substantial evidence indicating that the 2003 Medicare Modernization Act did not apply to Medicaid or to the states, and the main opinion mistakenly draws the wrong conclusions from the two surveys and the dependent relationship of the AWP to the WAC. The evidence is undisputed that the WAC was the primary basis for reimbursement by the AMA."

AstraZeneca, 41 So. 3d at 35-40 (Parker, J., dissenting).

The Effect of the WAC in This Case

Here, the AWP is even less significant than in AstraZeneca, accounting for only two percent of the reimbursements. The WAC + 9.2% accounts for 42%, the FUL

(federal upper limit) accounts for 20%, and the MAC (maximum allowable cost) accounts for 21% of the reimbursements. The FUL is established by the Centers for Medicare and Medicaid Services ("CMS") by reviewing prices reported by manufacturers (WAC, AWP, and direct price) and setting the FUL at 150% of the lowest published price. The MAC is established by the AMA when there are at least two generic drugs equivalent to a single brand-name drug. The MAC is set at the 65th percentile of the range between the highest and the lowest published WAC.[22] Thus, the WAC is involved in the calculation of 83% of the reimbursements in this case.

The Evidence in This Case

The main opinion relies upon four pieces of evidence to conclude that the State could not show reasonable reliance that the WAC was a net figure, that is, that it was net of all discounts. I disagree with the conclusion of the main opinion that the first two pieces of evidence, taken chronologically, showed that the State knew that the WAC was not a net figure. I disagree with the conclusion of the main opinion as to the

[22]The effect of this formula is to provide for reimbursement of brand-name drugs at a lower price when there are generic equivalents available.

effect of the next two pieces of evidence, again taken chronologically. I will discuss each piece of evidence separately.

The November 22, 1985, letter from Commissioner Faye Baggiano to Richard Morris, then regional director of the United States Department of Health and Human Services, was analyzed and addressed in that part of my AstraZeneca dissent quoted above.

The March 13, 1998, memo from Mary Finch to then Commissioner of the AMA Gwendolyn Williams explained the calculation of the MAC. In the memo, Finch wrote: "[W]e continued to find drastic differences in what the providers were able to obtain certain products for and what we were paying ...." A proper understanding of the terminology will show that the memo did not indicate that the State knew that WAC was not a net-of-discounts figure. The AMA operates under the following definitions:

> "(1) Provider -- Provider shall mean an institution, facility, agency, person, partnership, corporation, or association which is approved and certified by Medicaid as authorized to provide the recipients the services in the plan at the time services are rendered.
>
> "(2) Recipient -- Recipient shall mean a person

> who has been assigned one or more Medicaid identification numbers and has been certified by Medicaid as eligible for medical assistance under the State Plan."

Rule 560-X-29-.01, Ala. Admin. Code (Medicaid Agency). Thus, the provider is the pharmacy -- the retailer selling to the customer. Therefore, Finch's memo did not refer to variations in prices pharmaceutical wholesalers actually paid to the manufacturers -- the WAC; instead it referred to variations in prices pharmacies were paying the pharmaceutical wholesalers. The memo does not show that the State knew that the WAC was not a true net figure.

On March 5, 2004, the AMA received a copy of research on the Federal Supply Schedule that expressly stated that "[p]ublicly disclosed or listed WAC amounts may not reflect all available discounts." Thus, the State at that point was put on notice that the WAC may not be a true net figure. Then on October 8, 2004, Mary Finch sent the first draft of her pricing study to Commissioner Carol (Herrmann) Steckel. This document shows that the State by then had concrete evidence that the WAC was not a true net figure.

Three months later, on January 26, 2005, the State filed this action against Sandoz and 78 other drug manufacturers.

Thus, 10 months after receiving notice that the WAC "may not reflect all available discounts" and 3 months after initial results of its own study showed actual knowledge, the State filed this lawsuit. Such a massive, complex lawsuit is not quickly put together; it can take months of research and formulation. There is no basis in the law for holding that the preparing and filing of a lawsuit is not a reasonable response to the discovery of an alleged fraud in lieu of changing the formula. I cannot say as a matter of law that the months between the notice of a possible problem and/or the hard figures showing the problem and the subsequent filing of this lawsuit were unreasonable.

Conclusion

In summary, I do not read the November 22, 1985, letter from then Commissioner Faye Baggiano to Richard Morris or the March 13, 1998, memo from Mary Finch to then Commissioner Gwendolyn Williams as "negat[ing] the assertion that the AMA believed that WACs amounted to a final, 'net' price." ___ So. 3d at ____. Nor do I find that the State's preparation and filing of a lawsuit in response to the notice it received of a potential problem, followed by a study to confirm the

existence of a problem, instead of changing the EAC formula, somehow negated the State's claim. Accordingly, I respectfully dissent.