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COBB, Chief Justice (concurring in the result).

To the extent that the main opinion relies on Hunt Petroleum Corp. v. State, 901 So. 2d 1 (Ala. 2004), I cannot concur in its rationale, because I believe that Hunt unduly restricts the jury's consideration of reliance issues in fraud cases. The application of <u>Hunt</u> to the facts of this case is as wrong in this case as it was in Exxon Mobil Corp. v. Alabama Department of Natural Resources, 986 So. 2d 1093 (Ala. 2007), in which I dissented. I discussed my concerns in this respect at length in my dissent in Exxon. However, unlike the situation in Exxon, I believe that the facts of this case fail to raise an issue of fact for the jury with respect to the issue of reliance. In addition to the fact that the wholesale acquisition cost ("WAC") is statutorily defined as a cost not including various discounts, see 42 U.S.C. § 1395w-3a(c)(6)(B) and 42 U.S.C. § 1396r-8(b)(3)(A)(iii)(II), the record contains compelling evidence indicating that the State was aware that neither the average wholesale price ("AWP") nor the WAC were actual costs. For example, in discussing her February 26, 1992, letter to the CMS, AMA Commissioner Carol Herrmann testified as follows:

"Q. [MR. CHRISTIAN, defense counsel:] And this is -- this is dated February 26th, 1992, the letter is?

"A. Yes.

"Q. All right. Could you -- and this says, '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 a drug product by as much as 10 to 20 percent because they do not reflect discounts, premiums, special offers, or incentives.' And then they say, 'Don't do that,' in effect, right?

"MR. O'REAR [State's counsel]: Objection. That's overbroad.

"MR. CHRISTIAN: I'll go ahead and read it.

"Q. 'Consequently, absent valid documentation to the contrary, a published AWP level as a state determination of EAC [estimated acquisition cost] without a significant discount being applied is not an acceptable estimate of prices generally and currently paid by the providers.' Is that exactly what it says?

"A. That's exactly what it says.

"Q. And this would be important information for you to know, would it not?

"A. Yes.

"Q. So at least on February the 26th, 1992, you knew that -- about all of these studies that have been made that told you that these -- that this AWP overstated the price by about as much as 10 to 20 percent?

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"A. We knew that CMS believed that there was a preponderance of evidence. Our AWP had already reflected a 10 percent reduction. And again, it gets to guesstimating by how much they're overestimating their AWP instead of reporting an accurate price to begin with."

(Emphasis added.) Similarly, when Commissioner Herrmann testified as to a March 1987 memorandum she had received from the Center for Medicaid and Medicare Services ("CMS"), she stated: "States were instructed through [CMS] 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 cost." (Emphasis added.)

Thus, I conclude that the State failed to meet its burden of showing that it reasonably relied on the AWP and WAC as actual costs, and the drug manufacturers—AstraZeneca, GSK, and Novartis—would therefore be entitled to judgments as a matter of law under a more appropriate legal analysis than the analysis in Hunt. See, e.g., Ex parte Alabama Farmers Coop., Inc., 911 So. 2d 696 (Ala. 2004); Alfa Mut. Fire Ins. Co. v. Thomas, 738 So. 2d 815 (Ala. 1999); and AT & T Info. Sys., Inc. v. Cobb Pontiac-Cadillac, Inc., 553 So. 2d 529, 532 (Ala. 1989). Accordingly, I concur in the result.

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1071439, 1071440, 1071704, & 1071759 PARKER, Justice (dissenting).

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 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

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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 (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

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wholesalers. The focus was the <u>markup on the WAC</u> 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.

2003 Medicare Law

I believe that the AMA presented substantial evidence that the 2003 Medicare Modernization Act, cited in the main

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On December 8, 2003, Congress passed the Medicare Prescription Drug Improvement and Modernization Act of 2003, Pub. L. No. 108-173, which contained the following definition for WAC, codified at 42 U.S.C. § 1395w-3a(c)(6)(B), applicable to Medicare, not Medicaid:

"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."

Pursuant to 42 U.S.C. § 1395w-3a(a)(1), "this section shall apply to payment for drugs and biologicals that are described in section 1395u(o)(1)(C) of this title and that are furnished on or after January 1, 2005."

Dr. Gerard Anderson, an expert witness for the AMA, described why the 2003 Medicare Modernization Act did not apply in this case:

"Q. [COUNSEL FOR THE AMA:] Would you tell the jury if [the 2003 Medicare Modernization Act] did,

in fact, have any application to either AWP or WAC?

"A. Well, I think in any number of reasons, it doesn't. First of all, it doesn't because as I read the Act - and I'm not a lawyer. But as I read the Act, it begins in 2005.

"[DEFENSE COUNSEL]: Object, Your Honor. He's giving a legal conclusion, saying he's not a lawyer. It's objectionable by his own admission.

"THE COURT: He just told you he's not a lawyer. Overruled.

"[ANOTHER DEFENSE COUNSEL]: Your Honor, we'd also just say that the jurors can read this document and see whether it's applicable or not.

"THE COURT: The jurors are going to be the final judge. Overruled. All right, [counsel for the AMA]. Finish up.

"[COUNSEL FOR THE AMA]: Yes, sir.

So, first of all, it -- I believe it starts in 2005. Second of all, I believe that it applies to physician-administered drugs, not selfadministered drugs. Third of all, I believe that it applies to the Medicare program only, not the Medicaid program. And probably most importantly, it re -- it's related to a thing that we've only heard a little bit about in this thing, which is the ASP, or average sales price, and that's how they're supposed to pay drugs under Medicare Part B for -- for physician-administered drugs. And when there isn't an average sale price, when there is not an average sale price, because there hasn't been any sales yet, then you defer to the WAC as a system. So the WAC only applies in a new -- newly issued drug in the first quarter when there haven't been any sales. And so,

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therefore, there would be no discounts or rebates or charge-backs or anything else because there have been no sales."

in the Medicaid program applies to self-The WAC administered drugs purchased from retail pharmacies, not to physician-administered drugs, but the WAC adopted in the 2003 Medicare Modernization Act applied to physician-administered drugs. Moreover, the WAC in the 2003 Medicare Modernization Act was a default provision for new drugs having no sales history, applicable in the first quarter only after the drugs were introduced into the market. Therefore, this list-price definition for new-drug launches under Medicare could not put the AMA on notice about a definition for the WAC for Medicaid purposes. In addition, its effective date was less than four weeks before the filing of all the cases against the pharmaceutical manufacturers on January 26, 2005. Accordingly, I disagree with the main opinion's reliance on the 2003 Medicare Modernization Act.

The main opinion further relies on the 2003 Medicare Modernization Act as "incorporat[ing] this definition of WAC into the Medicaid statutory scheme. See 42 U.S.C. § 1396r-8(b)(3)(A)(iii)(II)." ____ So. 3d at ____. This reliance is inappropriate because the definition applies to manufacturer

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information to be furnished to the Secretary of DHHS for the Federal Medicaid program for rebate purposes:

- "(b) Terms of rebate agreement
- "(1) Periodic rebates
 - "(A) In general

"A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this subchapter, a rebate for a rebate period in an amount specified in subsection (c) of this section for covered outpatient drugs the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period. rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

"(B) Offset against medical assistance

"Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a) (1) of this section or an agreement described in subsection (a) (4) of this section) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1396b(a) (1) of this title.

"(2) State provision of information

"(A) State responsibility

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"Each State agency under this subchapter shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, and shall promptly transmit a copy of such report to the Secretary.

"(B) Audits

"A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

"(3) Manufacturer provision of price information

"(A) In general

- "Each manufacturer with an agreement in effect under this section shall report to the Secretary--
- " $(\dot{-})$ not later than 30 days after the last day of each rebate period under the agreement--
 - "(I) on the average manufacturer price (as defined in subsection (k)(1) of this section) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug

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application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C.A. § 355(c)]); and

- "(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C) of this section) for such drugs for the rebate period under the agreement;
- "(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1) of this section) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and
- "(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size) --
 - "(I) the manufacturer's average sales price (as defined in section 1395w-3a(c) of this title) and the total number of units specified under section 1395w-3a(b)(2)(A) of this title;

"(II) if required to make payment under section 1395w-3a of this title, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section"

(Emphasis added.) Subsection (b)(3)(A)(iii)(II), emphasized above, authorizes manufacturers to use the WAC definition from the 2003 Medicare Modernization Act, 42 U.S.C. § 1395w-3a(c)(6)(B), in reporting to the Secretary of DHHS. The states have a separate reporting responsibility under subsection (b)(2)(A), also emphasized above, which has nothing to do with the WAC. There is no provision making the Medicare definition of the WAC applicable to the states; it applies only to the manufacturers for federal reporting purposes. The information furnished by the pharmaceutical manufacturers is required to be treated as confidential under 42 U.S.C. § 1396r-8(b)(3)(D):

"(D) Confidentiality of information

"Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) of this section (other than the wholesale acquisition cost for purposes of carrying out section 1395w-3a of this title) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices

charged for drugs by such manufacturer or wholesaler, except--

- "(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1395w-3a of this title (including the determination and implementation of the payment amount), or to carry out section 1395w-3b of this title,
- "(ii) to permit the Comptroller General to review the information provided,
- "(iii) to permit the Director of the Congressional Budget Office to review the information provided,
- "(iv) to States to carry out this subchapter, and
- "(v) to the Secretary to disclose (through a website accessible to the public) average manufacturer prices.

"The previous sentence shall also apply to information disclosed under section 1395w-102(d)(2) or 1395w-104(c)(2)(E) of this title and drug pricing data reported under the first sentence of section 1395w-141(i)(1) of this title."

There is no evidence cited by the parties indicating that any of this confidential information was furnished to the states, or specifically to Alabama. In contrast, there is a mandatory provision in this section that "[i]nformation on retail survey prices ... shall be provided to States on at least a monthly basis." 42 U.S.C. § 1396r-8(f)(1)(E). Thus, retail

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information is to be provided to the states; wholesale
information, however, is to be treated as confidential.

The furnishing of protected, confidential information by pharmaceutical manufacturers to the Secretary of DHHS using the definition of WAC in the 2003 Medicare Modernization Act for purposes of the rebate program did not put the AMA on notice that, for Medicaid purposes, the WAC was not a net wholesale figure.

Mathematical Relationship Between the WAC and the AWP

The main opinion recognizes that there is a mathematical relationship between the WAC and the AWP. ____ So. 3d at ____. Conceptually, if the WAC is inflated, then the AWP is likewise inflated. This point was made by GSK's corporate representative:

- "Q. And if that WAC price is false, then the multiplier would simply report a false AWP also, correct?
- "A. You've got to make that leap again of an assumption of --
- "Q. I'm going to make that leap, and the jury is going to be asked to do it later.
- "A. Okay.
- "Q. So, if that original WAC price is false, the multiplier simply takes a false price and multiplies against it; am I correct?

- "A. It is simply math, yes.
- "Q. Simply math. Exactly."

This point was also made by the State's witness, Dr. Gerard Anderson:

- "Q. If the WAC is false and not a true price, a calculated AWP will also be false and not a true price.
- "A. Okay. There is a mathematical relationship between one -- the WAC price and the AWP price. So -- and essentially if the WAC price is not a true price, then mathematically the AWP cannot be a true price either."

Contrary to the implication in the main opinion, however, I believe that this mathematical relationship is a one-way relationship, not a two-way relationship; dependent, not interdependent. That is, the AWP is based upon the WAC: an increase to the WAC causes an equal increase to the AWP; but the WAC is not tied to the AWP in a fixed relationship: a deduction from the AWP does not cause an equal deduction from the WAC.

The defendants refer to the AWP as a benchmark that is based upon the WAC plus 20% or 25%. The AMA discovered through the retail surveys it had performed by two Alabama pharmaceutical wholesalers that the AWP was not a true representation of the prices that Alabama pharmacies were

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paying for drugs. Thus, the deduction from the AWP in the formula: AWP - 10%. But the fact that there has to be a deduction from the AWP to more closely approximate the true price paid by pharmacies does not mean that there has to be an equal deduction from the WAC. No party is advocating that here. For these reasons I believe that the fact that the benchmark AWP was not a true price did not put the AMA on notice that the WAC was therefore not a true 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.

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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 the dependent the two surveys and conclusions from relationship of the AWP to the WAC. The evidence is undisputed that the WAC was the primary basis for reimbursement by the AMA.

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Therefore, I respectfully dissent from the holding in the main opinion that the AMA could not reasonably rely on the WAC as a net figure.