

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
FIFTH DIVISION

STATE OF ARKANSAS

PLAINTIFF

v.

CASE NO. CV04-634

DEY, INC.; WARRICK
PHARMACEUTICALS CORPORATION;
SCHERING-PLOUGH CORPORATION;
and SCHERING CORPORATION,

DEFENDANTS

**DEFENDANTS' JOINT MEMORANDUM IN SUPPORT OF THEIR
MOTION FOR JUDGMENT ON THE PLEADINGS**

Defendants Dey, Inc., Warrick Pharmaceuticals Corporation, Schering-Plough Corporation, and Schering Corporation ("Defendants") submit the following memorandum of law in support of their motion for judgment on the Complaint brought by the Attorney General on behalf of the State of Arkansas ("Plaintiff" or "State").

SUMMARY OF ARGUMENT

The State brings this action alleging that Defendants committed common law fraud and violated the Arkansas Deceptive Trade Practices Act at the expense of the Arkansas Medicaid Program, Arkansas Medicare beneficiaries who made co-payments for certain drugs, and all Arkansas consumers. Although the Complaint offers almost no detail, the gravamen of these two counts appears to be that that the State and its citizens "paid grossly inflated amounts for their prescription drugs," Compl. ¶ 54, because the Average Wholesale Price ("AWP") reported by Defendants to national reporting services "bears no relation to any actual purchase price paid by any health provider." *Id.* at ¶ 35.

Plaintiff's claims must fail. The crux of Plaintiff's claim is that third-party pricing

information services published prices for drugs manufactured by Defendants that did not reflect discounts, rebates and other deductions commonly offered in the competitive prescription drug marketplace. *See* Compl. ¶ 35. It is a matter of well-established public record that the State has known for decades that the pricing information contained in industry publications did not reflect commonly-available industry discounts and amounted to a "reference" price. Indeed, as the State carefully explains in its Complaint, it takes a *substantial* discount off of those published prices when calculating its own reimbursement rates. *See, e.g.*, Compl. ¶ 14 (explaining that the Arkansas Medicaid program now takes a 20% discount off of the published "Average Wholesale Price" when computing its reimbursement for generic drugs). Simply put, the State cannot claim to have been "defrauded" by facts it clearly knew, and there can be no fraud in "inaccurately" reporting a reference price.

Plaintiff's Complaint is legally deficient for several other reasons as well. First, the State fails to allege that it reasonably relied on the pricing information published in industry compendia or that – given the State's well-documented knowledge that the published price represented an undiscounted "reference" price – any harm the State may have suffered was caused by the publication of those prices. *See, e.g., In re Arkansas Dep't of Human Servs.*, DAB No. 1273, 1991 WL 634857 (HHS Dept. App. Bd. Aug. 22, 1991). Second, Plaintiff fails to allege the facts required by Ark. R. Civ. P. 8(a) and to make its fraud-based allegations with the particularity required by Ark. R. Civ. P. 9(b). For example, the Complaint does not specify what drugs manufactured by Defendants are at issue, what the State or any of its citizens actually paid for any of the Defendants' products, or whether that amount was calculated based on pricing information provided by Defendants – all of which are particularly

within the State's knowledge. Third, the State's claims under the Arkansas Deceptive Trade Practices Act ("ADTPA") must fail because the directors of the Arkansas Department of Human Services have not required or authorized the Attorney General to bring this action, as explicitly required by statute and because the Attorney General has no authority to seek money damages for violations of that statute. Finally, judgment should enter for Defendants on the pleadings to the extent they assert claims outside of the limitations period or relating to drugs for which the State reimbursed at rates that were not calculated based on any particular Defendant's published AWP. For these and the other reasons set forth below, judgment should enter for Defendants on the pleadings.

BACKGROUND

Medicaid programs provide health benefits to low-income individuals and are jointly administered and funded by federal and state governments. *See* 42 U.S.C. § 1396. The federal government funds some portion of the costs of a state Medicaid program so long as the state program complies with certain federal guidelines. Although states are not required to reimburse for prescription drugs, where states choose to do so, federal regulations limit Medicaid reimbursement for prescription drugs to the lowest of (a) the provider's "usual and customary charges," (b) the Federal Upper Limit set by the federal government plus a reasonable dispensing fee, or (c) the "estimated acquisition cost" ("EAC") plus reasonable dispensing fees established by the state Medicaid agency. 42 C.F.R. § 447.331. EAC is defined as the state Medicaid 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. § 447.301. Arkansas has

opted to reimburse providers for certain prescription drugs through its Medicaid program.

Ark. Code Ann. § 20-77-400 to -405; 42 C.F.R. § 440.225.

In accordance with federal regulations, Arkansas limits reimbursement to the lowest of (1) the provider's "usual and customary charges," (2) the Federal/State Generic Upper Limit ("GUL"),¹ or (3) the EAC. See Arkansas Department of Human Services Pharmacy Provider Manual, (hereinafter "*Pharmacy Manual*"), Section 251.000; Compl. ¶¶ 13-15. Arkansas has chosen to define EAC by reference to the Average Wholesale Price ("AWP") published by third-party publications. *Id.* at Section 251.200. Recognizing that participants in the market generally receive substantial discounts off of published AWP's – generally larger for generics than for branded products – Arkansas has chosen to define EAC as the published AWP minus 14% for brand drugs and the published AWP minus 20% for generic drugs. Compl. ¶¶ 14-15; *Pharmacy Manual*, Section 251.200. There is no allegation that Arkansas ever asked any Defendant to submit pricing information directly to the State.

Medicare, on the other hand, is solely a federal program that provides health insurance to individuals aged 65 or older and certain other individuals who elect to enroll in the program, regardless of income level. See 42 U.S.C. §§ 1395 *et seq.* One part of Medicare, Part B, provides coverage for, among other things, certain prescription drugs, including those furnished incident to a physician's professional services. 42 U.S.C. §§ 1395k(a), 1395x(s)(2)(A), (T). If a claim submitted by a physician or other provider is payable, Medicare pays that provider directly. See 42 C.F.R. § 424.51. For generic drugs such as those identified in Exhibit A to the Complaint, reimbursement is limited to the lower of the

¹ GUL is the maximum drug cost used to compute reimbursement for multiple-source drugs (commonly known as "generic" drugs), unless the provisions for a generic-upper-limit override have been met. *Pharmacy Manual*, Section 251.300.

provider's actual charge or 95% of the median AWP for all generic forms of the drug. *See* 42 C.F.R. § 405.517. Medicare pays 80% of the allowable amount, and Medicare beneficiaries are billed the remaining 20% as a co-payment. *See* Compl. at ¶ 23.

None of the Defendants sells any drugs directly to patients, including Medicaid and Medicare beneficiaries, or even directly to state Medicaid plans. Typically, patients receive a prescription that is filled at a pharmacy or they receive a drug directly from their physician during the course of treatment. The pharmacy or physician may have purchased the drug from a wholesaler, a retailer, another pharmacy, or any other entity in the distribution chain. When the patient receives the drug, Medicare or Arkansas Medicaid reimburses the physician or pharmacy, as the case may be, using the applicable reimbursement formula. *See* Compl. ¶¶ 17, 23. That reimbursement formula is determined by the state (in the case of Medicaid) or the federal government (in the case of Medicare). *See* Compl. ¶¶ 13-15, 23. Neither the Arkansas Medicaid program nor Medicare or Medicaid beneficiaries reimburse or otherwise pay Defendants directly for prescription drugs.

ARGUMENT

I. Judgment Should Be Entered for the Defendants Because Plaintiff Has Not Pleaded Justifiable Reliance on Defendants' Purportedly Fraudulent Statements or that Those Statements Caused Harm.

To state a claim for fraud – whether arising under the Arkansas Deceptive Trade Practices Act ("ADTPA") or common law fraud – Plaintiff must allege that it: (1) reasonably relied on the allegedly "false" statements, and (2) suffered harm as a result of that reasonable reliance. *Wiseman v. Batchelor*, 864 S.W.2d 248, 250 (Ark. 1993) (affirming dismissal of complaint with prejudice where plaintiff failed to make "any allegation of justifiable reliance," and explaining that "false statements by themselves are not sufficient to state a claim for

fraud); Ark. Code Ann. § 4-88-113(f). The State has not pled facts on either of these elements sufficient to support its claim of fraud. The State has not pled either that it reasonably relied on the published AWP to be "the actual average of the wholesale price," Compl. ¶ 35, or that the publication of AWP as an undiscounted reference price actually caused Arkansas or any of its citizens any harm.

It is a matter of well-established public record that Arkansas has *long been aware* that published AWP "greatly exceeded the actual average of the wholesale price" and that "the Average Wholesale Prices reported by Defendants for each of these drugs bears no relation to any actual purchase price paid by any health provider." Compl. ¶ 35.² Indeed, in 1988, the Director of the State's Division of Economic and Medical Services stated that "AWP is an artificially high basis for reimbursement." *In re Arkansas Dep't of Human Servs.*, DAB No. 1273, 1991 WL 634857 (HHS Dept. App. Bd. Aug. 22, 1991). Three years later, the federal government refused to approve Arkansas's Medicaid program when it tried to use the published AWP as its "best estimate" of drug cost. *In re Arkansas Dep't of Human Servs.*, DAB No. 1273, at 1, 1991 WL 634857 (HHS Dept. App. Bd. Aug. 22, 1991). After lengthy evidentiary hearings, the United States Department of Health and Human Services ("HHS") concluded that Arkansas "*was aware* that pharmacists generally paid less than that amount" and

² For purposes of part of this argument, Defendants rely on the cited public record documents, which may be considered in this motion. Courts "may take judicial notice of public records and may consider them on a motion to dismiss." *Stahl v. United States Dep't of Agric.*, 327 F.3d 697, 700 (8th Cir. 2003) (citing *Faibisch v. Univ. of Minn.*, 304 F.3d 797, 802-03 (8th Cir. 2002)); *Porous Media Corp. v. Pall Corp.*, 186 F.3d 1077, 1079 (8th Cir. 1999) (holding that courts may consider matters of public record without converting the motion to a summary judgment motion). See also *Pub. Loan Corp. v. Stanberry*, 272 S.W.2d 694, 697 (Ark. 1954) (holding that the Arkansas Supreme Court takes "judicial notice of the public records required to be kept").

Arkansas lacked "pertinent records to support a determination that the AWP represented the price generally and currently paid." *Id.* (emphasis added). HHS reaffirmed its ruling that Arkansas's use of AWP was not a reasonable estimate of drug cost just a year later. *In re Arkansas Dep't of Human Servs.*, DAB No. 1329, at 2, 1992 WL 685312 (HHS Dept. App. Bd. Apr. 29, 1992).³

Arkansas's experience with HHS in 1991 and 1992 is just the tip of the iceberg.⁴ For example, a federal audit of drug prices in six states, *including Arkansas*, conducted in 1983 by the HHS Office of the Inspector General found that drug costs average about 16% below AWP. *In re Arkansas Dep't of Human Servs.*, DAB No. 1273, at 2. Another study from 1989 concluded that AWP was not "even an adequate estimate of the prices providers are generally paying for their drugs" and it admonished states to "abandon the AWP reimbursement

³ Arkansas was not alone in having its plan rejected by HHS: the Medicaid plans of Oklahoma, Pennsylvania and Louisiana were rejected for the same reason. *See Louisiana v. United States Dep't of Health & Human Servs.*, 905 F.2d 877, 879 (5th Cir. 1990) (observing that "[t]here has been considerable doubt for a number of years whether AWP provides the closest estimate of the price generally and currently paid by pharmacists for drugs"); *In re Oklahoma Dept of Human Servs.*, 1991 WL 634860 (HHS Dep't App. Bd. Aug 13, 1991 (same result; noting "problem" caused by the States' use of AWP as a "measure of acquisition cost"). *See also Rite Aid of Pennsylvania, Inc. v. Houstoun*, 171 F.3d 842, 847 (3d Cir. 1999) (noting that "HCFA informed [Pennsylvania] that it would not accept AWP levels for EAC without a significant discount being applied, unless the [State] provided documentation that the actual acquisition cost equaled the full AWP").

⁴ As early as 1974, the predecessor agency to HHS publicly announced that when states peg Medicaid reimbursement to AWP, they frequently pay "in excess of actual acquisition cost to the retail pharmacist." 39 Fed. Reg. 41,480 (Nov. 27, 1974). In 1975, HHS specifically warned states that "AWP data are frequently inflated," and urged them to stop reimbursing Medicaid providers on the basis of AWP. *See* 40 Fed. Reg. 34,518 (Aug. 15, 1975). *See also* 40 Fed. Reg. 32, 284-293 (July 31, 1975).

methodology."⁵ Arkansas state officials admitted seeing these report and that they have been "on notice through it of the discrepancy between AWP and the actual price paid." *In re Arkansas Dep't of Human Servs.*, DAB No. 1273, at 5.

In addition to the federal government's admonitions, Arkansas's own independent audits have confirmed that pharmacies typically receive discounts off of the published AWP. In December 1997, Arkansas hired the firm of Myers & Stauffer to conduct a survey of the acquisition and dispensing costs incurred by Arkansas pharmacies. *Wal-Mart Stores Inc. v. Knickrehm*, 101 F.Supp.2d 749, 756 (E.D. Ark. 2000). That firm concluded that pharmacies were paying only 82.7% of AWP for brand name dugs. *Id.*

Arkansas's own reimbursement formulas confirm its understanding that the published AWP is not, as it claims, "the actual average of the wholesale price." Compl. ¶ 35. The Complaint admits that Arkansas has set its reimbursement formula at a significant discount off of AWP since 1995, Compl. ¶ 13, and the public record makes clear that Arkansas knew that AWP was an undiscounted price long before that. In 2002, Arkansas adjusted its reimbursement formula to take an even larger discount off of AWP for both branded (AWP – 14%) and generic (AWP – 20%) drugs. Compl. ¶¶ 14-15.

Thus, the State has not pled facts from which it could be inferred that any alleged reliance on the published AWP as representing "the actual average of the wholesale price," Compl. ¶ 35, was reasonable. Nor has it pled facts that could support the inference that the publication of AWP as an undiscounted reference price actually caused Arkansas or any of its

⁵ Office of Inspector General, *Use of Average Wholesale Prices in Reimbursing Pharmacies Participating in Medicaid and the Medicare Prescription Drug Program* (Oct. 1989): Medicare Action Transmittal No. 84-12, *reprinted* in *Medicare & Medicaid Guide* (CCH) 34,157 at 10,191 - 10,206 (1984).

citizens any harm. The Complaint does not state a claim for either common law fraud or a violation of the ADTPA for these reasons alone, and judgment should enter for Defendants.

II. Judgment Should Be Entered for Defendants Because the Complaint Fails To Allege Facts Sufficient to State a Claim and Fails To Allege Fraud With Sufficient Particularity.

Arkansas is a fact-pleading state, and judgment should enter in favor of the defendant on any complaint that does not set forth facts sufficient to state a claim. Ark. R. Civ. P. 8(a), 12(c). Arkansas courts have long held that these two concepts must be read together in testing the sufficiency of the complaint and that *facts* – not mere conclusions – must be alleged. *Ark. Dep't of Envtl. Quality v. Brighton Corp.*, 102 S.W.3d 458, 466 (Ark. 2003) (affirming dismissal of complaint for failure to meet pleading requirements where complaint consisted of "nothing more than generalities and conclusions of law with no specifics alleged as to the individual defendants"); *Harvey v. Eastman Kodak Co.*, 610 S.W.2d 582, 584 (Ark. 1981) (affirming dismissal of complaint under Ark. R. Civ. P. 12(b)(6) for failure to comply with fact pleading required by Ark. R. Civ. P. 8).

Even more is required for allegations of fraud. *See Evans Indus. Coatings, Inc. v. Chancery Court of Union County*, 870 S.W.2d 701, 703 (Ark. 1994) (granting writ of prohibition on appeal after trial court's denial of motion to dismiss complaint under Ark. R. Civ. P. 9(b) on the ground that the complaint was "clearly conclusory and insufficient as an allegation of actual fraud under our rules or caselaw"). In a fraud case, the facts and circumstances constituting the fraud must be set forth with specificity and the complaint should specify the "who, what, when, where and how" of any alleged fraud. *See United States ex rel. Costner v. United States*, 317 F.3d 883, 888 (8th Cir. 2003). The Complaint, however, does

nothing more than postulate conclusory allegations, and fails to satisfy the heightened requirements of Rule 9(b).

Although Defendants have not found a decision of any Arkansas court which speaks to the pleading requirement applicable to claims under the ADTPA, many courts across the country have imposed the heightened pleading requirements of rules analogous to Rule 9(b) on claims of unfair or deceptive trade practices grounded in fraud. *See, e.g., Tuttle v. Lorillard Tobacco Co.*, 118 F. Supp. 2d 954, 963-64 (D. Minn. 2000) (dismissing statutory fraud claims, including claim under the Minnesota Uniform Deceptive Trade Practices Act, for failure to plead with particularity); *Stires v. Carnival Corp.*, 243 F. Supp. 2d 1313, 1322 (M.D. Fla. 2002) (dismissing claim under Florida Deceptive and Unfair Trade Practices Act for failure to plead with particularity); *Adams v. NVR Homes, Inc.*, 193 F.R.D. 243, 251-52 (D. Md. 2000) (dismissing claim under the Maryland Unfair or Deceptive Trade Practices Act for failure to comply with Fed. R. Civ. P. 9(b)); *Frith v. Guardian Life Ins. Co. of America*, 9 F. Supp. 2d 734, 742 (S.D. Tex. 1998) (applying the particularity requirement for pleading fraud to claims for the violation of the Texas Insurance Code and the Texas Deceptive Trade Practice – Consumer Protection Act); *Smith v. Central Soya of Athens, Inc.*, 604 F. Supp. 518, 528-30 (D.C.N.C. 1985) (dismissing claim under the North Carolina Unfair and Deceptive Trade Practices Act for failure to comply with the particularity requirements of Fed. R. Civ. P. 9(b)). So too should this Court. Plaintiff's claim under the ADTPA is undoubtedly founded upon fraud. Indeed, the Complaint does not even suggest any other basis for these claims. Rather, the entire Complaint rests on its assertion that "Defendants' *fraudulent* practices for pricing and marketing their prescription drugs" have injured the State of Arkansas

and its citizens. Compl. ¶ 1 (emphasis added). Plaintiff has failed to plead facts to support this assertion – the only basis for the ADTPA claim – with sufficient particularity, and the claim should therefore be dismissed.

A complaint should not leave a party guessing as to any element. *Kohlenberger v. Tyson's Foods, Inc.* 510 S.W.2d 555, 560 (Ark. 1974) (holding that the facts constituting the cause of action must be pleaded in direct and positive allegations, not by way of argument, inference, or belief). The State's complaint leaves unanswered numerous questions central to the preparation of a defense. First, the Complaint does not specify which drugs are subject to this action. Although the Complaint identifies some drugs, the Plaintiff purports to cast a wider net to include "drugs, including, but not limited to, those listed on Exhibit A of this Complaint" without identifying any additional drugs. *See* Compl. ¶ 28. Further, although the gravamen of the Complaint is that the State and its citizens purportedly overpaid for prescription drugs, it does not state what it or a single one of its citizens ever paid for any of the drugs at issue, or that the payment was based in any way on the particular Defendant's published AWP. Nor does the Complaint specify the period of time during which the charged conduct occurred. The Complaint also fails to specify who made the allegedly fraudulent statements, or when they were made.

Moreover, the Plaintiff alleges that "Defendants had a duty to report pricing information that fairly and reasonably reflected actual prices paid," Compl. ¶ 33, but fails to identify any source of this alleged duty. The Plaintiff does not allege, for example, that the State has ever required Defendants to submit pricing information directly to the State, or that Defendants are in privity with or have a fiduciary duty to the Plaintiff. *Evans Indus. Coatings.*

Inc., 870 S.W.2d at 703 (Ark. 1994) (granting writ of prohibition following denial of motion to dismiss because, in addition to failure to plead elements of fraud, "there was no basis in the complaint for a fiduciary relationship" alleged by plaintiff). Mere conclusory statements are not enough to survive a motion to dismiss or for judgment on the pleadings.

Plaintiff further fails to state a claim on behalf of Arkansas consumers not covered by the Medicaid or Medicare programs because Plaintiff does not allege with the requisite particularity how inflated AWP's cause consumers to pay inflated prices for their prescription drugs. Plaintiff conclusory asserts that Defendants' alleged submission of false and inflated pricing information causes inflated usual and customary charges to ordinary Arkansas consumers "since it is illegal to charge consumers less than Medicaid." (Compl. ¶¶ 51-52.) Plaintiff provides no statutory basis for its assertion that allegedly inflated AWP's would lead to inflated charges to consumers. Furthermore, Plaintiff does not allege even a single instance where Defendants' reported AWP's actually impacted the amount providers charged ordinary consumers for their prescription drugs. A theory of what *might* happen based on Plaintiff's construction of the Arkansas Medicaid Program's reimbursement provisions is insufficient to state a claim for fraud. Rather, to satisfy the pleading requirements for its claims on behalf of consumers, Plaintiff would have to allege specific providers who inflated their prices for particular drugs based on certain inflated AWP's and specific consumers who paid those inflated prices. As Plaintiff has failed to do so, judgment on the pleadings should be entered for Defendants as to Plaintiff's claims on behalf of Arkansas consumers.

Finally, the Complaint alleges in wholly generalized terms that Defendants created a "spread" and used the "spread" "to market [its] drugs to providers." Compl. ¶¶ 37-40. The

Complaint does not identify a single specific instance in which any Defendants allegedly engaged in this practice, nor does it identify a single "spread" between a drug's AWP and what the State, any of its citizens, or any provider paid. The Complaint also makes a blanket allegation that Defendants "used free goods, educational grants, and other incentives to induce providers to purchase their drugs," Compl. ¶ 40, without identifying a single instance of such conduct, and makes no allegations explaining how providing such incentives could possibly lower the actual cost of drugs or otherwise harm the State or its citizens. Without fact-specific allegations, the claims cannot survive.

In sum, Plaintiff simply has not alleged any facts from which the Court can infer that Defendants reported "fraudulent" AWP's for any of their drugs, that any party overpaid for any of Defendants' prescription drugs at a price that was based on Defendants' published AWP, or that Defendants engaged in any of the other allegedly fraudulent practices such as "marketing the spread" or providing improper incentives. Consequently, judgment should enter for Defendants on the pleadings.

III. Judgment Should Be Entered for Defendants Because Plaintiff Has Not Stated a Claim Under the Deceptive Trade Practices Act.

Plaintiff alleges that Defendants have engaged in deceptive and unconscionable trade practices prohibited by the ADTPA, Ark. Code Ann. §§ 4-88-107 *et seq.*, by reporting false and inflated prices to the reporting services, thereby causing the Arkansas Medicaid Program, Medicaid recipients, Medicare Part B recipients, and other Arkansas consumers to pay inflated prices for their prescription drugs in violation of Section 4-88-107(a)(10) of the ADTPA.

Compl. ¶ 59. Judgment should enter for Defendants and Plaintiff's claims under the ADTPA should be dismissed. First, Plaintiff has failed to allege facts sufficient to support the elements

of a claim under the ADTPA. Second, the ADTPA does not apply to transactions involving the Arkansas Medicaid Program without an express request by directors of the HCFA and Arkansas Department of Human Services for the Attorney General to implement the powers of the ADTPA. Finally, the Attorney General has no authority to seek money damages on behalf of the State under the ADTPA.

A. Plaintiff Fails To Allege Facts Sufficient To State A Claim Under Section 4-88-107(a)(10) of the ADTPA

Based on the plain language of Section 4-88-107(a)(10), to state a claim for relief Plaintiff must establish that Defendants' reporting of AWP's to the price reporting services was "unconscionable, false or deceptive." Plaintiff does not, because it cannot, state a claim under this section.

Central to Plaintiff's claim is the notion that the AWP's reported by Defendants were "false and inflated" because they did not equal what a true AWP should have been. However, Plaintiff has not expressly defined AWP nor explained what a "true" AWP should represent. If Plaintiff cannot say what a true AWP should represent, it cannot allege that Defendants' AWP reporting was "unconscionable, false or deceptive." Moreover, as set forth at length in Section I, *supra*, AWP has been widely recognized for years as nothing more than a reference price. Plaintiff cannot now contend that Defendants' reporting of AWP's that allegedly exceed the prices paid by medical providers are unconscionable, false or deceptive.

B. The ADTPA Does Not Apply To Transactions Involving the Arkansas Medicaid Program

Ark. Code Ann. § 4-88-101(3) provides, in pertinent part that the ADTPA does not apply to:

(3) Actions or transactions permitted under laws administered by the Insurance Commissioner, the Securities Commissioner,

the State Highway Commission, the Bank Commissioner, or other regulatory body or officer acting under statutory authority of the United States, unless a director of these divisions specifically requests the Attorney General to implement the powers of this chapter.

Ark. Code. Ann. § 4-88-101(3). The Arkansas Medicaid Program is jointly administered by the HCFA and the Arkansas Department of Human Services. Compl. ¶ 11. Pursuant to the methodology established by the State Plan as outlined in the State's Pharmacy Manual, at all times relevant to the Complaint, the Arkansas Medicaid Program reimbursed medical providers for prescription drugs according to federal regulations. Compl. ¶ 17. Thus, the transactions at issue in this case undoubtedly fall within the scope of Section 4-88-101(3).

Plaintiff does not, however, allege that the HCFA or the Arkansas Department of Human Services requested the Attorney General to implement the powers of the ADTPA to bring claims based on these transactions. Judgment should therefore enter for Defendants on Plaintiff's ADTPA claims. *See, e.g., Robertson v. White*, 633 F. Supp. 954, 978 (W.D. Ark. 1986) (dismissing claims under the Arkansas Consumer Protection Act where Ark. Stat. Ann. § 70-913, replaced by Ark. Code Ann. § 4-88-101, removed from purview of the Consumer Protection Act those transactions governed by the State Commissioner of Securities).

C. The Attorney General Is Not Entitled To Seek Money Damages On Behalf Of the State Under The ADTPA

Although the Attorney General has the authority to bring civil actions to enforce the provisions of the ADTPA, *see* Ark. Code Ann. § 4-88-113(a), his office has no authority under the ADTPA to seek money damages on behalf of the State. The statutory scheme of the ADTPA itself limits the right to money damages to "any *purchaser* who has suffered any ascertainable loss by reason of the use or employment of the prohibited practices any moneys or real property which may have been acquired by means of any practice declared to be

unlawful by this chapter, together with damages sustained." Ark. Code Ann. § 4-88-113(a)(2)(A) (emphasis added).

Plaintiff does not, and cannot, allege that the Arkansas Medicaid Program was a purchaser of any of Defendants' drugs. Indeed, Plaintiff concedes that Arkansas Medicaid only reimburses "medical providers, including pharmacies and physicians, for prescription drugs" acquired by the providers and dispensed or administered to Medicaid recipients. Compl. ¶¶ 12 – 15. Accordingly, even if the Attorney General can bring a claim for restitution on behalf of allegedly defrauded Arkansas consumers – something he has not done here where the Complaint does not even name a single consumer allegedly harmed – he cannot exercise that power merely for the State's economic benefit. Therefore, judgment should enter for Defendants on Plaintiff's claim for money damages on behalf of the Arkansas Medicaid Program pursuant to the ADTPA.

IV. To the Extent that Either Claim Involved a Drug that Is Reimbursed Without Reference to AWP, That Claim Should Fail as a Matter of Law.

The Complaint does not allege that either the State or any of its citizens actually paid for a single one of Defendants' drugs at a price that was calculated based on any particular Defendant's allegedly fraudulent AWP. Arkansas's reimbursement formula requires it to compare the result of several different formulae and pay the lowest of those results. Only one of those formulae even references a particular Defendant's published AWP. *See* Compl. ¶¶ 13-15. Thus, in many instances the reimbursement rate has nothing whatsoever to do with a Defendant's published price.

By Arkansas regulation, reimbursement for prescription drugs by the Medicaid program shall be the lowest of (1) EAC plus a dispensing fee, (2) the pharmacy's usual and customary

charge to the general public plus a dispensing fee, or (3) GUL plus a dispensing fee. Compl. ¶¶ 13-15; *Pharmacy Manual*, Sections 240.000-250.000. The Arkansas regulation may use an individual Defendant's AWP for determining its EAC, but it *does not* use an individual Defendant's AWP for either GUL or a pharmacy's usual and customary charge.⁶ Consequently, if either of the other two other reimbursement formulas is lower than EAC, the price the Arkansas Medicaid program pays for a drug does not necessarily have anything to do with an AWP reported by one of the Defendants. The State has failed to allege that it or its citizens ever paid for any of Defendants' drugs based on that Defendant's published AWP and, consequently, judgment should enter for Defendants on the pleadings.

The same concept applies to reimbursement under Medicare. Medicare allows reimbursement for generic drugs at a flat rate calculated as "the lesser of the median average wholesale price for all sources of the generic forms of the drug or biological or the lowest average wholesale price of the brand name forms of the drug or biological." 42 C.F.R. § 405.517. Thus, for example, the reimbursement rate is the same for the same dosage of both Warrick's and Dey's albuterol products that are identified in Exhibit A. Under this

⁶ Usual and customary charge is defined as "the price that is charged for 90% of the prescriptions for private pay customers for the same product and quantity. Stores may choose the pricing method they desire, and must apply the same pricing formula to prescriptions filled with the Arkansas Medicaid Program that is applied to prescriptions for private pay customers. *Pharmacy Manual*, Section 251.100. GUL is defined as the "maximum drug cost used to compute reimbursement for multiple-source drugs unless the provisions for a generic-upper-limit override have been met," as decided by the federal government or the Arkansas state agency. *Pharmacy Manual*, Section 251.300. See 42 C.F.R. § 447.331 (Upper Limits are established by CMS and are equal to 150% of the published priced for the least costly therapeutic equivalent). In accordance with *Pharmacy Manual*, Section 251.300, a current list of Arkansas's GULs is on the Arkansas Medicaid website: <http://www.medicaid.state.ar.us>. In addition, the Federal Upper Limit for the drugs is listed in the third-party pricing publications Plaintiff claims to consult.

methodology, reimbursement is based on the median average wholesale price, not the specific AWP reported by any particular defendant (or non-defendant manufacturer). Accordingly, judgment should enter for Defendants on these claims as well.

V. All Claims Are Limited by the Applicable Statute of Limitations.

While Plaintiff fails to set forth a period of time for which relief is sought, the ADTPA claims in this action are subject to a limitations period of no longer than five years, *see* Ark. Code Ann. § 4-88-115, and the common law fraud claims are subject to a limitations period of no longer than three years. *See* Ark. Code Ann. § 16-56-105. Accordingly, as a matter of law, Plaintiff's ADTPA claims are limited to those accruing on or after January 20, 1999 and Plaintiff's common law fraud claims are limited to those accruing on or after January 20, 2001, long after Arkansas admitted in public records that it knew full well that AWP did not represent an average of actual wholesale prices.

Implicitly acknowledging that at least some of its claims are time barred, Plaintiff tries to obtain the benefit of a toll of these limitations periods by alleging that Defendants "knowingly, willfully, and intentionally concealed the drugs' true and accurate pricing information from the Arkansas Medicaid Program." Compl. ¶ 34. To be entitled to a toll of these limitations periods, however, Plaintiff must have alleged – with the specificity required by Rule 9(b) – that Defendants fraudulently concealed their actions from the Arkansas Medicaid Program. *See F.D.I.C. v. Deloitte & Touche*, 834 F. Supp. 1129, 1151-52 (E.D. Ark. 1992). As Plaintiff has failed to allege the requisite particulars, Plaintiff is not entitled to a tolling of any of the limitations periods.

Furthermore, given the common understanding of the state and federal governments that the reported AWP's were not actual prices, Plaintiff indisputably knew about any purported

"fraud" it alleges as the basis for all of its claims decades ago. Plaintiff, therefore, cannot be entitled to a tolling of the statutes of limitations or to an expansion of the common law fraud statute of limitations normally allowed where a plaintiff establishes that it could not have discovered the fraud through the exercise of reasonable diligence. *See Smith v. St. Paul Fire & Marine Ins. Co.*, 64 S.W.3d 764, 771 (Ark. App. 2001), *O'Mara v. Dykema*, 942 S.W.2d 854 (Ark. 1997). Thus, judgment should enter for Defendants on the ADTPA claims arising prior to January 20, 1999 and common law fraud claims arising prior to January 20, 2001.

CONCLUSION

WHEREFORE, for the foregoing reasons, Defendants respectfully request that the Court enter judgment in favor of Defendants on the pleadings.

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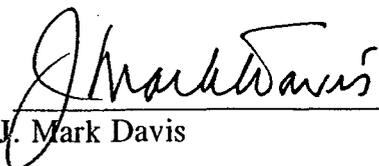
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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing was served by hand delivery this 22nd day of
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