

COPY

COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT
DIVISION II
Civil Action No. 03-CI-01134

COMMONWEALTH OF KENTUCKY,
EX REL. ALBERT CHANDLER, ATTORNEY GENERAL

PLAINTIFF

v.

ABBOTT LABORATORIES, INC.

DEFENDANT

* * * * *

**DEFENDANT ABBOTT LABORATORIES, INC.'S MEMORANDUM OF LAW IN
SUPPORT OF ITS MOTION TO DISMISS THE AMENDED COMPLAINT**

In support of its Motion to Dismiss the Amended Complaint, Defendant Abbott Laboratories, Inc. ("Abbott") hereby adopts and incorporates by reference the Memorandum of Law in Support of Defendants' Motion to Dismiss Plaintiff's Amended Complaint filed today in *Commonwealth of Kentucky ex rel. Chandler v. Warrick Pharmaceuticals Corporation et al.* Franklin Circuit Court, No. 03-CI-01135 (the "Joint Brief"). A copy of the Joint Brief (without exhibits) is attached hereto as Exhibit 1

The reasons to dismiss set out in the Joint Brief apply equally to the Amended Complaint ("Complaint") in this action. Below, Abbott explains how some of the pleading defects identified in the Joint Brief apply specifically to the claims and drugs at issue in this action.

ARGUMENT

A. The Commonwealth Has Known The "Average Manufacturer's Price" For The Drugs Identified In The Complaint Because Of The Statutory Rebates That Abbott Has Paid.

The Joint Brief explains that as a consequence of federal and Kentucky Medicaid statutes and regulations, the Cabinet for Health Services actually knows (and indisputably should know) two points that doom the Complaint:

- AWP's do not correspond to actual sales prices; and
- AWP's typically exceed actual sales price, particularly for multiple-source drugs.

See Joint Brief at 10-20.

One source of Kentucky's indisputable knowledge is the rebates that manufacturers pay for every drug dispensed to Medicaid beneficiaries. *See* Joint Brief at 10-11. Federal law required Abbott and other pharmaceutical to pay rebates to Kentucky. *See* 42 U.S.C. § 1396r-8; Joint Brief at 10. These rebates revealed to Kentucky the "average manufacturer's price" of Abbott's drugs. "Average manufacturer's price" is defined by the statute to mean the average price for an outpatient drug paid to the manufacturer by wholesalers for drugs distributed to retail pharmacies, after deducting prompt pay discounts. *See* 42 U.S.C. § 1396r-8(k)(1).

Exhibit 1 of the Complaint identifies sixteen drugs for which Kentucky Medicaid allegedly overpaid. All but one of these drugs are "non-innovator multiple-source" drugs. *See* 42 U.S.C. § 1396r-8(k)(7)(A). For these drugs, Abbott paid Kentucky per-unit rebates equal to 11% of the drug's average manufacturer price. *See* 42 U.S.C. § 1396r-8(c)(3)(B)(ii). Dividing the rebate payment by 0.11 gives the average manufacturer's price.

Unlike the other fifteen drugs, for EES/Sulfisoxazole, the Medicaid rebate is the greater of: (i) the difference between average manufacturer's price and best price; and (ii) 15.1% of

average manufacturer's price. *See* 42 U.S.C. § 1396r-8(1)(A)-(B).¹ For this drug, dividing the rebate payment by 0.151 gives the most that average manufacturer's price can be.

The Commonwealth has not alleged that Abbott ever misstated what an AWP represents. Nor does it allege that Abbott provided inaccurate average manufacturer's price data. Accordingly, as explained in the Joint Brief, the Complaint should be dismissed under CR 9.02 and CR 12.02(f). *See* Joint Brief at 21-45.

B. The Complaint Fails To Allege The Reported Or True AWP's For Fourteen Drugs, And Fails To Allege True AWP's For The Other Two Drugs.

As noted, Exhibit to the Complaint lists sixteen Abbott-manufactured drugs for which Medicaid and Medicare beneficiaries allegedly overpaid. For fourteen of the drugs, however, the Complaint fails to allege both the reported AWP and the true AWP. The failure to make any AWP allegations for these fourteen drugs is fatal under CR 9.02. To allege the "circumstances of fraud" with "particularity," the plaintiff must allege, among other things, the supposedly false statements. *See McAlpin v. Burnett*, 185 F.Supp.2d 730, 736 (W.D. Ky. 2001) (complaint failed to plead fraud with particularity where it did not identify a false or reckless material statement). As a result of these failures, the Complaint also fails to state a claim under CR 12.02(f) as to these fourteen drugs.

For two of the sixteen drugs, vancomycin and sodium chloride, the Complaint alleges an AWP and an "actual price" for two years. *See* Compl., Exs. 2-5. Even as to these two drugs, the Complaint fails to satisfy CR 9.02 and fails to state a claim under CR 12.02(f). Critically, the Complaint fails to allege the true AWP's for vancomycin and sodium chloride. CR 9.02 requires,

¹This is the Medicaid rebate formula for single-source and innovator multiple source drugs. "Best price" is defined as the "lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit

at a minimum, that the Complaint allege the false statement as well as the truthful statement that the Defendant should have made. *See United States v. Cheng*, 184 F.R.D. 399, 402 (D. N.M. 1988) (granting motion to dismiss for failure to plead fraud with particularity where plaintiff failed to state what about alleged fraudulent statements was false). Here, the Complaint fails to allege what the true AWP's were for vancomycin and sodium chloride.

Moreover, the Complaint fails to satisfy CR 9.02 as to vancomycin and sodium chloride because it alleges an AWP only for 1997 and either 1999 (sodium chloride) or 2000 (vancomycin). *See Compl.*, Exs. 2-5. The 1997 allegations are not relevant since 1997 is outside the applicable statutes of limitations. *See Joint Brief* at 45-46. Alleging only a reported AWP for a point in time in 1999 or 2000, without alleging a true AWP or the reported AWP's at other time periods, does not suffice under CR 9.02.

C. The Other CR 9.02 Deficiencies Identified in the Joint Brief Apply Here.

The other CR 9.02 deficiencies discussed in the Joint Brief apply equally to this Complaint and include:

- Failure to allege any false statements by Abbott;
- Failure to allege why it is false for an AWP to exceed sales price, given the regulatory, legislative and public record concerning Medicaid and Medicare reimbursement;
- Failure to allege who at Abbott made false statements or when the statements were made; and

(continued...)

entity or governmental entity,” excluding certain purchasers, and inclusive of rebates, discounts and free goods. *See* 42 U.S.C. § 1396r-8(c)(1)(C).

- Failure to allege who at Abbott "marketed the spread," to whom they marketed, how they marketed, or when they marketed, or what actions providers took in response to any marketing.

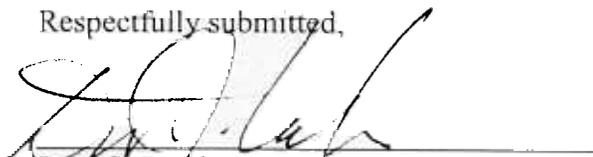
See Joint Brief at 21-30.

CONCLUSION

For the foregoing reasons, and for those set out in the Joint Brief adopted here, the Amended Complaint should be dismissed.

Dated: February 6, 2004

Respectfully submitted,



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CIVIL ACTION NO. 03-CI-1135
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COMMONWEALTH OF KENTUCKY
Ex. Rel. ALBERT B. CHANDLER, III, Attorney General

PLAINTIFF

vs.

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

DEFENDANTS

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO DISMISS THE COMMONWEALTH'S AMENDED COMPLAINT**

Defendants Warrick Pharmaceuticals Corporation, Schering-Plough Corporation, Schering Corporation, and Dey, Inc. ("Defendants"), by counsel, submit the following memorandum of law in support of their motion to dismiss the Commonwealth's Amended Complaint.

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SCHERING-PLOUGH CORPORATION
SCHERING CORPORATION
DEY, INC.**

DEFENDANTS

**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO DISMISS THE COMMONWEALTH'S AMENDED COMPLAINT**

Defendants Warrick Pharmaceuticals Corp., Schering-Plough Corp., Schering Corp. (collectively, "Warrick"), and Dey, Inc. ("Dey") submit this memorandum in support of their motion to dismiss the Amended Complaint. The Attorney General of the Commonwealth of Kentucky brought this action on behalf of the Commonwealth of Kentucky (the "Commonwealth") and, allegedly acting in his *parens patriae* capacity, on behalf of the Commonwealth's citizens who are Medicare beneficiaries and who paid co-payments for Medicare-covered drugs manufactured by Dey or Warrick. Abbott Laboratories, Inc. ("Abbott") is a defendant in *Kentucky ex. rel. Chandler v. Abbott Laboratories, Inc.*, Civil Action No. 03-CI-1134, Division II (Franklin County Circuit Court) (the "Abbott Action"), an action which makes the same – often, word-for-word – allegations. Abbott, therefore, joins in this

memorandum in support of its motion to dismiss all claims asserted in the Abbott Action. (Dey, Warrick, and Abbott will be referred to collectively herein as the “Defendants.”)

SUMMARY OF ARGUMENT

The First Amended Complaint (the “Complaint”)¹ asserts eight counts. The Complaint alleges that the Defendants deceived both the Commonwealth and federal Medicare regulators by allegedly reporting to third-party publishers average wholesale prices (“AWPs”) for their drugs that exceeded the prices actually paid by Defendants’ customers. This purported deception allegedly caused Medicaid and Medicare beneficiaries to pay too much for drugs.

The Commonwealth’s conclusory and rote allegations of Defendants’ fraud are entirely inconsistent with the 35-year history of Medicare and Medicaid regulation of prescription drug coverage. Indeed, for years federal and state governments have understood that AWPs do not correspond to sales prices and have called AWPs undiscounted “sticker prices.”² During this time, the use of AWP as the basis for reimbursement for prescription drugs under the Medicare and Medicaid programs has – again and again – been debated, discussed, and criticized as wasteful. Still, states, including the Commonwealth, and the federal government, have made an informed and deliberate decision to base Medicaid and Medicare reimbursement

¹ The First Amended Complaint in this action and the First Amended Complaint in the Abbott Action assert identical claims in Counts I-VIII. As such, this Memorandum will refer, whenever possible, to both amended complaints collectively as the “Complaint” or “Amended Complaints.” Where specific references are required, the First Amended Complaint in this action will be referred to as the “Am. Compl.” The First Amended Complaint in the Abbott Action will be referred to as the “Abbott Am. Compl.”

² Submitted herewith is Defendants’ Appendix In Support of Their Motion To Dismiss (the “Appendix” or “App.”), which includes numerous public-record documents, cited herein, which demonstrate the long-held position at the state and federal level regarding the nature of AWP. The Court may take judicial notice of the contents of the Appendix and consider the sources therein on this motion. *See, e.g., Commonwealth v. Howard*, Ky., 969 S.W.2d 700, 705 (1998) (“[T]he court is not required to act in a vacuum when determining the purpose of legislation . . . we may take judicial notice of the historical settings and conditions out of which the legislation was enacted.”) (App. 98); *Pattie A. Clay Infirmary Ass’n v. First Presbyterian Church*, Ky., 551 S.W.2d 572, 574 (1977) (“[C]ourts may take judicial notice of facts beyond the scope of reasonable dispute which[, *inter alia*,] . . . are susceptible to immediate and accurate determination by resort to readily accessible and indisputable sources.”) (App. 121).

on AWP. Under such circumstances, the Commonwealth cannot claim that it relied on AWP's to be actual sales prices when the voluminous public record demonstrates the Commonwealth's knowledge to the contrary.

Indeed, the Commonwealth's regulators, federal regulators, the United States Congress, and even President Clinton all understood that AWP's often exceed actual sales prices.

See, infra, at 10-20. For example:

- Between 1999 and 2001, the Kentucky Cabinet for Health Services (the "Kentucky Cabinet"), which administers Medicaid, solicited audit reports from consultants. These reports confirm that AWP's exceed actual sales price and explain that the difference between AWP and sales price was needed to offset Medicaid's underpayments to providers for professional services related to dispensing drugs.
- Kentucky Medicaid is a program in which providers may choose, but are not required, to participate. In this context, the Commonwealth's decision to reimburse providers for their participation at a significant percentage off of AWP (*see* Am. Compl. ¶ 14, Abbott Am. Compl. ¶ 11) is a frank admission that the Commonwealth believed that AWP's exceeded the prices providers actually paid for Defendants' drugs.
- Similarly, as to Medicare, Congress selected AWP as the basis for reimbursement with knowledge that doing so would enable physicians and other providers to earn a profit on the drugs they administer. Congress even took action to stop the Clinton Administration from using actual sales prices as the measure of reimbursement because it wanted providers to earn a profit to offset perceived underpayments to providers for professional services related to dispensing drugs.
- The Commonwealth reimburses certain health care providers (*i.e.*, providers described in Section 340B of the federal Public Health Act, 42 U.S.C. § 256b) (App. 26) an amount equal to the actual price that those providers paid for the drugs. Thus, there is no support for the Commonwealth's conclusory allegation that it did not know that AWP exceeds the price at which the Defendants sell their products when the Commonwealth knew exactly how much 340B Providers paid for the drugs.
- Pursuant to a 1990 federal statute, the Kentucky Medicaid program receives rebates based on each drug's "average manufacturer's price,"

which is a statutorily defined term that corresponds to actual sales prices. Thus, it is baseless for Kentucky to allege that it did not know that AWP exceeds the price at which the Defendants sell their products to healthcare providers when the Defendants were simultaneously providing average manufacturer's price information that revealed a measure of actual sales prices.

- Years of public audits and other reports of the federal government have disclosed that AWP is not a measure of actual sales price. Indeed, President Clinton even likened AWP to the "sticker price" of a car.

In light of this history, the Commonwealth has not plead the central allegations underlying its fraud claims: (i) a false statement by Defendants and (ii) the Commonwealth's reasonable reliance thereon. *See, infra*, Argument, Point II. Accordingly, the Complaint should be dismissed for that reason alone.

Numerous other grounds warrant dismissal of the Complaint. First, the Complaint fails to allege the necessary particulars concerning the Defendants' alleged fraud as required by CR 9.02 (App. 11). For example, the key allegations of fraud are based solely on "information and belief." Moreover, the Complaint fails to identify Defendants' allegedly fraudulent statements, who made the statements, or when they were made. Further, for all but a few of the drugs at issue (and then only for one or two years), the Commonwealth does not even bother to allege a specific AWP. Nor does the Commonwealth purport to allege what AWP should have been. The Commonwealth does not allege a supposedly "true AWP" for any of the drugs named in the Complaint. The Commonwealth also does not allege that it used Defendants' AWP's as the basis for reimbursement. Allegations of this sort are not sufficient to meet the Commonwealth's obligations under CR 9.02. Therefore, all of the Commonwealth's claims should be dismissed. *See, infra*, Argument, Point I.

The Commonwealth's promissory estoppel claim, which hinges on the allegation that Defendants "represented" they were providing the Commonwealth with an allegedly "true

AWP” should also be dismissed. First, the Commonwealth does not allege even one instance where a Defendant made a promise to report a “true AWP” nor to whom such a promise was made. Second, since AWP is a term known by the Commonwealth not to represent the price prevalent in the market, the Commonwealth fails to allege that Defendants’ purported promise was definite or reasonably relied upon. *See, infra*, Argument, Point III.

The Commonwealth’s statutory fraud and consumer protection claims fare no better. The Commonwealth’s claim under KRS 15.060 fails for at least two reasons. First, nothing in KRS 15.060 creates a cause of action under which the Commonwealth may seek to recover damages. Rather, the statute merely enables the Attorney General to prosecute actions on the Commonwealth’s behalf where a cause of action already exists. Second, as the Commonwealth concedes, Defendants did not receive a single cent from the Commonwealth’s Treasury. Since KRS 15.060 enables the Attorney General, at most, to recover monies erroneously or improperly disbursed from the Treasury, this claim fails and should be dismissed. *See, infra*, Argument, Point IV.

The Commonwealth’s statutory fraud claims are inapt and similarly fail. For example, the Commonwealth’s Consumer Protection Act claim fails because the Commonwealth is not a “consumer” under the statute. Similarly, the Commonwealth cannot state a claim under the Medicaid Fraud Statute, which is aimed at redressing fraud committed by providers, because Defendants are not providers. In addition, the Commonwealth’s False Advertising Statute claim must be dismissed because the Commonwealth cannot allege that Defendants advertised or, even if they did, that those advertisements were false or misleading. *See, infra*, Argument, Point V.

All of the Commonwealth’s claims concerning multiple-source drugs, regardless of how they are styled, must be dismissed. Although the Commonwealth ignores them, under

the regulations applicable to reimbursement for multiple-source drugs under the Medicaid and Medicare programs, the fraud alleged in the Complaint is simply impossible in many circumstances because reimbursement is tied not to AWP but is based on fixed levels. The Commonwealth's Complaint glosses over this issue and fails to provide the Court or the parties with information – certainly within the Commonwealth's possession at least as to the Kentucky Medicaid program – which would allow a determination to be made as to how the Commonwealth actually reimbursed or whether or not the Commonwealth states a claim in light of these regulations. Such a failure is inexcusable, and the Commonwealth's claims should be dismissed. *See, infra*, Argument, Point VI.

Finally, at a minimum, all of the Commonwealth's claims are limited by the applicable statutes of limitation, the shortest of which is two years (applicable to the Commonwealth's consumer fraud claims) and the longest of which is five years (applicable to the Commonwealth's common law fraud, promissory estoppel, KRS 15.060, Medicaid fraud, and false advertising claims). As such, all claims in this Action must be dismissed to the extent they concern claims accruing before September 15, 1998 and, for some claims, those accruing before September 15, 2001. *See, infra*, Argument, Point VII.

REGULATORY HISTORY

I. BACKGROUND

A. The Kentucky Medicaid Program and The Medicare Program

1 Kentucky Medicaid

The Medicaid program provides health benefits to certain individuals and families with low incomes and resources. *See* 42 U.S.C. § 1396 (App. 32). The Medicaid program is jointly-administered and funded by the federal government and the states. *See generally* 42 U.S.C. §§ 1396 *et seq.* The federal government administers Medicaid programs through the

Centers for Medicare and Medicaid Services (“CMS”), formerly known as the Health Care Financing Administration (“HCFA”),³ an agency within the United States Department of Health and Human Services (“HHS”). The Kentucky Cabinet administers the state component of Medicaid in the Commonwealth (“Kentucky Medicaid”). (Am. Compl. ¶ 12; Abbott Am. Compl. ¶ 9.)

Although not required by federal law, the Commonwealth has opted to pay for certain prescribed drugs as part of its Medicaid program. *See* KRS 205.560(1)(c) (App. 2); 42 C.F.R. § 440.225 (App. 62). The Commonwealth has identified six Warrick drugs; seven Dey drugs; and sixteen Abbott drugs that it contends are covered by Kentucky Medicaid and for which the Commonwealth allegedly overpaid. (*See* Am. Compl. ¶ 1 & Ex. 1; Abbott Am. Compl. ¶ 1 & Ex. 1.) Under federal regulations in effect at all relevant times, state Medicaid programs were required to pay providers dispensing a drug to a Medicaid beneficiary the lowest of: (a) the estimated acquisition cost of the drug plus a dispensing fee; (b) the provider’s usual and customary charge for the drug to the general public; or (c) the Federal Upper Limit of a drug, as established by HCFA for certain multiple-source drugs, plus a reasonable dispensing fee. *See* 42 C.F.R. § 447.331 (App. 63).

The Commonwealth has purported to implement these requirements by requiring reimbursement for prescription drugs to be the lower of: (1) the Federal Upper Limit established for the drug; (2) Kentucky’s maximum allowable cost, plus a dispensing fee; (3) 90% of AWP plus a dispensing fee; or (4) the provider’s usual and customary billed charges.⁴ (*See* Am.

³ HCFA was renamed the Centers for Medicare and Medicaid Services (“CMS”) in 2001. For ease of reference, this Memorandum will refer to both HCFA and CMS jointly herein as “HCFA.”

⁴ Healthcare providers set their own charges. Defendants have no role in how providers set their charges, and none is alleged in the Complaint. According to federal law, providers must not charge Medicaid or Medicare “substantially in excess” of their usual “charges.” 42 U.S.C. § 1320a-7(b)(6)(A) (App. 27).

Compl. ¶ 14, Abbott Am. Compl. ¶ 11 (citing KAR 1:021 (App. 15)). The Commonwealth circularly defines “AWP” as the “average wholesale price published in a nationally recognized comprehensive drug data file for which the department has contracted.” 907 KAR 1:018(1)(2) (2003) (App. 13). On April 1, 2003, the Kentucky Cabinet reduced the AWP-based alternative standard from 90%-of-AWP to 88%-of-AWP. *See* Am. Compl. ¶ 14, Abbott Am. Compl. ¶ 11 (citing 907 KAR 1:018E (App. 14)).⁵

2. Medicare Part B

Medicare is a federal health program administered by HCFA. Medicare provides health benefits for individuals over age 65 and individuals with end-stage renal disease. *See* 42 U.S.C. § 1395c (App. 28). 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. *See* Am. Compl. ¶ 18, Abbott Am. Compl. ¶ 15; 42 U.S.C. §§ 1395k(a) (App. 29) & 1395x(s)(2)(A), (T) (App. 31). HCFA contracts with private contractors, known as “carriers,” to process claims submitted by providers and to determine payments to providers for Part B drugs and services. *See* 42 U.S.C. § 1395u (App. 30); 42 C.F.R. § 421.200 (App. 60). If the carrier determines that a claim submitted by a physician or other provider is payable, Medicare pays that provider directly. *See* 42 C.F.R. § 424.51 (App. 61).

For “multiple-source” drugs (*i.e.*, drugs that have a therapeutic equivalent), Medicare pays providers based on the lower of the provider’s actual charge or 95% of the median AWP for all generic forms of the drug. *See* 42 C.F.R. § 405.517 (App. 59). For “single-source” drugs (*i.e.*, drugs that lack a therapeutic equivalent), Medicare pays providers based on

⁵ 907 KAR 1:018E was an emergency regulation that was replaced by 907 KAR 1:018, a final regulation, on August 20, 2003. The reimbursement standards in each are the same, and the reduction in the AWP-based standard further belies any suggestion by the Commonwealth that it understood AWP to be an actual average of wholesale prices. (*See* Am. Compl. ¶¶ 27-30, Abbott Am. Compl. ¶¶ 23-26.)

the lower of the provider's actual charge or 95% of the drug's AWP. Medicare then pays 80% of the allowable amount, *i.e.*, *either* Medicare pays 80% of actual charges *or* Medicare pays 80% of 95% of the AWP or, in the case of multiple-source drugs, 80% of 95% of the median AWP. The Medicare beneficiary is responsible for the remaining 20% as a co-payment. (*See* Am. Compl. ¶ 19, Abbott Am. Compl. ¶ 16.)

B. Medicaid And Medicare Pay Providers, Not Defendants

Healthcare providers, such as physicians and pharmacies, buy drugs manufactured by the Defendants. Providers may buy them either directly from the Defendants or through wholesalers. In either case, the providers' acquisition cost depends on market forces, *i.e.*, the price is determined by supply and demand. For multiple-source drugs, there is often considerable price competition, typically driving acquisition cost well below the manufacturers' list prices.

Healthcare providers dispense the drugs to patients. If a patient is a Medicaid or Medicare beneficiary, the healthcare provider may submit a claim to Medicaid or Medicare for covered drugs and related professional or dispensing services and Medicaid or Medicare will, pursuant to certain formulae, pay the provider. Thus, while the Commonwealth alleges that Kentucky Medicaid and Medicare beneficiaries paid inflated amounts as a result of Defendants' alleged scheme, in fact Medicaid and Medicare beneficiaries made these alleged overpayments to *providers*, not to the Defendants. Indeed, the Commonwealth concedes in its Amended Complaint that no payments were made to the Defendants (Am. Compl. ¶ 122); Abbott Am. Compl ¶ 9) and neither Kentucky Medicaid nor Medicare beneficiaries paid Defendants a penny for the drugs at issue.

II. THE COMMONWEALTH AND THE FEDERAL GOVERNMENT HAVE KNOWN FOR YEARS THAT AWP DOES NOT CORRESPOND TO ACQUISITION COST

A. The Commonwealth Knows The Average Manufacturer's Price Of Medicaid-Covered Drugs

The Complaint's description of Medicaid drug reimbursement is incomplete. The Complaint discusses Medicaid's payments to providers, but entirely omits the second part of the Medicaid program: for each drug that Medicaid pays providers, Defendants pay Kentucky Medicaid a rebate.

In order for a manufacturer's drugs to be reimbursed under a state's Medicaid program, the manufacturer must enter into a contract to pay rebates to the states for the cost of drugs reimbursed by the state for Medicaid patients. *See* 42 U.S.C. § 1396r-8(a)(1), (b)(2) & (3) (App. 34). The Medicaid rebates for non-innovator multiple-source drugs, including most of the drugs listed in the Complaints, equal 11% of the drug's average manufacturer's price. *See* 42 U.S.C. § 1396r-8(c)(3)(B)(ii) (App. 34). Average manufacturer's price is defined by federal statute as the average price paid to the manufacturer for a particular drug in the United States by wholesalers for drugs distributed to retail pharmacies, after deducting certain discounts. *See* 42 U.S.C. § 1396r-8(k)(1) (App. 34).

Pharmaceutical manufacturers calculate and submit an average manufacturer's price to the federal government for each of their drugs. *See* 42 U.S.C. § 1396r-8(b)(2) & (3) (App. 34). Based on the pricing information provided by the manufacturers, the federal government then calculates each state's per-drug rebates. As a result of these rebates, the Commonwealth knows average manufacturer's price, or could readily calculate it. Indeed, the Kentucky Cabinet need only divide the per-unit Medicaid rebate it received for non-innovator multiple-source drugs by 0.11 to calculate the average manufacturer's price for each such drug.

More importantly, however, because the Commonwealth knows each drug's average manufacturer's price, the Commonwealth also knows that AWP varies from average manufacturer's price.

B. The Commonwealth Knows The Actual Acquisition Costs Of 340B Providers

The Complaint's discussion of Kentucky Medicaid reimbursement also is incomplete because it does not mention how Kentucky Medicaid reimburses certain providers ("340B Providers").⁶ 340B Providers are entitled to purchase drugs from manufacturers at no more than average manufacturer's price minus the rebate percentage arising from the Medicaid rebate program. *See* 42 U.S.C. § 256b(a) (App. 26). Thus, 340B Providers may purchase non-innovator multiple-source drugs at 89% of average manufacturer's price (*i.e.*, average manufacturer's price minus the Medicaid rebate). Both federal law and Kentucky Medicaid require 340B Providers to bill Medicaid the "pharmacy's actual acquisition cost for a drug." *See* 58 Fed. Reg. 27,293 (May 7, 1993) (App. 66); 907 KAR 1:018 § 2(13)(a) (App. 13). Therefore, the Commonwealth knows the actual prices paid for drugs by 340B Providers.

C. The Kentucky Cabinet's Own Audits Have Disclosed That AWP Exceeds Acquisition Costs, Especially For Multiple-Source Drugs

In 1999, 2000, and 2001, the Kentucky Cabinet contracted with an accounting firm to perform an audit on the cost of dispensing prescription medications to Medicaid recipients in the Commonwealth. *See* "A Survey of Acquisition Costs of Pharmaceuticals in the Commonwealth of Kentucky," Myers & Stauffer LC (Nov. 21, 2001).⁷ In each of these audits,

⁶ A 340B provider is a provider described in section 340B of the federal Public Health Act, 42 U.S.C. § 256b (App. 26). There are eleven categories of 340B Providers, including disproportionate share hospitals, public housing primary clinics, migrant health centers, homeless clinics, certain AIDS clinics, "federally-qualified health centers," black lung clinics receiving federal funds, and urban Indian organizations receiving funds under the Indian Health Care Improvement Act. *See* 42 U.S.C. § 256b(a)(4) (App. 26).

⁷ Available at <http://chs.ky.gov/dms/pharmacy/Dispensing/default.htm> (App. 23).

the auditors reported that providers purchase drugs at prices well below AWP (particularly in the case of multiple-source drugs):

- In 1999, the auditors reported that the average sales price for multiple source drugs was 31% to 62% below AWP.
- In 2000, the auditors reported that the average sales price for multiple source drugs was 39% to 79% below AWP.
- In 2001, the auditors reported that the average sales price for multiple source drugs was 56% to 84% below AWP.

Id. at Appendix A, at 17-18 & Appendix B, at 20 (App. 23).

In 2001, the auditors also reviewed dispensing fees paid by the Kentucky Medicaid program. *See* “A Survey of Dispensing Costs of Pharmaceuticals in the Commonwealth of Kentucky,” Myers & Stauffer LC (Nov. 21, 2001) (App. 24). The audit stated that the cost of dispensing certain drugs often exceeded the dispensing fees paid by the Kentucky Medicaid program. Excess ingredient reimbursement, the audit emphasized, was used to offset such shortfalls in dispensing fees:

Although dispensing costs at intravenous pharmacies is well in excess of the current dispensing fee, this reimbursement methodology has been accepted by these pharmacies because the margin on ingredient reimbursement has allowed pharmacies to offset any shortfall from the dispensing fee.

Id. at Appendix D, at 46 (App. 24). Similarly, a recent federal government audit concluded that many state Medicaid agencies persist in using a percentage of AWP as the reimbursement formula to offset perceived underpayments for professional services, and to ensure an adequate number of Medicaid providers. *See* HHS-OIG, “State Strategies to Contain Medicaid Drug Costs,” (Oct. 2003) at 11 (“Concerns about beneficiary access influence attempts to reduce drug reimbursement.”) (App. 85).

D. The Decision To Reduce AWP's By A Significant Discount Demonstrates That The Commonwealth Did Not Believe That AWP Was An Actual Price

The Complaint confirms that, in setting its reimbursement rate, the Commonwealth acted with the understanding that AWP is not the actual acquisition price paid by providers. The Commonwealth reimburses at AWP-12%. (See Am. Compl. ¶ 14, Abbott Am. Compl. ¶ 11.) In light of the decision to reimburse at a significant discount off AWP, the Commonwealth cannot claim that it believed AWP represented true average wholesale prices for pharmacies, or that the publication of AWP's caused it any actual harm. It is readily apparent that the Commonwealth's real claim is not that it was misled into believing that AWP represented actual wholesale prices, but that it may have chosen the wrong discount off of AWP in estimating acquisition cost.

E. HCFA, Congress, And Even President Clinton Have Stated for Decades That AWP Is A "Sticker Price" That Exceeds the Price Typically Paid for Drugs

1 In 1974, HCFA Rejected AWP As A Benchmark For Medicaid Reimbursement, Adopting "Estimated Acquisition Cost" Instead

In 1974, the United States Department of Health Education & Welfare ("HEW") issued a regulation (now published at 42 C.F.R. § 447.331 (App. 63)) governing how state Medicaid agencies may pay for drugs under Medicaid. HEW rejected the use of AWP as a benchmark because such prices "are frequently in excess of actual acquisition cost to the retail pharmacist" and instead favored "actual acquisition cost" "to achieve maximum savings to the Medicaid program." 39 Fed. Reg. 41,480 (Nov. 27, 1974) (App. 64). In fact, HEW specifically rejected a plea from pharmacists to let state Medicaid agencies continue to reimburse based on AWP as a means of boosting "pharmacy income" in favor of adopting the "estimated acquisition cost" benchmark in order to "achieve savings." 40 Fed. Reg. 34,516, 34,518 (Aug. 15, 1975) (App. 65).

Indeed, when Louisiana, Arkansas and Oklahoma ignored HCFA's mandate to use estimated acquisition cost rather than undiscounted AWP, HCFA refused to pay the federal share of Medicaid prescription drug payments for those states on grounds that AWP was universally known to exceed acquisition cost. *See Louisiana v. U.S. Dep't of Health & Human Servs.*, 905 F.2d 877 (5th Cir. 1990) (App. 113); *In re Arkansas Dep't of Human Servs.*, DAB No. 1273, 1991 WL 634857 (HHS Dept. App. Bd. Aug. 22, 1991) (App. 107); *In re Oklahoma Dep't of Human Servs.*, DAB No. 1271, 1991 WL 634860 (HHS Dep't App. Bd. Aug. 13, 1991) (App. 108). In addition, HCFA threatened the Pennsylvania Medicaid agency with a similar sanction if it continued to use AWP to estimate drug acquisition cost. *See Rite Aid of Pa., Inc. v. Houstoun*, 171 F.3d 842, 847 (3d Cir. 1999) (App. 125).

Meanwhile, the Senate Special Committee on Aging issued a report in 1989 recognizing that AWP exceeds actual drug prices. The Committee reported that the "[Veteran's Administration] achieves an average discount of 41% off [AWP] for single source drugs and an average of 67% off the published AWP for multiple source drugs . . . [and] hospitals, [HMOs] and nursing homes that contract with wholesalers . . . are able to *achieve discounts up to 99% off [AWP].*"⁸

2. Between 1984 and 1997, The Federal HHS Office Of Inspector General Released At Least Fifteen Audit Reports Criticizing The Use Of AWP By State Medicaid Agencies

Between 1984 and 1997, the United States Department of Health and Human Services Office of Inspector General ("HHS-OIG") repeatedly criticized the use of AWP by state Medicaid agencies as a measure of estimated acquisition cost.

⁸ Majority Staff Report, Special Comm. on Aging, United States Senate, "Prescription Drug Prices: Are We Getting Our Money's Worth?," S. Rep. 101-49 at 11 (1989) (emphasis added) (App. 38).

- A 1984 HHS-OIG report stated that “[w]ithin the pharmaceutical industry, AWP means non-discounted list price. Pharmacies purchase drugs at prices that are discounted significantly below AWP or list price.” The report further stated that “AWP cannot be the best – or even an adequate – estimate of the prices providers generally are paying for drugs. AWP represents a list price and does not reflect several types of discounts.”⁹
- A 1989 HHS-OIG report stated that “we continue to believe that AWP is not a reliable price to be used as a basis for making reimbursements for either the Medicaid or Medicare Programs. When AWP is used, we believe it should be discounted.”¹⁰
- In 1996 and 1997, the HHS-OIG issued thirteen audit reports finding that, on average, pharmacies can purchase generic drugs at a 42.5% discount off AWP and brand drugs at an 18.3% discount off AWP. Once again, in these reports, the HHS-OIG criticized the use by state Medicaid agencies of AWP as a benchmark for Medicaid reimbursement (App. 72-84).

3. In 1997, Congress Set Reimbursement at 95%-of-AWP, With Knowledge That AWP Substantially Exceeds Acquisition Cost

Congress and the Clinton Administration debated changes to Medicare drug reimbursement as part of legislation for the federal government’s fiscal-year 1998 budget. The debate eventually led to the Balanced Budget Act of 1997 (“BBA”) in which Congress set the Medicare allowable amount at 95%-of-AWP.

President Clinton proposed reducing Medicare drug reimbursement to the amount the provider actually paid for the drug.¹¹ Explaining that AWP is like an undiscounted “sticker price” not tied to any legal standard, Secretary of HHS Donna Shalala cautioned Congress that AWP-based reimbursement creates improper financial incentives for healthcare providers.

⁹ HCFA Medicaid Transmittal, No. 84-12 (Sept. 1984) at 3, 16 (enclosing HHS-OIG, “Changes to the Medicaid Prescription Drug Program Could Save Millions”) (App. 71).

¹⁰ HHS-OIG, “Use of Average Wholesale Prices in Reimbursing Pharmacies in Medicaid and the Medicare Prescription Drug Program,” (Oct. 1989) at 5 (App. 86).

¹¹ See *Medicare Provisions in the President’s Budget: Hearing Before the Subcomm. on Health of the House Comm. on Ways and Means*, 105th Cong. at 11 (1997) (testimony of HCFA Administrator Bruce Vladek) (App. 51).

Hearing on President's Fiscal Year 1998 Budget Proposal for Medicare, Medicaid, and Welfare Before the Senate Committee on Finance, 105th Cong. 265 (1997) (written response of Secretary Donna Shalala to questions of Senator Hatch) (App. 52).

Congress rejected President Clinton's proposal, instead amending the Medicare Act to set the Medicare allowable amount as 95%-of-AWP and to eliminate estimated acquisition cost as a criterion for payment. *See* Pub. L. No. 105-33 § 4566(a) (codified at 42 U.S.C. § 1395u(o)) (App. 35). Congress announced its understanding that AWP substantially exceeded acquisition cost, yet elected to set the Medicare allowable at 95%-of-AWP anyway. H. Rep. No. 105-149 at 1354 (1997) (noting that "the [HHS] Office of Inspector General reports that Medicare reimbursement for the top 10 oncology drugs ranges from 20 percent to nearly 1000 percent per dosage more than acquisition costs") (App. 40); S. Rep. 105-30 at 157-58 (1997) (reporting that Medicare pays "substantially more than most other payers for prescription drugs") (App. 39).

In contrast to its decision to pay Medicare providers a markup for Part-B covered drugs, Congress prohibited physicians from charging a markup for certain other purchased services, such as diagnostic laboratory tests. Physicians must bill Medicare precisely the amount that they pay for purchased clinical laboratory testing services, without a markup. *See* 42 U.S.C. § 1395u(n) (App. 50). Thus, Congress demonstrated that it knows how to prevent Medicare from paying a markup to providers when it wants, but knowingly chose to pay providers a markup for Part B-covered drugs equal to 95%-of-AWP minus acquisition cost.

4. In 2000, Congress Prevented HCFA From Equating AWP With Actual Acquisition Cost of the Provider

Shortly following passage of the BBA, President Clinton criticized Congress's policy in a radio address to the nation. But, even as he criticized the system as wasteful,

President Clinton also stated there was *nothing illegal* about it and emphasize that it was well-known that AWP was akin to a “sticker price”:

Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system. Last week, the Department of Health and Human Services confirmed that our Medicare program has been systematically overpaying doctors and clinics for prescription drugs – overpayments that cost taxpayers hundreds of millions of dollars. . . . Now, these overpayments occur because Medicare reimburses doctors according to the published average wholesale price – the so-called sticker price – for drugs. Few doctors, however, actually pay the full sticker price. In fact, some pay just one tenth of the published price. That's why I'm sending to Congress again the same legislation I sent last year – legislation that will ensure that doctors are reimbursed no more, and no less, than the price they themselves pay for the medicines they give Medicare patients.

White House Office of Press Secretary, Remarks by the President in Radio Address to the Nation, 1997 WL 767416 (White House Dec. 13, 1997) (emphasis added) (App. 58). Congress did not enact the legislation referred to by President Clinton. Indeed, in the two years following enactment of the BBA, Congress refused to act on at least ten bills that were introduced into the House or Senate to reduce Medicare drug reimbursement either to the provider's actual acquisition cost or to 83%-of-AWP (App. 41-50, 57). A consistent theme sounded by Congress in resisting any effort to reform the AWP-based reimbursement system was that by knowingly over-reimbursing for certain drugs, Medicare was covering costs for professional services, not otherwise covered by Medicare, which were vital to senior citizens and the poor (App. 53-55).

After legislative efforts to repeal the BBA's drug reimbursement provisions failed, HCFA tried indirectly to accomplish the same objective. In May 2000, Secretary Shalala informed Congress that HCFA was preparing to instruct carriers to equate AWP with provider actual acquisition cost rather than referring to industry publications. *See* Letter from Secretary of HHS Donna Shalala, dated May 31, 2000 to Representative Thomas Bliley (App. 53). This

regulatory reinterpretation of AWP would have had the same effect as the proposed, but never enacted, legislative proposals.

Congress acted swiftly and decisively to stop HCFA's effort to indirectly change the BBA standard for drug reimbursement. For example, Senator (now Attorney General) Ashcroft introduced a bill to bar HCFA from implementing "any reduction to the rates of reimbursement for outpatient cancer therapy services under the [Medicare program]," explaining that "these margins . . . help cover costs for professional services, which are inadequately reimbursed." 146 Cong. Rec. at S8022 (Sep. 5, 2000) (App. 55). He feared that HCFA's plan to cut drug reimbursement by "changing the definition" of AWP would "force doctors to send seniors with cancer out of the community settings" and into more expensive hospital settings, ironically causing overall Medicare spending to rise. *Id.* (App. 55).¹²

Despite the legislative opposition, HCFA continued with the plan announced in Secretary Shalala's May 31, 2000 letter to Congress. In September 2000, HCFA formally directed carriers to use alternative wholesale pricing data instead of AWPs published in pharmaceutical industry publications as the source for reimbursement. *See* HCFA Transmittal AB-00-86 (Sept. 8, 2000) (App. 67).

The policy disagreement between HCFA and Congress culminated in December 2000, with the enactment of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 ("BIPA"). In BIPA, Congress codified the arguments advanced in the Congress in favor of using the AWPs published in industry publications. BIPA barred the

¹² *See also* 146 Cong. Rec. S8091, S8093 (Sept. 6, 2000) (statement of Sen. Abraham) ("I am cosponsoring with Senator Ashcroft the Cancer Care Preservation Act, which will guarantee that HCFA cannot implement any reductions in Medicare reimbursements for outpatient cancer treatment unless those changes are developed in conjunction with the Medicare Payment Advisory Commission and representatives of the cancer care community, provides for appropriate payment rates for outpatient cancer therapy services, and is specifically authorized by an act of Congress.") (App. 56).

Secretary of HHS from “directly or indirectly decreas[ing] the rates of reimbursement” for drugs covered by Part B until the Comptroller General (*i.e.*, General Accounting Office) studied the related issues of Medicare drug reimbursement and payment for provider professional services. Pub. L. No. 106-554 § 429 (App. 36).¹³

5. In 2003, Congress Adopted Changes in Medicare Reimbursement, but Required that such Changes Not be Implemented Unless CMS Adopted Changes in Dispensing Fees

In 2003, Congress retained AWP as the benchmark for Medicare Part B payments to providers in the “Medicare Prescription Drug, Improvement, and Modernization Act of 2003” (the “Prescription Drug Act”). *See* Pub. L. No. 108-173, 117 Stat. 2066 (2003), pp. 173-74 (references to page numbers are as published in H.R. 1) (App. 37). Specifically, under the Prescription Drug Act, Medicare will pay providers, with certain exceptions, 85%-of-AWP in 2004 (only a 10% decrease from the previous Medicare payment formula of 95%-of-AWP). *Id.* The Prescription Drug Act gives HCFA the authority to increase or decrease the payment amount based on certain data obtained from the General Accounting Office, HHS-OIG or from the manufacturers. *Id.* (App. 37). Payment to providers, however, may not be less than 80%-of-AWP during this time. *Id.* (App. 37).¹⁴

¹³ Following the passage of BIPA, at a September 21, 2001, hearing on Medicare drug reimbursement, numerous Members of Congress, including Representatives Elliot Engle, Gene Green, Sherod Brown, John Dingell, Fred Upton, and Robert Elrich, acknowledged that in the BBA of 1997 Congress used 95% of AWP for Medicare reimbursement to permit providers to earn a profit on drugs, to offset perceived underpayments for professional services. *See Medicare Drug Reimbursements: A Broken Systems for Patients and Taxpayers: House Comm. on Energy & Commerce, 107th Cong. (2001) (App. 57).*

¹⁴ Beginning in 2005, and for subsequent years, Medicare generally will pay providers, who dispense Medicare Part B covered drugs, 106% of the Average Sales Price (“ASP”). *Id.* at 174-75 (App. 37). ASP will be calculated as the total revenue received by the manufacturer for a particular drug, divided by the total number of units sold. *Id.* at 175-76 (App. 37). On or after January 1, 2006, HCFA is required to establish a competitive acquisition program. *Id.* at 180-81 (App. 37). Medicare providers will then have the option annually to obtain its drugs through a contractor or to purchase its drugs and seek Medicare reimbursement at 106% of ASP. *Id.* at 181 (App. 37).

Recognizing that payment amounts have in the past been used by providers to offset inadequate payments for dispensing Medicare drugs, the Prescription Drug Act provides that HCFA “*shall not* implement the revisions in payment amounts for drugs and biologicals administered by physicians as a result of the amendments . . . with respect to 2004 *unless the Secretary concurrently makes adjustments*” to the professional fees Medicare pays providers for administering Medicare Part B drugs. *Id.* at 188 (emphasis added) (App. 37).

ARGUMENT

I. ALL COUNTS FAIL TO COMPLY WITH CR 9.02

The Commonwealth's vague allegations of fraud fail to satisfy the heightened pleading requirements of CR 9.02. All counts should be dismissed because the Complaint specifies neither the circumstances surrounding the alleged fraud nor the manner in which Defendants' actions were allegedly fraudulent.

A. CR 9.02 Applies to All Counts Regardless of How They Are Styled

Kentucky Civil Rule 9.02, like Federal Rule of Civil Procedure 9(b), provides that “[i]n all averments of fraud or mistake, the circumstances constituting fraud or mistake shall be stated with particularity.” CR 9.02. CR 9.02 applies, regardless of the cause of action or theory of liability, whenever a plaintiff avers fraud on the part of the defendant. *See Red Bird Motors, Inc. v. Endsley*, Ky. Ct. App., 657 S.W.2d 954, 956 (1983) (applying heightened pleading requirement of CR 9.02 to claim for damages under the Kentucky Consumer Protection Act) (App. 123); *see also Veal v. First Am. Sav. Bank*, 914 F.2d 909, 913 (7th Cir. 1990) (App. 135); *Harvey v. Ford Motor Credit Co.*, 8 S.W.3d 273 (Tenn. Ct. App. 1999) (applying heightened pleading standard to claims under the Tennessee Consumer Protection Act) (App. 106); *Connick v. Suzuki Motor Co.*, 675 N.E.2d 584 (Ill. 1996) (holding that “a complaint alleging a violation of consumer fraud must be pled with the same particularity and specificity as that required under common law fraud”) (App. 100).

CR 9.02 applies to each count of the Complaint because each and every count relies on averments of fraud:

Count I (Action To Recover Money Due Commonwealth Under KRS 15.060) (See, e.g., Am. Compl. ¶ 42; Abbott Am. Compl. ¶ 37 (“Defendants have caused fraudulent . . . claims to be paid out of the Kentucky State Treasury . . .”) (emphasis added).)

Count II (Kentucky Consumer Protection Act and Kentucky Medicaid Fraud Statute) (See, e.g., Am. Compl. ¶ 49; Abbott Am. Compl. ¶ 44 (“Defendants violated KRS 205.8463 . . . by . . . knowingly and willfully (a) engaging in a scheme to *falsify* the true AWP of their drugs . . .”) (emphasis added).)

Count III (Kentucky Consumer Protection Act and False Advertising Statute) (See, e.g., Am. Compl. ¶ 55; Abbott Am. Compl. ¶ 50 (“Defendants violated KRS 517.030 . . . by knowingly and willfully reporting *false, misleading and inflated* AWP pricing information . . .”) (emphasis added).)

Count IV (Kentucky Consumer Protection Act) (See, e.g., Am. Compl. ¶ 59; Abbott Am. Compl. ¶ 54 (“Defendants have committed violations of KRS 367.170 by *willfully (a) engaging in a scheme to falsify* the true AWP of their drugs . . . (b) reporting *false and inflated* AWP . . .”) (emphasis added).)

Count V (Kentucky Medicaid Fraud Statute) (See, e.g., Am. Compl. ¶ 64; Abbott Am. Compl. ¶ 59 (“Defendants violated KRS 205.8463 . . . by . . . *knowingly engaging in a scheme to falsify* the true AWP of their drugs . . .”) (emphasis added).)

Count VI (Kentucky False Advertising Statute) (See, e.g., Am. Compl. ¶ 69; Abbott Am. Compl. ¶ 64 (“Defendants violated KRS 517.030 . . . by knowingly reporting *false, misleading and inflated* AWP . . .”) (emphasis added).)

Count VII (Common Law Fraud) (See, e.g., Am. Compl. ¶ 73; Abbott Am. Compl. ¶ 68 (“Defendants committed common law fraud by . . . (a) reporting *false* AWP or other pricing information . . .”); Am. Compl. ¶ 74; Abbott Am. Compl. ¶ 69 (“Defendants have engaged and continue to engage in repeated *fraudulent* acts . . .”) (emphasis added).)

Count VIII (Promissory Estoppel) (See, e.g., Am. Compl. ¶ 76; Abbott Am. Compl. ¶ 71 (“Defendants . . . represented they were providing true AWP . . . with knowledge or reasonable expectation that the *false* representations would be relied upon by (a) the Kentucky Medicaid program and (b) Medicare, Part B beneficiaries.”) (emphasis added).)

B. The Commonwealth Fails To Allege the Necessary Particulars of the Alleged Fraud

The circumstances of fraud that must be pleaded with particularity are “the time, place, and content of the alleged misrepresentation on which he or she relied; the fraudulent scheme; the fraudulent intent of the defendants; and the injury resulting from the fraud.” *St. Martin v. KFC Corp.*, 935 F. Supp. 898, 909 (W.D. Ky. 2003) (App. 129). As discussed below, the Complaint fails to satisfy these requirements.

1. The Commonwealth's Allegations Made "Upon Information and Belief"
Do Not Satisfy CR 9.02

Allegations made "upon information and belief" meet the requirements of CR 9.02 only where the information being alleged is exclusively in the control of the opposing party, and even then, the plaintiff must allege the basis of his suspicions. *Craighead v. E.F. Hutton & Co., Inc.*, 899 F.2d 485, 489 (6th Cir. 1990) (App. 101). Pleading on "information and belief" is the very antithesis of CR 9.02.

The Commonwealth's Amended Complaints against Dey, Warrick and Abbott should be dismissed because key allegations of fraud are based solely "upon and information and belief." The allegation that Defendants reported false AWP's to price reporting services is pleaded on "information and belief." (See, e.g., Am. Compl. ¶¶ 21, 28; Abbott Am. Compl. ¶¶ 18, 24.) The allegation that the AWP's for Defendants' drugs exceeded the actual sales price is pleaded on "information and belief." (Am. Compl. ¶ 29; Abbott Am. Compl. ¶ 25.) The allegations that Defendants gave improper discounts, rebates, free goods, and chargebacks is pleaded on "information and belief." (Am. Compl. ¶ 34; Abbott Am. Compl. ¶ 30.) Finally, the allegations that Defendants marketed the "spread" between the Medicare or Medicaid reimbursement and actual sales price is pleaded on "information and belief." (Am. Compl. ¶ 32; Abbott Am. Compl. ¶ 30.)

Moreover, the Commonwealth does not allege that the information underlying these allegations is within the exclusive control of Defendants. Indeed, such information is obviously not within Defendants' control. Even if it could, the Commonwealth neither "plead(s) a particular statement of facts upon which [its] belief is based" nor "states the grounds for [its] suspicions." *Craighead*, 899 F.2d at 489 (App. 101); *Uni*Quality, Inc. v. Infotronx, Inc.*, 974 F.2d 918, 924 (7th Cir. 1992) (App. 132).

Since key allegations of the Amended Complaints depend on these deficient allegations, the Complaint should be dismissed.

2. The Commonwealth Fails To Identify Fraudulent Statements

The Commonwealth also fails to allege false statements – the most basic CR 9.02 requirement.

First, the Commonwealth fails to identify *any* allegedly false AWP for five of the seven Dey drugs, five of the six Warrick drugs and fourteen of the sixteen Abbott drugs. For these drugs, the Complaint makes only boilerplate allegations that Defendants submitted “false” or “inflated” AWPs to industry publications. (*See, e.g.*, Am. Compl. ¶¶ 21-29; Abbott Am. Compl. ¶¶ 18-26.)¹⁵ Nor does the Complaint allege a “true AWP” for these drugs or what a “true AWP” represents. This does not satisfy CR 9.02. Courts regularly dismiss fraud claims that fail to identify the fraudulent statement. For example, in *Ackerman v. Northwestern Mut. Life Ins. Co.*, 172 F.3d 467, 470-71 (7th Cir. 1999) (App. 87), the court affirmed dismissal of a fraud claim on Rule 9(b) grounds where the plaintiff failed to identify the specific fraudulent statements allegedly made or the content of those statements. The court in *Birrane v. Master Collectors, Inc.*, 738 F. Supp. 167, 170 (D. Md. 1990) (App. 91), likewise dismissed a fraud claim where the plaintiff “utterly failed to state the time, place and content of the allegedly false misrepresentations and the benefits which [defendant] received.” The Commonwealth’s boilerplate allegation that the Defendants knowingly made false statements regarding more than twenty-four drugs, without identifying even one false statement relating to these products, does not satisfy CR 9.02.

¹⁵ Exhibit 1 of both Amended Complaints identifies multiple forms or dosages for most of the “subject” drugs. Thus, in all, Exhibit 1 of the Amended Complaints identifies twenty Dey products (corresponding to seven Dey drugs), sixteen Warrick products (corresponding to six Warrick drugs), and approximately fifty-eight Abbott products (corresponding to sixteen Abbott drugs).

Second, the scant allegations that relate to the remaining drugs, for which an allegedly false AWP is alleged, fail to provide the requisite particularity under CR 9.02. For instance, although the Commonwealth alleges the reported AWP for two Dey drugs (Albuterol Sulfate and Cromolyn Sodium), one Warrick drug (Albuterol Sulfate), and two Abbott drugs (Sodium Chloride and Vancomycin), (Am Compl., Exs. 2-5; Abbott Am. Compl. Exs. 2-5), the Commonwealth fails to allege what was false about these AWP. The Commonwealth also fails to allege the “true AWP” for these drugs or what a “true AWP” represents. Similarly, the Commonwealth provides “Actual Price” information in Exhibits 2-5 of the Complaint for select drugs, but fails to allege any particular facts, including how the purported “Actual Price” was determined or derived, when it was paid, and who paid it. These allegations do not satisfy CR 9.02, which requires the Commonwealth to plead with particularity the alleged misstatements made by each Defendant.

3. The Commonwealth Does Not Explain How The Alleged Misstatements Are False

The crux of the Commonwealth’s fraud allegations is that Defendants allegedly submitted false AWP to industry publications. Yet the Commonwealth does not allege how the published AWP (mostly unspecified in the Complaints) simply were false or misleading. Nor could it since the Commonwealth has defined AWP to mean the “average wholesale price published in [third-party pricing publications].” 907 KAR 1:018 1(2) (App. 13). Significantly, the Commonwealth never alleges that the Defendants misrepresented the meaning of the term “average wholesale price.”

Under these circumstances, CR 9.02 requires the Commonwealth to plead more than that the AWP for Defendants’ drugs exceeded their actual sales price. *See Williams v. WMX Tech.*, 112 F.3d 175, 179 (5th Cir. 1997) (complaint that did not “set forth an explanation

as to why the statement or omission complained of was false or misleading” dismissed under Rule 9(b)) (App. 136); *see also Mills v. Polar Molecular Corp.*, 12 F.3d 1170, 1175 (2d Cir. 1993) (Rule 9(b) requires plaintiff to “specify the [allegedly fraudulent] statements, identify the speaker, state when and where the statements were made, and *explain why the statements were fraudulent*”) (emphasis added) (App. 117); *Harrison v. Westinghouse Savannah River Co.*, 176 F.3d 776, 789 (4th Cir. 1999) (dismissing false signature claim where plaintiff failed to state how signature was fraudulent) (App. 105).

The Commonwealth also fails to explain how the published AWP’s could have been misunderstood as actual sales prices when the Commonwealth was simultaneously receiving rebate information that disclosed each drug’s average manufacturer’s price and actual acquisition cost from 340B Providers. *See, supra*, at 10-11.

4. The Commonwealth Fails To Allege Who Made Allegedly False Statements or When They Were Made

The Commonwealth also fails to allege *who* at Dey, Warrick or Abbott submitted the allegedly false information to the publications, or *where* and *how* the information was communicated. These omissions likewise are fatal to the Commonwealth’s claims. *See United States v. EER Systems Corp.*, 950 F. Supp. 130 (D. Md. 1996) (App. 134); *see also Uni*Quality, Inc.*, 974 F.2d at 923-24 (dismissing claim because plaintiff “[did] not even hint at the identity of those who made the misrepresentations, the time the misrepresentations were made, or the places at which the misrepresentations were made”) (App. 132). In *EER Systems*, the plaintiff brought multiple fraud claims against the defendant for “artificially inflated” charges submitted to the federal government for payment. 950 F. Supp. at 130 (App. 134). Although the court found that plaintiff had alleged sufficient particularity with respect to the time, place, and content of the false representations, the court still dismissed the claims because plaintiff failed to “(1) name the

person(s) who made the representations; (2) specifically state what he or she said; and (3) state what he or she acquired as a result of the representations.” *Id.* at 132 (App. 134).

Commonwealth’s allegations here are even more vague in this regard than the insufficient allegations in *EER Systems*, and should, therefore, be dismissed.

The Commonwealth further fails to identify when the alleged misrepresentations were made. The closest that the Commonwealth comes to satisfying CR 9.02 in this regard is in Exhibits 2-5 to the Complaint, where the Commonwealth identifies the *year* that Defendants purportedly reported AWP’s for certain products. This is not enough to satisfy CR 9.02. In *Clark v. Robert W. Baird Co.*, 142 F. Supp. 2d 1065, 1071-72 (N.D. Ill. 2001) (App. 96), the plaintiff alleged that the defendant committed mail fraud by writing unauthorized checks from various accounts for a period “in excess of twelve months.” The court dismissed the claim under Rule 9(b) and held that “for the ‘when’ [element], it is not enough to merely allege a period of months or years, or the duration of the activity.” *Id.* at 1072 (App. 96). Similarly, in *McCarthy, Wilson & Ethridge v. Provident Life and Accident Ins. Co.*, No. CIV.A.AW-00-2581, 2000 WL 1929780 (D. Md. Dec. 18, 2000) (App. 116), a law firm sued its disability insurer for fraud based on allegedly fraudulent statements about the extent of the firm’s insurance coverage. The plaintiff in *McCarthy* alleged that the fraudulent statements “occurred every year beginning in 1991.” *Id.* at *3 (App. 116). The court dismissed the fraud claim, finding that “a general allegation of fraudulent statements occurring over the last nine years without more detail as to the ‘when’ of the fraud fails to meet the specificity requirements of Rule 9(b).” *Id.* (App. 116.) Commonwealth’s insufficient allegations regarding time in this case are virtually identical to the allegations in *Clark* and *McCarthy*. The Commonwealth’s claims should, therefore, be dismissed.

5. The Commonwealth Fails to Allege That the Kentucky Medicaid Program or Kentucky Medicare Beneficiaries Reimbursed Defendants Based on Defendants' AWP

The Commonwealth does not allege that it ever actually reimbursed providers based on published AWP for Defendants' drugs. As noted above, by regulation Kentucky's Medicaid program reimburses providers at the *lesser* of: (a) the Federal Upper Limit; (b) Kentucky's maximum allowable cost; (c) the published AWP minus 10% (and AWP minus 12% since April 1, 2003); or (d) the usual and customary billed charges. 907 KAR 1:021 (App. 15), 907 KAR 1:018 (App. 13); Am. Compl. ¶ 14; Abbott Am. Compl. ¶ 11. Accordingly, if either the Federal Upper Limit, Kentucky maximum allowable cost or the usual and customary billed charge is lower than 90% or 88% of AWP, the amount the Kentucky Medicaid program reimburses for a drug is not based on the published AWP.¹⁶

Similarly, Medicare co-payments are based on the lesser of provider's actual charges or 95%-of-AWP. *See* 42 C.F.R. § 405.517 (App. 59). If a provider's charges are less than 95%-of-AWP, Medicare reimbursement and co-payments are not based on AWP. Furthermore, federal Medicare regulations provide that multiple-source drugs are reimbursed by reference to 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. Therefore, the Medicare program and, accordingly, Medicare beneficiaries do not necessarily make co-payments based on the particular AWP of the manufacturer whose drug was used.

Speculation that the Commonwealth could have relied on Defendants' reported AWP to reimburse providers of Defendants' drugs is not enough to satisfy CR 9.02.

¹⁶ This fact provides an independent basis for the dismissal of all of the Commonwealth's claims concerning multiple-source drugs. *See, infra*, Point VI.

6. The Commonwealth Fails To Specify How Defendants Allegedly “Marketed the Spread” or Improperly Used Incentives

The Commonwealth alleges that Defendants “marketed the ‘spread’ on their drugs with the intent of inducing Kentucky Medicaid providers to purchase and prescribe their drugs” (Am. Compl. ¶ 32; Abbott Am. Compl. ¶ 28.) Yet the Commonwealth alleges no particular facts about *how* Dey, Warrick, or Abbott allegedly marketed the spread. For instance, the Commonwealth does not allege:

- Who at Dey, Warrick, or Abbott “marketed the spread.”
- When Dey, Warrick, or Abbott “marketed the spread.”
- What Dey, Warrick, or Abbott did or said to “market the spread.”
- To whom the spread was “marketed.”
- What specific action providers took as a result of this “marketing.”
- How such “marketing” is unlawful or fraudulent.

The Commonwealth further contends that Defendants used free goods, educational grants and other incentives “to induce providers to purchase their drugs, all of which lowered the actual prices of the Defendants’ drugs, resulting in increased profits for providers, as well as market share and profits of the Defendants, at the expense of the Kentucky Medicaid program and Kentucky Medicare, Part B beneficiaries.” (Am. Compl. ¶ 34 (stating “to induce providers to purchase or *administer* its drugs” (emphasis added)); Abbott Am. Compl. ¶ 30.) The Commonwealth fails, however, to allege even a single specific instance of any defendant offering incentives to any provider. Moreover, the Commonwealth does not explain how such incentives could lower the actual prices of drugs and result in profits for providers and Defendants at the expense of Kentucky Medicaid and the Commonwealth’s Medicare

beneficiaries or, even if that were true, how offering the incentives constitutes unlawful or fraudulent activity.

The Commonwealth's omissions are fatal defects under CR 9.02.

II. THE COMMONWEALTH FAILS TO STATE A CLAIM FOR COMMON LAW FRAUD

Count VII should be dismissed because the Commonwealth has not pleaded all of the necessary elements of common law fraud. To state a claim for fraud, the Commonwealth must allege: (1) a material representation; (2) which is false; (3) known to be false or made recklessly (4) made with inducement to be acted upon; (5) acted in reliance thereon; and (6) causing injury. *See United Parcel Serv. Co. v. Rickert, Ky.*, 996 S.W.2d 464, 468 (1999) (App. 133). The Commonwealth has not sufficiently alleged that Defendants made a false representation or that the Commonwealth reasonably relied on any alleged misrepresentation.

A. The Commonwealth Fails to Allege That Defendants Made a False Representation

As noted, the Commonwealth alleges that Defendants allegedly submitted false prices to industry publications, thereby causing Medicaid and Medicare beneficiaries to overpay providers. (*See, e.g., Am. Compl. ¶ 73; Abbott Am. Compl. ¶ 68.*) Yet, the Commonwealth neither defines "AWP" nor alleges what the "true AWP" should have been. Moreover, the Commonwealth does not allege that AWP equals acquisition cost or that Defendants ever represented that it did. Indeed, the Commonwealth defines AWP simply as the average wholesale price published by pricing compendia. 907 KAR 1:018 1(2) (App. 13).

The Kentucky Medicaid regulation that provides the formula for reimbursement of prescription drugs contradicts the Commonwealth's fraud theory. As noted, and according to the Commonwealth's Complaint, "[a]t all times material hereto prior to April 1, 2003, pursuant to 907 KAR 1:021, Kentucky Medicaid reimbursed providers the lesser of (a) the Federal

maximum allowable cost (FMAC), plus a dispensing fee, (b) *average wholesale price* (“AWP”) *of the drug minus 10%*, plus a dispensing fee, or (c) usual and customary billed charges.” (Am. Compl. ¶ 14; Abbott Am. Compl. ¶ 11 (emphasis added).) By discounting AWP in its reimbursement formula, the Commonwealth has acknowledged that AWP exceeds providers’ acquisition cost.

Not only did the Commonwealth know that AWP exceeded acquisition cost based on the extensive public record discussed above, but the Commonwealth also was aware that the government had characterized AWP as, in President Clinton’s words, a “sticker price.” *See, supra*, at 10-20. It is irrational to allege that one can “falsely” represent a sticker price. Since the Commonwealth has not adequately alleged that Defendants made a false representation, Count VII must fail.

B. The Commonwealth Fails to Allege Reasonable Reliance

Count VII also should be dismissed because the Commonwealth has not alleged reasonable reliance. To maintain an action for fraud, the Commonwealth must allege, among other things, that it *reasonably* relied on a false representation. *See Kentucky Laborers Dist. Council Health & Welfare Trust Fund v. Hill & Knowlton, Inc.*, 24 F. Supp. 2d 755, 771 (W.D. Ky. 1998) (App. 110). A plaintiff’s knowledge and experience are relevant in determining whether its reliance was reasonable. *Id.* (App. 110.)

The very essence of actionable fraud or deceit is the belief in and reliance upon the statements of the party who seeks to perpetrate the fraud. Where the plaintiff does not believe the statements or where he has knowledge to the contrary, recovery is denied.

Wilson v. Henry, Ky., 340 S.W.2d 449, 451 (1960) (internal citations omitted) (App. 137). The Commonwealth has not adequately pleaded that it *reasonably* relied on published AWP’s as actual sales price, nor can it. As set forth above, a host of public records, governmental reports

and memoranda, and sworn testimony from government officials preclude any allegation of the Commonwealth's reasonable reliance on Defendants' alleged misstatements. *See, supra*, at 10-20.

Faced with similar allegations, courts have dismissed fraud claims where it is clear that plaintiff either knew or should have known of the alleged misrepresentation or omission. *See, e.g., Blount Fin. Servs. v. Walter E. Heller & Co.*, 819 F.2d 151, 153 (6th Cir. 1987) (affirming dismissal of fraud-based claim where ordinary and prudent business person would have verified allegedly deceptive information independently) (App. 92); *Caraluzzi v. Prudential Sec., Inc.*, 824 F. Supp. 1206, 1212 (N.D. Ill. 1993) (dismissing fraud claim and stating “[o]missions do not amount to scheme to defraud where the items allegedly omitted could be discovered through the exercise of ordinary diligence”) (App. 95). The Commonwealth plainly knew the average manufacturer's price for each relevant drug and further knew or should have known that the federal government had characterized AWP as a “sticker price.” Therefore, the Commonwealth cannot allege reasonable reliance, and Count VII should be dismissed.

III. THE COMMONWEALTH FAILS TO STATE A CLAIM FOR PROMISSORY ESTOPPEL

Count VIII of the Commonwealth's complaint purports to assert a claim for promissory estoppel. (Am. Compl. ¶¶ 76-80; Abbott Am. Compl. ¶¶ 70-75.) The Commonwealth's claim hinges on the allegation that Defendants “represented” that they were providing a “true AWP” to pricing compendia “with knowledge or reasonable expectation” that “true AWP” would be relied upon by the Kentucky Medicaid Program and the Commonwealth's Medicare Part B beneficiaries, (Am. Compl. ¶¶ 76-78; Abbott Am. Compl. ¶¶

71-73), and that such reliance was reasonable, (Am. Compl. ¶¶ 79-80; Abbott Am. Compl. ¶¶ 74-75). Count VIII should be dismissed for failure to state a claim.

To state a claim for promissory estoppel, a plaintiff must allege each of the following elements: (1) a clear and definite promise; (2) which the promisor should reasonably expect to induce action or forbearance on the part of the promisee or a third person; (3) which does induce such action or forbearance; and (4) injustice can be avoided only by enforcement of the promise. *McCarthy v. Louisville Cartage Co.*, Ky. Ct. App., 796 S.W.2d 10, 11 (1990) (noting Kentucky courts have adopted the doctrine of promissory estoppel as stated in the Restatement (Second) of Contracts § 90 (1965)) (App. 115); *FS Investments, Inc. v. Asset Guar. Ins. Co.*, 196 F. Supp. 2d 491, 506-07 (E.D. Ky. 2002) (App. 103); *Res-Care, Inc. v. Omega Healthcare Investors, Inc.*, 187 F. Supp. 2d 714, 718 (W.D. Ky. 2001) (App. 124); *Auto Channel, Inc. v. Speedvision Network, LLC*, 144 F. Supp. 2d 784, 792 (W.D. Ky. 2001) (App. 90). Count VIII fails with regard to at least two of these elements.

First, the Commonwealth does not, because it cannot, allege even one instance of a Defendant actually making a promise to report a “true AWP.” The Commonwealth similarly does not allege to whom Defendants made such alleged promises. Where a plaintiff has not alleged facts sufficient to show that a defendant made a promise, a claim for promissory estoppel should be dismissed. *See, e.g., Drake Ctr., Inc. v. Ohio Dep’t of Human Servs.*, 709 N.E.2d 532, 549 (Ohio Ct. App. 1998) (finding claim for promissory estoppel not supported where defendant did not make assurances that it would reimburse plaintiff at certain rate) (App. 102).

Second, the core allegation of Count VIII is that Defendants made promises to provide a “true AWP” to certain pricing compendia. This alleged promise is not sufficiently clear and definite because, by its very nature, AWP is not a clear and definite term. Indeed,

neither federal law nor the law of any state, defines what “AWP” is supposed to represent or sets forth how AWP should be calculated. The Commonwealth cannot allege a definite promise to report the “true” measure of an indefinite and unknown quantity. The Commonwealth cannot even allege what a “true AWP” would be.

Third, the indefinite nature of AWP further prevents the Commonwealth from meeting its pleading burden as to the second element of its promissory estoppel claim, that Defendants should have reasonably expected the Commonwealth to rely on their reporting of AWPs. First, as noted above, *see supra*, at 13-20, the federal government has taken the position that AWP is nothing more than a “sticker price.” Indeed, the Commonwealth concedes as much by alleging that the Kentucky Medicaid Program discounts AWP by as much as 12% when AWP is used as the basis for reimbursement by the Medicaid program. (Am. Compl. ¶ 14; Abbott Am. Compl. ¶ 11) This deduction is consistent with the federal government’s characterization of AWP as akin to a “sticker price,” not an actual or “true” price. Under these circumstances, Defendants could not have expected the Commonwealth to rely on published AWP data, and the Commonwealth could not have reasonably relied on those published AWPs as actual or “true” prices.

IV. THE COMMONWEALTH HAS NOT STATED A CLAIM UNDER KRS 15.060 BECAUSE THE COMMONWEALTH DID NOT PAY TO DEFENDANTS THE MONEY IT SEEKS TO RECOVER

In Count I, the Attorney General purports to bring a cause of action under KRS 15.060. That effort fails because KRS 15.060 does not create a cause of action. Rather, it is an enabling statute that authorizes the Attorney General to bring actions to recover Treasury funds on his own initiative.

The statute provides, in pertinent part, that the Attorney General shall, “[w]hen he believes that any fraudulent, erroneous or illegal fee bill, account, credit, charge or claim has

been erroneously or improperly approved, allowed or paid out of the Treasury to any person, *institute the necessary actions* to recover the same.” KRS 15.060(2) (emphasis added) (App. 1). In other words, the Attorney General is enabled to bring “necessary actions,” such as actions for unjust enrichment, breach of contract, common law fraud, or causes of action created by Kentucky statutes. The statute does not provide for a separate cause of action.

Indeed, KRS 15.060 was codified in the Kentucky Code under Title III Executive Branch, Chapter 15 Department of Law. KRS 15.060, and the statutes surrounding it, all set forth the duties, powers, and limits on power, of the Attorney General. *See Strong v. Chandler*, Ky., 70 S.W.3d 405, 408 (2002) (“KRS 15.060 outlines the duties of the Attorney General in regard to actions to collect and recover money due the Commonwealth”) (App. 131).¹⁷

Moreover, even if KRS 15.060 did create a cause of action, which Defendants do not concede, the claim should nevertheless be dismissed since the Commonwealth’s KRS 15.060 claim seeks to significantly expand the scope of KRS 15.060 to permit the Commonwealth to “recover” from Defendants the money it paid to other entities and individuals or, alternatively, the money certain of the Commonwealth’s citizens allegedly paid to other entities. KRS 15.060 provides for an action to recover funds “erroneously or improperly approved, allowed or paid out of the Treasury to any person.” *See Strong*, 70 S.W.3d at 410 (“it is clear that the legislature intended the Attorney General to act as a protector of the treasury . . .”) (App. 131). However, there is nothing in the case law or the legislative history to suggest that the Attorney General may “recover” funds from parties like Defendants that were not paid out of the state Treasury.

¹⁷ In *All-American Movers, Inc. v. Kentucky ex rel. Hancock*, Ky. App., 552 S.W.2d 679 (1977) (App. 88), the court noted that the Attorney General filed suit “pursuant to” KRS 15.060 in a case in which the Attorney General was seeking to recover funds paid to a moving company. It is unclear from the opinion whether the Attorney General purported to bring a cause of action arising under KRS 15.060. In *All-American Movers*, the facts make plain that the Attorney General could assert claims for breach of contract or unjust enrichment. The opinion does not discuss whether KRS 15.060 creates a cause of action, or rather authorizes the Attorney General to bring “necessary actions” on his own initiative.

As the Commonwealth admits, the Kentucky Medicaid program does not make payments directly to manufacturers like Defendants; instead, it reimburses physicians and pharmacists directly for drugs they dispense to Medicaid beneficiaries. (Am. Compl. ¶ 12; Abbott Am. Compl. ¶ 9.) There is no allegation that any money from the Commonwealth's Treasury was ever paid to any of the Defendants. The Commonwealth cites no precedent for the expansion of KRS 15.060 to permit the Attorney General to recover from a party funds that were paid to someone else.

To the extent the Commonwealth seeks to assert claims on behalf of Medicare beneficiaries who made co-payments for drugs manufactured by Defendants, there is similarly no allegation – because there cannot be – that those co-payments came from the Treasury. Prescription drugs covered by Medicare Part B generally are administered by a physician (Am. Compl. ¶ 18; Abbott Am. Compl. ¶ 15), and beneficiaries make co-payments to the administering physician. (Am. Compl. ¶ 19; Abbott Am. Compl. ¶ 16.) Thus, the Medicare Part B co-payments do not come from the Commonwealth's Treasury, and the Commonwealth may not recover those funds pursuant to KRS 15.060. Count I of the Complaint accordingly should be dismissed.

V. THE COMMONWEALTH'S STATUTORY FRAUD CLAIMS SHOULD BE DISMISSED

The Commonwealth's claims under the consumer protection statutes also should be dismissed. First, the Complaint fails to state a claim for violation of the Kentucky Consumer Protection Act, KRS 367.170 (App. 6), because there are no allegations of privity or any duty to report specific pricing information. Furthermore, the Attorney General may not seek money damages on behalf of the Commonwealth because the Commonwealth is not a "consumer." In addition, the Commonwealth's claim for violation of the Kentucky Medicaid Fraud Statute, KRS

205.8463 (App. 4), must be dismissed because the Commonwealth cannot allege that Defendants are “providers.” Finally, the charge that Defendants violated Kentucky’s False Advertising Statute, KRS 517.030 (App. 10), must be dismissed for failure to allege that Defendants advertised or that the purported advertisements were false or misleading.

A. The Consumer Protection Act Claim (Count IV) Should Be Dismissed for Failure To State a Claim

1. Count IV Should Be Dismissed Because Neither the Commonwealth Nor the Commonwealth’s Medicare Beneficiaries Are In Privity With Defendants

Even though the scope of the Consumer Protection Act is broad, the Commonwealth’s legislature and courts have limited the class of individuals protected by the statute. *See* KRS 367.220. As courts have consistently held, a plaintiff may bring a claim only against a seller from whom the plaintiff dealt directly: “[t]he legislature intended that privity of contract exist between the parties in a suit alleging a violation of the Consumer Protection Act.” *Skilcraft Sheetmetal, Inc. v. Kentucky Mach., Inc.*, Ky. App., 836 S.W.2d 907, 909 (1992) (App. 128). *See also* *Potter v. Bruce Walters Ford Sales, Inc.*, Ky. App., 37 S.W.3d 210, 213 (2001) (granting defendant’s motion for summary judgment where “it is clear that no privity of contract existed between” plaintiff and defendant) (App. 122); *Kentucky Laborers*, 24 F. Supp. 2d at 773 (dismissing complaint where plaintiffs “purchased nothing from Defendants, and were not otherwise in privity with them”) (App. 110); *Motorists Mut. Ins. Co. v. Glass*, Ky., 996 S.W.2d 437, 447 (1997) (“The Consumer Protection Act has no application to third-party claims.”) (App. 118). *See also* *Anderson v. Nat’l Sec. Fire and Cas. Co.*, Ky. App., 870 S.W.2d 432, 435-36 (1993) (App. 89).¹⁸

¹⁸ This case is nothing like *Stafford v. Cross Country Bank*, 262 F. Supp. 2d 776, 793 (W.D. Ky. 2003) (App. 130), in which the Court found that privity was not required for a claim brought under the Consumer Protection Act. There the defendant bank repeatedly claimed that plaintiff was obliged to pay the balance

Here, the allegations of the Complaint make clear that neither Medicaid nor Medicare beneficiaries bought anything from Defendants, or paid the Defendants a penny for their drugs. Instead, the Kentucky Medicaid program and Medicare beneficiaries pay medical providers (*e.g.*, pharmacies and physicians) who dispense drugs directly to beneficiaries. (Am. Compl. ¶ 12; Abbott Am. Compl. ¶ 9.) Nor is there any allegation that either the Kentucky Medicaid program or the Commonwealth’s Medicare beneficiaries ever dealt directly with Defendants concerning the pricing of drugs. The Complaint concedes that reimbursement under both the Kentucky Medicaid program and Medicare is keyed to pricing information provided by third-party publishers. (Am. Compl. ¶ 25; Abbott Am. Compl. ¶ 22.) Since there is no privity between any of the entities on whose behalf the Attorney General purports to sue – either the Kentucky Medicaid program or Medicare beneficiaries – and any of the Defendants, Count IV should be dismissed in its entirety.

2. Count IV Should Be Dismissed Because Defendants Were Not Required To Report Pricing Information as a Matter of Law

The Consumer Protection Act only reaches conduct that violates an express or implied duty. For example, in *Mullins v. Commonwealth Life Ins. Co.*, Ky., 839 S.W.2d 245, 246 (1992) (App. 119), plaintiffs alleged that an insurance company violated the Consumer Protection Act by failing to advise plaintiffs of the availability of underinsured motorist coverage and added reparation benefits. The Court rejected the claim, explaining that there could be no Consumer Protection Act violation because the Commonwealth’s legislature did not require insurers to offer the coverage in question. *Id.* at 250 (App. 119). Similarly, in *Schlenk v. Ford Motor Credit Co.*, the Sixth Circuit affirmed the trial court’s dismissal of the Consumer

due on a credit card in his name. The Commonwealth denied that he had ever applied for a credit card from defendant. The Court found that “the Bank’s own continued assumption of privity” made this case different. *Id.* (App. 130.)

Protection Act claim that defendant had not itemized certain leasing fees because no statute or regulation required the disclosure or itemization of those fees. 308 F.3d 619, 621-22 (6th Cir. 2002) (App. 126). And in *Red Bird Motors, Inc.*, 657 S.W.2d at 955 (App. 123), the Kentucky Court of Appeals held that the district court erred in denying a motion for judgment on the pleadings. There, the plaintiff alleged that the defendant violated the Consumer Protection Act when it failed to transfer automobile registration within ten days of purchase. The Court of Appeals explained that no Kentucky statute required transfer of the registration from the dealer to the purchaser within ten days of the sale. *Id.* at 956 (App. 123). *Accord Lawson v. Bank One*, 35 F. Supp. 2d 961, 966 (E.D. Ky. 1997) (App. 111).

In an attempt to create the illusion that the requisite duty exists here, the Commonwealth charges that Defendants had a common law and statutory duty to report specific pricing information. (Am. Compl. ¶ 27; Abbott Am. Compl. ¶ 23.) The Commonwealth is wrong as a matter of law. The Commonwealth cites no common law or statutory duty to this effect because there is none. While the Commonwealth has demonstrated its ability to regulate in the complex field of pharmaceutical reimbursement, it has never suggested or required that pharmaceutical manufacturers submit pricing information directly to the state or its Medicaid program. Indeed, by its own admission, the Commonwealth claims to have “relied upon the AWP and other drug pricing information provided by the Defendants to nationally known price reporting services in determining” reimbursement levels. (Am. Compl. ¶ 25; Abbott Am. Compl. ¶ 21.) If the Commonwealth wanted a particular type of pricing information, it could have asked for it. Having failed to do so, it cannot now claim that Defendants violated a common law or statutory duty by the practice of providing what the government acknowledges is

a list price to a third-party publisher. Count IV of the Complaint should be dismissed in its entirety.

3. **The Commonwealth Is Not a Consumer and Lacks Standing To Bring a Claim for Its Own Benefit Under the Consumer Protection Act**

Although the Attorney General has broad authority to “curtail” unfair or deceptive commercial practices, *see, e.g., Commonwealth v. North Am. Van Lines, Inc.*, Ky. App., 600 S.W.2d 459, 462 (1979) (App. 99), his office has no authority under the Consumer Protection Act to seek money damages on behalf of the Commonwealth. The statutory scheme limits the right to money damages to “[a]ny person who purchases or leases goods or services primarily for personal, family or household purposes” KRS 367.220 (App. 7). The Commonwealth asks this Court to extend the Consumer Protection Act for the first time to permit the Attorney General to bring an action to recover money damages on behalf of the Commonwealth itself. Even if the Attorney General could otherwise state a claim for restitution on behalf of allegedly defrauded consumers, *Commonwealth v. ABAC Pest Control, Inc.*, Ky. App., 621 S.W.2d 705, 706-07 (1981) (App. 97), it cannot exercise that power on its own behalf because the Commonwealth is not a consumer within the meaning of KRS 367.220.¹⁹ Consequently, at the very least the Commonwealth’s claim for money damages on the Commonwealth’s behalf pursuant to the Consumer Protection Act should be dismissed.

B. The Medicaid Fraud Statute Claims (Counts II and V) Should Be Dismissed Because Defendants Are Not “Providers” Who Dispensed Goods to “Recipients”

The Commonwealth seeks money damages for Defendants’ alleged violations of KRS 205.8463(2) and (4) (App. 4). However, KRS 205.8467 makes clear that money damages

¹⁹ Even the Commonwealth’s injunctive claim is simply an attempt to accomplish by judicial fiat what has never been required by the legislature. If Kentucky needs a particular type of pricing information directly from Defendants, the legislature should so require or the Commonwealth should ask for it.

may be recovered only from “providers,” a class specifically limited to companies that have been approved to provide goods to recipients under the Medical Assistance Program “directly” to “recipients.” KRS 205.8451(7) (App. 3). There is no allegation that any of the Defendants are “providers” within the meaning of that statute, and the Complaint does not allege facts from which the Court could conclude that Defendants are “providers” as required by the statute. Moreover, there is no allegation that Defendants provide goods directly to “recipients,” a term defined to include “any person receiving or who has received medical assistance benefits.” KRS 205.8451(9). Indeed, the Complaint concedes that Defendants do not provide pharmaceuticals directly to patients; instead, the patients receive pharmaceuticals from providers, such as physicians and pharmacists. (Am. Compl. ¶ 12; Abbott Am. Compl. ¶ 9) (defining “providers” to include pharmacists and physicians). In fact, Defendants are “suppliers” rather than “providers” in this context. *See* 907 KAR 1:671(38) (defining “suppliers” to include “an organization from which a provider purchases goods or services used in carrying out its responsibilities under the Medicaid program”) (App. 16). The Medicaid Fraud Statute by its terms does not impose liability on suppliers.

Moreover, in 1998, the legislature rejected a proposal to amend the definition of “provider” to include entities that, like the Defendants, supply goods or services but do not provide them directly to recipients. *See* 98RS HB227 (App. 12); 907 KAR 1:671 (App. 16). Thus, the face of the statute and its legislative history demonstrate that the legislature did not intend for manufacturers like the Defendants to be subjected to money damages for allegedly false or fraudulent claims submitted by providers. Such liability would be particularly unjustified since, as noted above, under the regulations applicable to Medicare and the Kentucky Medicaid program, reimbursement based on AWP is only used where the providers’ charge for a

drug (which is set by providers alone) is more than 95% of the median AWP (for multiple-source drugs under Medicare) or 90%-of-AWP for the Kentucky Medicaid program.

Finally, as discussed in more detail in Section I, *supra*, the Commonwealth has failed to allege, consistent with CR 9.02, even a single example of a false or fraudulent claim that was submitted by anyone in violation of the Medicaid Fraud Statute, let alone any submitted or caused to be submitted by Defendants. The Commonwealth's wholly conclusory allegations must be dismissed for that reason as well.

C. The False Advertising Statute Claims (Counts III and VI) Should Be Dismissed for Failure To State a Claim

KRS 517.030 targets only those who make a "false or misleading statement in any advertisement addressed to the public or to a substantial number of persons." To "advertise" is to "draw[] the public's attention to something to promote its sale." Black's Law Dictionary 43 (7th ed. 2000). *See Kentucky Bar Ass'n v. Stuart, Ky.*, 568 S.W.2d 933, 934 (1978) (referring to Black's Law Dictionary for the meaning of "advertise") (App. 109). Thus, the purpose of the prohibition is to prevent sellers from making misleading statements intended to influence purchasing decisions of the buying public. *See Genlyte Thomas Group LLC v. Nat'l Serv. Indus., Inc.*, 262 F. Supp. 2d 753, 756 (W.D. Ky. 2003) (explaining that false advertising requires "that the deception is material in that it is likely to influence purchasing decisions") (App. 104).

There are no allegations in the Complaint from which this Court could conclude that the specialized third-party publications that allegedly reported Defendants' pricing information were available to the general public, let alone that those publications promoted the sale of Defendants' products. The sole allegation is that the reporting services published pricing information. (Am. Compl. ¶¶ 23-24; Abbott Am. Compl. ¶ 20.) There is no suggestion that the statements at issue contained any representations about the efficacy of any product or any other

information designed to induce a consumer to buy the product. Indeed, the Complaint admits – as it must – that neither the Kentucky Medicaid program nor the Commonwealth’s Medicare beneficiaries buy drugs directly from Defendants. (Am. Compl. ¶¶ 12, 19; Abbott Am. Compl. ¶¶ 9, 16.)

VI. ALL MULTIPLE SOURCE DRUG CLAIMS FAIL AS A MATTER OF LAW

The Commonwealth’s claims in this action are completely dependent upon the notion that Defendants inflated AWP as part of competition and that this AWP inflation caused the Kentucky Medicaid program and Medicare beneficiaries to overpay for drugs. (*See, e.g.*, Am. Compl. ¶ 37; Abbott Am. Compl. ¶ 32.) However, in various circumstances, which the Commonwealth simply glosses over, gaining competitive advantage via the inflation of AWP is simply impossible because the rate at which multiple-source drugs are reimbursed is not determined with reference to any single manufacturer’s AWP.

A. All Medicaid Claims Should Be Dismissed

As alleged in the Complaint, the Commonwealth’s reimbursement for prescription drugs dispensed under the Kentucky Medicaid program is equal to the lower of the Federal Upper Limit, Kentucky’s maximum allowable cost (“KMAC”), 90%-of-AWP plus a dispensing fee; or the provider’s usual and customary billed charges. The Commonwealth’s vague and conclusory allegations make it impossible for Defendants or the Court to determine how any of the drugs at issue were reimbursed, or whether any of them were reimbursed on the basis of AWP. According to published FUL and KMAC lists, at least some of the drugs were subject to FUL or KMAC-based reimbursement for at least some portion of the time period encompassed by the Commonwealth’s claims. (App. 17-22, 68-70.) Aggravating the Commonwealth’s failure to specify how the drugs at issue were reimbursed is the fact that the Commonwealth’s claims fall apart under three of the four methodologies. Indeed, if the Kentucky Medicaid program

reimbursed claims for Defendants' multiple-source drugs based upon FUL, KMAC, or the "usual and customary price charged to the public," any misrepresentation of AWP would be irrelevant. Neither FUL nor KMAC are based on the AWP's reported by a single drug manufacturer; the provider's usual and customary charge is not based on AWP at all. Since neither FUL, KMAC, or usual and customary charge are based on any one manufacturer's reported AWP, if they are based on this AWP at all, the manufacturer of a drug reimbursed under these methodologies cannot change the reimbursement rate by changing its reported AWP. Therefore, the central thesis of the Commonwealth's case – that Defendants inflate AWP as a means of competition – would simply not be possible for drugs that are subject to reimbursement based on FUL, KMAC or "usual and customary price charged to the public."

B. All Medicare Part B Claims Should Also Be Dismissed

Medicare pays for multiple-source drugs and biologicals 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 (App. 59). Under this methodology, a single drug manufacturer cannot obtain a competitive advantage over another by increasing the AWP for that drug. Any effect that such an increase would have on Medicare payments would apply equally to all forms of the drug. As such, the Commonwealth's allegation that Defendants inflated AWP's for their drugs for the purpose of creating larger "spreads" to induce providers to purchase their drugs simply does not make sense in the case of Defendants' multiple-source drugs. *See Lerma v. Univision Communications, Inc.*, 52 F. Supp. 2d 1011, 1025 (E.D. Wis. 1999) (In determining whether a claim is stated, "the Court is not required to don blinders and to ignore commercial reality' .. To survive a motion to dismiss, a claim must make economic and factual sense.") (App. 112); *Brunson Communications, Inc. v. Arbitron*, 239 F. Supp. 2d 550, 564 (E.D.

Pa. 2002) (dismissing conspiracy claim because “the conspiracy theorized by Plaintiff is, for several reasons, economically implausible”) (App. 93).

Therefore, all of the Commonwealth’s claims – which are based on the notion that Defendants’ AWP were inflated as a means of competition – should be dismissed.

VII. ALL OF THE COMMONWEALTH’S CLAIMS ARE LIMITED BY THE APPLICABLE STATUTES OF LIMITATION

The Commonwealth’s claims in this action are limited, at best, to those accruing after September 15, 1998 or, in the case of some claims, after September 15, 2001. Counts I and V-VIII are subject to a limitations period of no longer than five (5) years. *See* KRS 413.120(2) (App. 8) (Counts V-VI); KRS 413.120(12) and 413.130(3) (App. 9) (Counts I and VII); KRS 413.120(1) (Count VIII). Counts II-IV, all alleging violations of the Consumer Protection Act, are each subject to a limitations period of no longer than two (2) years. *See* KRS 367.220 (App. 7).²⁰

The Commonwealth appears to anticipate taking advantage of a toll of these periods by alleging, that “[u]pon information and belief, the Defendants knowingly, willfully, and intentionally concealed their drugs’ true AWP and other pricing information from Kentucky Medicaid and the Commonwealth’s Medicare beneficiaries.” (Am. Compl. ¶ 28; Abbott Am. Compl. ¶ 24) To toll these limitations periods, however, the Commonwealth is required to have

²⁰ As the reporting of allegedly false or inflated AWP’s by Defendants forms the basis for all of the Commonwealth’s claims, causes of action for each count accrued when the AWP’s were allegedly reported. *See* KRS 367.220(5) (Counts II-IV - a cause of action under the Consumer Protection Act accrues upon its violation) (App. 7); KRS 446.070 (Count V-VI – causes of action for civil recovery for violations of penal statutes KRS 205.8463(4) and KRS 517.030 through KRS 446.070 accrue upon violations of the penal statutes); KRS 413.130(3) (App. 9); *Madison County v. Arnett*, Ky., 360 S.W.2d 208, 210 (1962) (Count VII – cause of action for common law fraud accrues upon discovery of fraud or when, by the exercise of ordinary care, the fraud ought to have been discovered) (App. 114); *Madison*, 360 S.W.2d at 210 (Count I – where averments of fraud are present in an action by a government entity to recover sums paid illegally to any person, cause of action accrues when, by the exercise of ordinary care, the fraud ought to have been discovered) (App. 114); *Nettles v. Am. Tel. and Tel. Co.*, 55 F.3d 1358, 1364-65 (8th Cir. 1995) (Count VIII - cause of action for promissory estoppel generally accrues at the date of the breach of the alleged promise) (App. 120).

alleged – with the specificity required by CR 9.02 – that Defendants fraudulently concealed their actions from the Commonwealth during the limitations periods. *See Skaggs v. Vaughn*, Ky. Ct. App., 550 S.W.2d 574, 577 (1977) (App. 127); *Campbell v. Upjohn Co.*, 676 F.2d 1122, 1126 (6th Cir. 1982) (App. 94). The Commonwealth has failed to provide the requisite particulars required by CR 9.02 and, therefore, the Commonwealth is not entitled to a tolling of any of the limitations periods.²¹ As such, at a minimum, Counts II-IV must be dismissed as to all claims arising prior to September 15, 2001 and Counts I and V-III must be dismissed as to all claims arising prior to September 15, 1998.

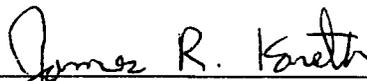
²¹ Furthermore, given the common understanding of the state and federal governments that the reported AWP's were not actual prices, the Commonwealth ought to have discovered the fraud it alleges as the basis for all of its claims decades ago. Therefore, the Commonwealth cannot be entitled to a tolling of any of the statutes of limitation nor 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 via the exercise of reasonable diligence. *See* KRS 413.130(3) (App. 9); *Madison County*, 360 S.W.2d at 210 (App. 114).

CONCLUSION

For the foregoing reasons, Warrick, Schering, and Dey respectfully request that the First Amended Complaint be dismissed in its entirety.

Dated: February 6, 2004

Respectfully submitted,



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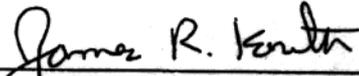
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I certify that a copy of the foregoing was served by hand delivery, this 6th day of February, 2004, upon the following:

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