

**COMMONWEALTH OF KENTUCKY
FRANKLIN CIRCUIT COURT – DIV. I
CIVIL ACTION NO. 04-CI-1487**

COMMONWEALTH OF KENTUCKY
ex rel. GREGORY D. STUMBO, Attorney General,

PLAINTIFF

v.

SECOND AMENDED COMPLAINT

ALPHARMA USPD, INC.	DEFENDANT
AMGEN INC.	DEFENDANT
APOTHECON, INC.	DEFENDANT
ASTRAZENECA PHARMACEUTICALS LP	DEFENDANT
ASTRAZENECA LP	DEFENDANT
AVENTIS PHARMACEUTICALS, INC.	DEFENDANT
AVENTIS BEHRING, LLC	DEFENDANT
B. BRAUN MEDICAL, INC.	DEFENDANT
BARR LABORATORIES, INC.	DEFENDANT
BAXTER HEALTHCARE CORPORATION	DEFENDANT
BEN VENUE LABORATORIES, INC.	DEFENDANT
BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.	DEFENDANT
BOEHRINGER INGELHEIM ROXANE, INC.	DEFENDANT
BRISTOL-MYERS SQUIBB COMPANY	DEFENDANT
BRISTOL-MYERS SQUIBB SANOFI PHARMACEUTICALS HOLDING PARTNERSHIP	DEFENDANT
CENTOCOR, INC.	DEFENDANT
DURAMED PHARMACEUTICALS, INC.	DEFENDANT

FOREST PHARMACEUTICALS INC.	DEFENDANT
IMMUNEX CORPORATION	DEFENDANT
IVAX CORPORATION	DEFENDANT
IVAX PHARMACEUTICALS INC.	DEFENDANT
JANSSEN PHARMACEUTICAL PRODUCTS, LP	DEFENDANT
JOHNSON & JOHNSON, INC.	DEFENDANT
MCNEIL-PPC, INC.	DEFENDANT
MERCK & COMPANY, INC.	DEFENDANT
MYLAN LABORATORIES, INC.	DEFENDANT
MYLAN PHARMACEUTICALS, INC.	DEFENDANT
NOVARTIS PHARMACEUTICALS CORPORATION	DEFENDANT
ORTHO BIOTECH PRODUCTS, LP	DEFENDANT
ORTHO-MCNEIL PHARMACEUTICAL, INC.	DEFENDANT
PAR PHARMACEUTICALS COMPANIES, INC.	DEFENDANT
PFIZER, INC.	DEFENDANT
PHARMACIA	DEFENDANT
PUREPAC PHARMACEUTICAL CO.	DEFENDANT
SANDOZ, INC. f/k/a GENEVA PHARMACEUTICALS, INC.	DEFENDANT
SICOR, INC. f/k/a Sisor Pharmaceuticals, Inc., f/k/a Gensia Sisor Pharmaceuticals, Inc.	DEFENDANT
SMITHKLINE BEECHAM CORPORATION d/b/a GlaxoSmithKline	DEFENDANT

TAP PHARMACEUTICAL PRODUCTS, INC.	DEFENDANT
TEVA PHARMACEUTICALS USA, INC.	DEFENDANT
WATSON PHARMA, INC.	DEFENDANT
WATSON PHARMACEUTICALS, INC.	DEFENDANT

* * * * *

The Plaintiff, Commonwealth of Kentucky, by its Attorney General, Gregory D. Stumbo, pursuant to leave of Court granted at the Case Management Conference conducted in this matter on July 18, 2007, and for its Second Amended Complaint against the Defendants listed above, alleges as follows:

I. Nature of the Action.

1. This is a lawsuit by the Commonwealth of Kentucky on its own behalf and acting in its *parens patriae* capacity on behalf of its citizens to recover damages and injunctive relief from defendants, who are manufacturers of prescription drugs. As described in this Complaint, defendants have taken advantage of the enormously complicated and non-transparent market for prescription drugs to engage in an unlawful scheme to cause the Commonwealth of Kentucky and its citizens to pay inflated prices for prescription drugs. The scheme involves the publication by defendants of phony “average wholesale prices,” which then become the basis for calculating the cost at which “providers” – the physicians, hospitals, and pharmacies who provide these prescription drugs to patients – are reimbursed by Kentucky. Defendants reinforce this basic tactic with other deceptive practices described in this Complaint, including the use of secret discounts and rebates to providers and the use of various devices to keep secret the prices of their drugs currently available in the market place to other purchasers. By willfully engaging in this scheme, defendants have succeeded in having Kentucky and its citizens finance windfall profits to these providers.

Defendants attempt to profit from their scheme by using the lure of these windfall profits competitively to encourage providers to buy more of their drugs instead of competing in the market place solely on the basis of legitimate factors such as price and the medicinal value of their drugs.

II. Parties and Jurisdiction.

2. The Commonwealth of Kentucky brings this action on behalf of itself, and certain of its citizens. As described in this complaint, defendants' unlawful scheme has resulted in higher prices for prescription drugs being paid by Kentucky itself (as payer under the Medicaid program, and other programs).

3. The defendants are all pharmaceutical companies whose fraudulent scheme, described in this Complaint, has resulted in drugs being sold to Kentucky and its citizens at inflated prices, as detailed below.

4. The following two defendants are hereinafter referred to as the Alharma Group:

a. Defendant Alharma USPD, Inc. ("Alharma") is a Delaware corporation in the business of manufacturing and selling pharmaceuticals. Alharma's principal place of business is One Executive Drive, Fort Lee, NJ 07024.

b. Defendant Purepac Pharmaceutical Co. ("Purepac") is a Delaware corporation in the business of manufacturing and selling pharmaceuticals. Purepac's principal place of business is 14 Commerce Drive, Suite 301, Cranford, NJ 07016. Purepac is a subsidiary of Alharma.

5. The following two defendants are hereinafter referred to as the Amgen Group:

a. Defendant Amgen Inc. ("Amgen") is a Delaware corporation in the business of manufacturing and selling pharmaceuticals. Amgen's principal place of business is located at One Amgen Drive, Thousand Oaks, California 91320-

1799.

- b. Defendant Immunex Corporation (“Immunex”), a wholly owned subsidiary of Amgen since July 2002, is a Washington State corporation engaged in the business of manufacturing and selling pharmaceuticals. Immunex’s principal place of business is located at 51 University Street, Seattle, Washington, 98101.

6. Defendants AstraZeneca Pharmaceuticals LP and AstraZeneca LP (“AstraZeneca”) are related Delaware corporations with their principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850.

7. Defendant Aventis Pharmaceuticals, Inc. is a Delaware corporation with its principal place of business located at 300-400 Somerset Corporate Boulevard, Bridgewater, New Jersey 08807-2854.

8. Defendant Aventis Behring, LLC, n/k/a ZLB Behring, is a Delaware corporation with its principal place of business located at 1020 1st Avenue, King of Prussia, Pennsylvania 19406-0901.

9. The following two defendants are hereinafter referred to as the Barr Group:

- a. Defendant Barr Laboratories, Inc. (“Barr Labs”), is a Delaware corporation in the business of manufacturing and selling pharmaceuticals with its principal place of business located at 400 Chestnut ridge Road, Woodcliff Lake, New Jersey 07677.
- b. Defendant Duramed Pharmaceuticals, Inc. (“Duramed”), is a Delaware corporation in the business of manufacturing and selling pharmaceuticals with its principal place of business located at 5040 Duramed Circle,

Cincinnati, Ohio 45213.

10. Defendant Baxter Healthcare Corporation (“Baxter”) is a Delaware corporation in the business of manufacturing and selling pharmaceuticals. Baxter’s principal place of business is at One Baxter Parkway, Deerfield, Illinois 60015. Baxter is a subsidiary of Baxter International, Inc.

11. The following three defendants are hereinafter referred to as the Boehringer Group:

a. Defendant Boehringer Ingelheim Pharmaceuticals, Inc. (“BIPI”), is a Connecticut corporation engaged in the business of manufacturing and selling pharmaceuticals. BIPI’s principal place of business is located at 900 Ridgebury Road, Ridgefield, Connecticut 06877. BIPI is a subsidiary of Boehringer Ingelheim Corporation.

b. Defendant Boehringer Ingelheim Roxane, Inc., f/k/a Roxane Laboratories, Inc. (“BIRI”), is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. BIRI’s principal place of business is located at 1809 Wilson Road, Columbus, Ohio 43216-6532. BIRI is a subsidiary of Boehringer Ingelheim Corporation.

c. Defendant Ben Venue Laboratories, Inc. (“Ben Venue”), is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Ben Venue’s principal place of business is located at 300 Northfield Road, Bedford, Ohio 44146. Ben Venue is a subsidiary of Boehringer Ingelheim Corporation.

12. Defendant B. Braun Medical, Inc. (“BBM”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. BBM’s principal place of business is located at 824 Twelfth Avenue, Bethlehem, Pennsylvania 18018-0027. BBM is a subsidiary of

BBA. BBM is also the successor in interest to McGaw, Inc. which was acquired by BBM in 1997 and was merged into BBM.

13. The following two defendants are hereinafter referred to as the BMS Group:

- a. Defendant Bristol-Myers Squibb Company (“Bristol-Myers”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Bristol-Myers’ principal place of business is located at 345 Park Avenue, New York, New York 10154-0037. Westwood-Squibb (“Westwood”) is a division of BMS.
- b. Defendant Apothecon, Inc. (“Apothecon”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals with its principal place of business located at 777 Scudders Mill Road, Plainsboro, New Jersey 08536. Apothecon is a subsidiary of Bristol-Myers.

14. Defendant Bristol-Meyers Squibb Sanofi Pharmaceuticals Holding Partnership (“BMS-Sanofi”) is a Delaware general partnership engaged in the business of manufacturing and selling pharmaceuticals with its principal place of business located at P.O. Box 4000, Route 206, Province Line Road, Princeton, New Jersey 08543. BMS-Sanofi is responsible for marketing Plavix® in the United States. The general partners of BMS-Sanofi are Bristol-Myers Squibb Investco, Inc. (“BMS Investco”) and Sanofi-Synthelabo, Inc. BMS Investco, Inc. is a Delaware corporation with its principal place of business located at 345 Park Avenue, New York, New York, and is a wholly-owned subsidiary of defendant Bristol-Myers Squibb Company. Sanofi-Synthelabo, Inc. is a Delaware corporation with its principal place of business located at 90 Park Ave, New York, New York, and is a wholly owned subsidiary of Sanofi-Aventis, a French corporation with its principal place of business located at 174 Avenue de France, Paris, France.

15. Defendant Forest Pharmaceuticals, Inc. (“Forest”) is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Forest’s principal place of business is located at 13600 Shoreline Drive, St. Louis, Missouri 63045.

16. The following two defendants are hereinafter referred to as the Ivax Group:

a. Defendant Ivax Corporation (“Ivax”) is a Florida (formerly Delaware) corporation engaged in the business of manufacturing and selling pharmaceuticals. Ivax’s principal place of business is located at 4400 Biscayne Blvd., Miami, Florida 33137.

b. Defendant Ivax Pharmaceuticals Inc. (“Ivax Pharm”), a wholly owned subsidiary of Ivax, is a Florida corporation engaged in the business of manufacturing and selling pharmaceuticals. Ivax Pharm’s principal place of business is located at 4400 Biscayne Blvd., Miami, Florida 33137.

17. The following six defendants are hereinafter referred to as the Johnson & Johnson Group:

a. Defendant Johnson & Johnson, Inc. (“J&J”) is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. J&J’s principal place of business is located at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

b. Defendant Janssen Pharmaceutical Products, LP (“Janssen”), a wholly owned subsidiary of J&J, is a New Jersey limited partnership engaged in the business of manufacturing and selling pharmaceuticals. Janssen’s principal place of business is located at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

- c. Defendant Ortho-McNeil Pharmaceutical, Inc. (“Ortho McNeil”), a wholly owned subsidiary of J&J, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Ortho McNeil’s principal place of business is located at 1000 U.S. Route 202 South, Raritan, New Jersey 08869.
- d. Defendant Ortho Biotech Products, LP (“Ortho Biotech”), a wholly owned subsidiary of J&J, is a New Jersey limited partnership engaged in the business of manufacturing and selling pharmaceuticals. Ortho Biotech’s principal place of business is located at 700 U.S. Highway 202, Raritan, New Jersey 08869.
- e. Defendant McNeil-PPC, Inc. (“McNeil”), a wholly owned subsidiary of J&J, is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. McNeil’s principal place of business is located at 7050 Camp Hill Road, Fort Washington, Pennsylvania 19034. McNeil Consumer & Specialty Pharmaceuticals (“McNeil Cons”) is a division of McNeil.
- f. Defendant Centocor, Inc. (“Centocor”), is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals with its principal place of business located at 200 Great Valley Parkway, Malvern Pennsylvania 19355. Centocor is a subsidiary of J&J.

18. Defendant Merck & Company, Inc. (“Merck”) is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Merck’s principal place of business is located at One Merck Dr., Whitehouse Station, NJ 08889-0100.

19. The following two defendants are hereinafter referred to as the Mylan Group:
 - a. Defendant Mylan Laboratories, Inc. (“Mylan”) is a Pennsylvania corporation engaged in the business of manufacturing and selling pharmaceuticals, mainly through its subsidiaries. Mylan’s principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317.
 - b. Defendant Mylan Pharmaceuticals, Inc. (“Mylan Pharm”), a wholly owned subsidiary of Mylan, is a West Virginia corporation engaged in the business of manufacturing and selling pharmaceuticals. Mylan Pharm’s principal place of business is located at 1500 Corporate Drive, Suite 400, Canonsburg, Pennsylvania 15317.
20. The following two defendants are hereinafter referred to as the Novartis Group:
 - a. Defendant Novartis Pharmaceuticals Corporation (“Novartis”) is a New Jersey corporation engaged in the business of manufacturing and selling pharmaceuticals. Novartis’ principal place of business is located at One Health Plaza, East Hanover, New Jersey 07936.
 - b. Defendant Sandoz, Inc. (“Sandoz”), formerly known as Geneva Pharmaceuticals, Inc., is a wholly owned subsidiary of Novartis. Sandoz is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Sandoz’s principal place of business is located at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.
21. Defendant Par Pharmaceuticals Companies, Inc. (“Par”) is a Delaware corporation with its principal place of business located at One Ram Ridge Road, Spring Valley, NY 10977. Par

is also being sued for the conduct of its subsidiaries and/or divisions, including, but not limited to, Par Pharmaceutical, Inc.

22. The following two defendants are hereinafter referred to as the Pfizer Group:

- a. Defendant Pfizer, Inc. (“Pfizer”) is a Delaware corporation engaged in the business of manufacturing and marketing pharmaceuticals with its principal place of business at 235 East 42nd Street, New York, New York 10017. In April 2003, Pfizer acquired defendant Pharmacia. Pfizer is also being sued for the conduct of its subsidiaries and/or divisions, including, but not limited to, Warner-Lambert, Pfizer-Warner-Lambert, and Parke-Davis.
- b. Defendant Pharmacia is a Delaware corporation with its principal place of business located at 100 Route 206 North, Peapack, New Jersey 07977. Pharmacia was created through the merger of Pharmacia and Upjohn, Inc., and Monsanto Company on March 31, 2000. Pharmacia was acquired by defendant Pfizer in April 2003.

23. Defendant SmithKline Beecham Corporation, d/b/a GlaxoSmithKline, (“GlaxoSmithKline”) is a Delaware corporation with its principal place of business at One Franklin Plaza, Philadelphia, Pennsylvania 19102.

24. Defendant TAP Pharmaceutical Products, Inc. (“TAP”) is a Delaware corporation headquartered at Bannackburn Lake, Office Plaza, 2355 Waukegan Road, Deerfield, Illinois 60015. TAP is jointly owned by Abbott Laboratories and Takeda Chemical Industries, Ltd.

25. The following two defendants are hereinafter referred to as the Teva Group:

- a. Defendant Teva Pharmaceuticals USA, Inc. (“Teva”) is a Delaware corporation engaged in the business of manufacturing and selling

pharmaceuticals. Teva's principal place of business is located at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva is a subsidiary of Teva Pharmaceutical Industries, Ltd., an Israeli corporation. Teva is also the successor in interest to Novopharm USA, Inc., the US subsidiary of Novopharm, Ltd., a Canadian corporation. In April 2000, Teva Pharmaceutical Industries, Ltd. acquired Novopharm, Ltd. and Novopharm USA, Inc. was subsequently merged into Teva.

- b. Defendant Sicor, Inc., f/k/a Sicor Pharmaceuticals, Inc., f/k/a Gensia Sicor Pharmaceuticals, Inc., is a Delaware Corporation with its principal place of business at 19 Hughes, Irvine, California 92618-1902. In January 2000, Sicor was acquired by Teva Pharmaceutical Industries, Ltd. and is now a subsidiary of that corporation.

26. The following two defendants are hereinafter referred to as the Watson Group:

- a. Defendant Watson Pharmaceuticals, Inc. ("Watson") is a Nevada corporation engaged in the business of manufacturing and selling pharmaceuticals. Watson's principal place of business is located at 311 Bonnie Circle, Corona, California 92880.
- b. Defendant Watson Pharma, Inc., f/k/a Schein Pharmaceuticals, Inc. ("Watson Pharma"), a wholly owned subsidiary of Watson since 2000, is a Delaware corporation engaged in the business of manufacturing and selling pharmaceuticals. Watson Pharma's principal place of business is located at 311 Bonnie Circle, Corona, California 92880.

27. This Court has jurisdiction over the plaintiff, Commonwealth of Kentucky's claims

as they involve claims arising exclusively under Kentucky statutes, Kentucky common law, and the *parens patriae* authority of the Attorney General to act on behalf of the Commonwealth of Kentucky and its citizens.

28. Venue is proper in Franklin County, Kentucky, pursuant to KRS 452.460 because injuries to the plaintiff occurred in Franklin County, Kentucky, and pursuant to 367.190 (1) because unlawful methods, acts and/or practices of the defendants were committed in Franklin County, Kentucky.

III. Factual Background.

A. The Kentucky Medicaid Program.

29. The Kentucky Medicaid program is a joint state and federal program which pays for medical care, including prescription drug benefits, for Kentucky's poor citizens. Medicaid currently covers approximately 669,000, or one (1) in six (6), Kentuckians. Twenty percent (20%) of Kentucky's entire state budget goes to the Medicaid program. Prescription drug benefits are the largest component of the Kentucky Medicaid budget. Since 1995, the cost of prescription drugs to the Kentucky Medicaid program has increased approximately 300% from total annual costs of \$237,102,055 in 1995 to \$693,529,535 for fiscal year 2002. Kentucky consistently ranks near the top nationally in the number of prescriptions obtained per person annually. The number of Kentuckians covered by Medicaid and the costs associated with providing care for them continue to increase annually, while the Kentucky Medicaid Program's ability to keep pace with these increases has been diminished due to state budget shortfalls.

30. The Kentucky Medicaid program is administered by the Kentucky Cabinet for Health and Family Services. Kentucky Medicaid reimburses medical providers ("providers"), including pharmacists and physicians, and otherwise pays for covered drugs dispensed and administered to

Medicaid recipients, pursuant to statutory formulas.

31. KRS 205.560 and Kentucky Administrative Regulations 907 KAR 1:018 establish the formulas used by Kentucky Medicaid to reimburse providers for prescription drugs dispensed or administered to Medicaid recipients by Kentucky Medicaid providers.

32. At 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. On April 1, 2003, 907 KAR 1:018E became effective, replacing 907 KAR 1:021. It provides reimbursement to Kentucky Medicaid providers at the lesser of (a) The federal upper limit plus a dispensing fee, (b) state maximum allowable cost, plus a dispensing fee, (c) AWP minus 12%, plus a dispensing fee, or (d) usual and customary billed charges. Many state Medicaid programs use similar reimbursement formulas based upon AWP.

33. At all relevant times material to this action, the defendants were aware of the drug reimbursement formulas used by Kentucky and other states.

B. The Market for Prescription Drugs.

34. The market for prescription drugs is extremely complex. It is composed of over 65,000 separate National Drug Codes (“NDCs”) and is non-transparent. The essential structure of the market is as follows. The drugs themselves are manufactured by enormous and hugely profitable companies such as defendants. Defendants sell the drugs (with varying numbers of intermediaries and agents involved in the process) to physicians, hospitals, and pharmacies. In medical jargon, these physicians, hospitals, and pharmacies are called “providers.” The providers then in essence resell the drugs to their patients when the drugs are prescribed for, administered or dispensed to

those patients. Most patients have private or public health insurance coverage. Where a patient has such insurance, the price that is paid for the patient's prescribed drug ultimately will be paid in whole or large part by a private insurance company, a self-insured entity, or, in the case of Medicaid programs, a government entity. In medical jargon, these private insurance companies, self-insured entities, and government entities are known as "payers." More often than not, the payer will make the reimbursement payment directly to the provider, not to the patient.

35. This market structure means that the market for prescription drugs differs in two crucial respects from most markets.

36. First, in most markets, demand for a product is determined by the ultimate consumers of the product. This is not the case for prescription drugs. In the prescription drug market, the decision to use a prescription drug is overwhelmingly made not by the recipient of the drug – the patient – but by physicians, hospitals in which the patient is treated, home health care agencies, long term care facilities or (with respect to the decision to use generic drugs versus brand-name drugs) a pharmacy. Since prescription drugs are dispensed only on a physician's order, the physician has the principal say in what drug will be chosen for the patient. However, hospitals, particularly teaching hospitals, also have considerable influence over this choice. If a hospital decides to put one drug as opposed to a competing drug on its "formulary" (the list of drugs that the hospital stocks), the result will be that the physicians (particularly residents and attending physicians who are employed by the hospital) will likely order that drug rather than a competing drug. Likewise, although pharmacies do not prescribe drugs, pharmacies can exert important influence over the choice of which drug the patient will purchase where there is a choice between buying the generic version or the brand-name version of the drug which the physician has prescribed.

37. A second difference of the prescription drug market from most markets is that in most

markets, the ultimate consumer of the product pays for it directly. In the prescription drug market, however, most payments for drugs are made by “payers” through private or public insurance programs.

38. This structure of the prescription drug market produces the following fundamental fact that underlies defendants’ unlawful scheme. If a defendant drug manufacturer can cause a “payer” to reimburse for defendant’s drug at a higher price than the price the provider paid to buy the drug from the defendant, there will be a “spread” between the two prices, and that “spread” is retained by the provider as profit. The larger the “spread” that can be created for a particular drug, the greater the incentive the provider has for choosing, or for influencing the choice of, that drug rather than a drug of a competing manufacturer.

IV. Defendants’ Average Wholesale Prices And The Scheme To Market The Spread At Kentucky’s Expense.

39. Defendants have engaged in a scheme to maximize the “spread” by maximizing the prices at which Kentucky and Kentucky citizens reimburse providers for defendants’ drugs. The scheme takes advantage of the fact that the Medicaid Program relies on defendants’ published wholesale prices for reimbursement guidance.

40. Each of the defendants and/or its subsidiaries has for years identified an average wholesale price (“AWP”) and, more recently, a price denominated as the wholesale acquisition cost (“WAC”) (or similar terms used to denote either the price charged by the wholesaler or a drug’s cost to the wholesaler) for most of their drugs. These prices are disseminated to the public by the defendants through publication in certain medical compendiums. Among the most prominent of these compendiums are the Drug Topics Red Book and First DataBank Annual Directory of Pharmaceuticals. These publications rely on the prices reported to them by the defendants. These

are the only prescription drug prices that defendants make public.

41. For many years, Kentucky, as a payer under the Medicaid program, has based its reimbursement formula for prescription drugs on the defendants' published AWP. Kentucky has relied on these prices for many reasons. First, simplified and reliable estimates of the cost of drugs prescribed for Kentucky citizens are needed because the huge number of different drugs and the non-transparency of the marketplace make it impracticable for Kentucky to track the drug price changes drug by drug on a daily basis. Second, the AWP come directly from the defendants, the most knowledgeable source. Third, by using the term "average wholesale price," defendants convey that term's commonly understood meaning – that the price is an average of actual prices that are charged by wholesalers. Fourth, the compendiums in which these prices are published are widely used and respected. Fifth, these published prices are the only prices publicly available. Sixth, defendants conceal the true cost of their drugs as set forth below. Seventh, Kentucky relies on the honesty of those who profit from Kentucky's Medicaid assistance programs and other Commonwealth programs.

42. As a result, Kentucky's drug reimbursement system has been, and remains, almost completely dependent on defendants' reported wholesale prices. Defendants know this fact and rely on it to make their AWP scheme work.

43. Since at least 1992, defendants have published false and inflated AWP for virtually all of their drugs. One purpose of this scheme was and is to create the spread between the true wholesale price of a drug and the false and inflated AWP and thereby increase the incentive for providers to choose the drug for their patients, or, at a minimum, to counteract the same tactic used by a competitor, since if competing manufacturers are also publishing false and inflated AWP for their drugs, a given defendant will be at a competitive disadvantage unless it does the same for its

own drugs.

44. The higher the spread between the AWP and the wholesale price the provider actually pays, the more profit a provider can make. Defendants often market their products by pointing out (explicitly and implicitly) that their drug's spread is higher than the spread of a competing drug.

45. One example of how defendants market this spread is Adriamycin, one of the drugs used in treating breast cancer. Defendant Pharmacia reported an AWP of \$241.36 for Adriamycin in April 2000 when it was actually selling the drug wholesale for as low as \$33.43, creating a "spread" of \$207.93. These spreads were then advertised to oncology providers in promotions which emphasized a wide margin of profit.

46. All of the defendants have inflated their reported average wholesale prices to levels far beyond any real average wholesale price of their drugs and their subsidiaries' drugs. One high-ranking industry executive has described it as the industry practice to do so. For example, Dey, Inc. ("Dey") is a manufacturer of generic drugs and a defendant in a companion lawsuit pending in the Franklin Circuit Court. Dey brought a lawsuit against First DataBank, the publisher of the medical compendium that Kentucky Medicaid relies on for prescription drug pricing, because it published the *actual* average wholesale price of Dey's drugs instead of the false average wholesale price sent to the publisher by Dey. Dey's principal allegation in that lawsuit was that the publication of its actual prices for drugs was inconsistent with the practice in the industry of accepting and publishing reported, inflated AWPs, and that such publication put Dey at a competitive disadvantage because it had no "spread" to advertise.

47. Attached as Exhibit A to this Complaint is a list of drugs manufactured by the defendants and/or their subsidiaries that the U.S. Department of Justice, after an extensive investigation, found to have inflated AWPs. The Department of Health and Human Services

concluded, with respect to all drugs utilized in the Medicare Program, that “[a] general conclusion reached in reviewing GAO [General Accounting Office] and OIG [Office of Inspector General] data is that there is a level of overstatement in the list AWP for *all* drugs” Payment Reform for Part B Drugs, 68 Fed. Reg. 50,430 (August 20, 2003) (emphasis added).

48. Examples of the defendants’ practices of inflating AWP’s include the following:

Manufacturer/Drug	2000 AWP	2000 Available Price	Spread	% Spread
Baxter Dextrose	\$ 542.88	\$ 86.40	\$ 456.48	528%
Ben Venue/Bedford Labs Etoposide, 20 ml.	\$ 550.00	\$ 45.13	\$ 504.87	1119%
Pharmacia/Upjohn Methylprednisolone Sodium Succinate (Solu-Medrol)	\$ 21.90	\$ 5.51	\$ 16.39	297%

49. Exhibit B contains additional examples of drugs manufactured by defendants with inflated AWP’s. Plaintiff has continued to obtain information relating to defendants’ publication of the prices of their drugs, including material obtained by the original qui tam whistleblower, Ven-A-Care, complaints filed by other states, and prices available to buyers other than Kentucky’s Medicaid program, and have found that the evidence uniformly supports the conclusion that defendants have pervasively inflated their published wholesale prices.

50. Defendants have similarly misrepresented and inflated the wholesale acquisition cost (“WAC”) of their drugs, making it appear that any reduction in the purchase price beyond the listed WAC would result in a loss to the wholesaler and was, hence, unachievable, when in fact the WAC was secretly discounted to purchasers other than the Medicaid program through an elaborate charge back system.

V. Defendants’ Exacerbation Of The Complexities of The Market And Affirmative Concealment Of Their Wrongdoing.

51. Defendants have been able to succeed in their drug pricing scheme for more than a decade by exacerbating the complexities of the incredibly huge, and dauntingly complex, drug market, and by purposely concealing their scheme from Kentucky and other payers, as set forth below.

52. The published wholesale price of the more than 65,000 NDC numbered drugs may, and often does, change at any time. As a consequence, just to track the current published prices of drugs utilized by a state's citizens requires resources and expertise that most states, including the Commonwealth of Kentucky, do not have.

53. Defendants have further exacerbated the inherent complexities of the drug market by utilizing marketing schemes which conceal the true price of their drugs in several different ways.

54. First, defendants sell their drugs in a unique manner which hides the true price of their drugs. This scheme works as follows. Upon agreeing on a quantity and price of a drug with a provider, or group of providers, the defendants purport to sell the agreed upon drugs to wholesalers with whom they have a contractual arrangement, at a price they call the Wholesale Acquisition Cost ("WAC"). The WAC may be, and usually is, higher than the price agreed upon by the provider and the drug manufacturer. The wholesaler then ships the product to the provider, charging the provider the (lower) price originally agreed upon by the drug manufacturer and the provider. When the wholesaler receives payment from the provider, it charges the manufacturer for handling, and any applicable rebates and discounts, and sends a bill to the manufacturer, called a "charge back", for the difference between the WAC and the price actually paid by the provider. These charge backs, (or shelf adjustments, or other economic inducements) are kept secret, so that it appears that the wholesaler actually purchased the drug at the higher WAC price. The effect of this practice is to create the impression that the "wholesale price" of the drug is higher than it really is.

55. Second, defendants further inhibit the ability of Kentucky and other ultimate purchasers to learn the true cost of their drugs by wrapping the sales agreements they negotiate with providers in absolute secrecy, terming them trade secrets and proprietary, to preclude providers from telling others the price they paid.

56. Third, defendants further obscure their true prices for their drugs with their policy of treating different classes of trade differently. Thus, for the same drug, pharmacies are given one price, hospitals another, and doctors yet another.

57. Fourth, some defendants have hidden their real drug prices by providing free drugs and phony grants to providers as a means of discounting the overall price of their drugs. For example, defendants TAP, AstraZeneca, and Pfizer have pled guilty to a federal criminal indictments for engaging in such conduct. These illegal practices appear to be part of an industry-wide marketing effort that may well represent the industry norm, but further discovery on this issue is required.

58. Defendants have hidden their motive for utilizing an inflated AWP from the public. Only with the disclosure of materials secured by litigants in recent discovery has it become apparent that one reason defendants were intentionally manipulating the nation's drug reimbursement system was to compete for market share on the basis of a phony price spread, instead of the true selling price of their drugs or the medicinal value of these drugs to their users.

59. Defendants have further concealed their conduct by making sure that all of the entities purchasing drugs directly from the defendants (and, hence, knowledgeable about the true price of their drugs) have had an incentive to keep defendants' scheme secret. Defendants' scheme permits all providers, pharmacies, physicians, and hospitals/clinics, to make some profit off defendants' inflated spread, because all of them are reimbursed in some manner on the basis of the

AWP for at least some of the drugs they sell or administer. For providers, therefore, the greater the difference between the actual price and the reported AWP, the more money they make. Thus, providers willingly sign drug sales contracts requiring them to maintain secrecy about the prices they pay for drugs.

60. Defendants have themselves continuously concealed the true price of their drugs and continued to publish AWP's and WAC's as if they were real, representative prices.

61. Although from time to time reports have emerged which indicate one drug or another, at one time or another, could be purchased for less than the AWP, Kentucky has been powerless to either discover the nature of defendants' fraud or arrest it for many reasons. First, defendants have fraudulently concealed their scheme by publishing AWP's and WAC's as if they were true prices and by hiding their true prices through elaborate cover-ups. To this day Kentucky has no idea what the true wholesale prices of defendants' drugs are. Second, only recently has the outline of defendants' scheme become known. Indeed, as late as 2000, the United States Congress was sufficiently confused by what defendants were doing that it directed the General Accounting Office to launch a full scale investigation of the market. And it was not until 2003 that the U.S. Department of Health and Human Services was able to modify the Medicare reimbursement system for drugs. Third, the motive for defendants engaging in this scheme—the belief that a larger spread enhances sales prospects—has only recently been discovered, making it clear, for the first time, that the disparities between reported AWP's and actual prices were not simply a result of transient market forces but were, instead, the result of a purposefully deceptive scheme by the defendants. Fourth, as a public policy matter, it is impracticable to respond effectively to evidence that some drugs, at some time, for some reason, have published AWP's higher than their actual purchase price. Kentucky does not have the resources to validate the reported prices of the more than 65,000 NDC

numbered drugs on an ongoing basis. And Kentucky is not at liberty simply to slash its drug reimbursement levels in the dark. If it unknowingly reduced its levels of reimbursement to below that which the providers actually pay for drugs, the providers would simply stop supplying the drugs, to the detriment of Kentucky citizens. Thus, although Kentucky has now uncovered the outline of defendants' unlawful scheme, the damage resulting to the Commonwealth and its citizens from defendants continues unabated and will continue until Kentucky learns the true wholesale prices of defendants' drugs.

62. Defendants' unlawful scheme has completely corrupted the market for prescription drugs. Instead of competing on prices and medicinal value alone, the defendants have deliberately sought to create a powerful financial incentive for providers to prescribe drugs based on the spread between the true price of a drug and its published AWP or WAC. Creating incentives for providers to prescribe drugs based on such a spread is inconsistent with Kentucky's public policy. Large price spreads on higher priced drugs encourage providers to prescribe more expensive drugs instead of their lower priced substitutes, thereby increasing the cost of healthcare. And competition on the basis of such spreads has the potential to influence (consciously or unconsciously) providers to prescribe less efficacious drugs over ones with greater medicinal value. Because of defendants' concealment of their scheme, Kentucky and its citizens have unknowingly underwritten this perversion of competition in the drug market. In sum, defendants have been, and continue to be, engaged in an insidious, fraudulent scheme that is causing Kentucky and its citizens to pay scores of millions of dollars a year more than they should for their prescription drugs, and may well be inducing some providers to prescribe less efficacious drugs.

VI. Damage From Defendants' Scheme To Kentucky's Medicaid Program.

63. The above-described scheme has damaged Kentucky's Treasury.

64. The Commonwealth of Kentucky's Medicaid program pays for medical benefits, including prescription drugs, for certain low income and disabled Kentucky citizens. The Medicaid Program is a program jointly funded by the Commonwealth of Kentucky and the United States Government. It reimburses physicians and pharmacies for drugs and other healthcare services according to a predetermined reimbursement formula.

65. With some exceptions, reimbursement to pharmacies, physicians, and hospitals for drugs covered by the Kentucky Medicaid Program is made at the defendants' published AWP minus a percentage (currently 12%), plus other fees.

66. At all times, each defendant was aware of the reimbursement formula used in the Kentucky Medicaid Program and the reliance of the Medicaid Program on the defendants' reported AWP.

67. By publishing, or causing to be published, false and inflated wholesale prices, and by keeping the prices for which they are actually selling their drugs secret, defendants have knowingly enabled providers of drugs to Medicaid recipients to charge Kentucky higher prices for these drugs than they could have charged had defendants not reported these false and inflated AWPs, and have knowingly interfered with Kentucky's ability to set reasonable reimbursement rates for their drugs.

68. As a consequence, Kentucky's Medicaid program has paid more for prescription drugs than it would have paid if defendants had published the prices they were receiving in the market place for their drugs.

COUNT I

**PER SE VIOLATION OF THE KENTUCKY
CONSUMER PROTECTION ACT KRS 367.170 THROUGH
VIOLATION OF THE KENTUCKY MEDICAID
FRAUD STATUTE, KRS 205.8463(4)**

69. Plaintiff hereby incorporates by reference all previous paragraphs.

70. KRS 205.520(2) provides: “The General Assembly of the Commonwealth of Kentucky recognizes and declares that it is an essential function, duty, and responsibility of the state government to provide medical care to its indigent citizenry; and it is the purpose of KRS 205.510 to 205.630 to provide such care.”

71. KRS 205.8463(4) provides: “No person shall, in any matter within the jurisdiction of the Cabinet for Health Services under this chapter, knowingly falsify, conceal, or cover-up by any trick, scheme, or device a material fact, or make any false, fictitious, or fraudulent statement or representation, or make or use any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry.”

72. KRS 367.170(1) provides: “Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful.”

73. Defendants have falsified and/or concealed the following material facts: 1) That their AWP's were not average wholesale prices of anything, 2) that the Wholesale Acquisition Cost was not the true cost of their drugs to wholesalers, 3) that defendants' deceptive pricing scheme was being utilized by providers to obtain windfall profits from Kentucky, and 4) that defendants competed on the basis of the spread instead of solely on the basis of the price and medicinal value of their drugs.

74. By engaging in the conduct described above, defendants have violated KRS

205.8463, and thereby committed *per se* violations of KRS 367.170(1).

75. As a direct result of defendants' *per se* violations of KRS 367.170 resulting from violations of KRS 205.8463(4), Defendants have caused damages to the Commonwealth, including the Kentucky Medicaid program, through the payment of grossly excessive prices for the defendants' prescription drugs.

COUNT II

PER SE VIOLATION OF THE KENTUCKY CONSUMER PROTECTION ACT KRS 367.170 THROUGH VIOLATION OF THE KENTUCKY FALSE ADVERTISING STATUTE, KRS 517.030

76. Plaintiff hereby incorporates by reference all previous paragraphs.

77. KRS 517.030 provides: "A person is guilty of false advertising when, in connection with the promotion of the sale of or to increase the consumption of property or services, he knowingly makes or causes to be made a false or misleading statement in any advertisement addressed to the public or to a substantial number of persons."

78. KRS 367.170 (1) provides that "Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

79. By engaging in the conduct described above, defendants have violated KRS 517.030, and thereby committed *per se* violations of KRS 367.170, by knowingly and willfully reporting false, misleading and inflated AWP and WAC pricing information on their drug products to national reporting services, while at the same time concealing actual pricing information. The reporting services in turn published the defendants' price information to substantial numbers of persons, including, but not limited to, the Kentucky Medicaid program, in connection with promotion of the sale, or to increase the consumption, of defendants' prescription drugs.

80. As a direct result of defendants' *per se* violations of KRS 367.170 resulting from violations of KRS 517.030, defendants have caused damages to the Commonwealth, including the Kentucky Medicaid program, through payment of grossly excessive prices for the defendants' prescription drugs.

COUNT III

VIOLATION OF THE KENTUCKY CONSUMER PROTECTION ACT KRS 367.170, KRS 446.070

81. Plaintiff hereby incorporates all previous paragraphs.

82. KRS 367.170 (1) provides: "Unfair, false, misleading, or deceptive acts or practices in the conduct of any trade or commerce are hereby declared unlawful."

83. By engaging in the conduct described above, defendants have committed violations of KRS 367.170.

84. As a direct result of defendants' violations of KRS 367.170, defendants have caused damages to the Commonwealth, including the Kentucky Medicaid program, through the payment of grossly excessive prices for the defendants' prescription drugs.

COUNT IV

VIOLATIONS OF KENTUCKY MEDICAID FRAUD STATUTE KRS 205.8463 (4), KRS 446.070

85. Plaintiff hereby incorporates by reference all previous paragraphs.

86. KRS 205.8463(4) provides: "No person shall, in any matter within the jurisdiction of the Cabinet for Health Services under this chapter, knowingly falsify, conceal, or cover-up by any trick, scheme, or device a material fact, or make any false, fictitious, or fraudulent statement or representation, or make or use any false writing or document knowing the same to contain any false,

fictitious, or fraudulent statement or entry.”

87. KRS 446.070 provides that: “A person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation.”

88. Defendants violated KRS 205.8463(4) by the conduct described above, including, but not limited to, knowingly (a) engaging in a scheme to falsify the true AWP or WAC of their drugs, (b) reporting false and inflated AWP or other pricing information on their drugs to reporting services relied upon by the Kentucky Medicaid program for reimbursement of Kentucky Medicaid providers, while at the same time concealing actual pricing information, (c) marketing the “spread” between the actual costs of the drugs and the reported AWP pricing information to Kentucky Medicaid providers to induce the use of defendants’ drugs, and thereby (d) obtaining excessive, unjust and illegal profits.

89. As a direct result of defendants’ violations of KRS 205.8463 (4), defendants have caused damages to the Commonwealth, including the Kentucky Medicaid program, through the payment of grossly excessive prices for the defendants’ prescription drugs.

COUNT V

VIOLATIONS OF KENTUCKY FALSE ADVERTISING STATUTE KRS 517.030, KRS 446.070

90. Plaintiff hereby incorporates by reference all previous paragraphs.

91. KRS 517.030 provides: “A person is guilty of false advertising when, in connection with the promotion of the sale of or to increase the consumption of property or services, he knowingly makes or causes to be made a false or misleading statement in any advertisement addressed to the public or to a substantial number of persons.”

92. KRS 446.070 provides that: “A person injured by the violation of any statute may recover from the offender such damages as he sustained by reason of the violation, although a penalty or forfeiture is imposed for such violation.”

93. By the conduct described above, defendants violated KRS 517.030, by knowingly reporting false, misleading and inflated AWP or other pricing information on their drug products to national reporting services, while at the same time concealing actual pricing information. The reporting services in turn published defendants’ AWP information to substantial numbers of persons, including, but not limited to, the Kentucky Medicaid program, in connection with the promotion of the sale, or to increase the consumption, of defendants’ prescription drugs, including, but not limited to those identified in Exhibit B.

94. As a direct result of defendants’ violations of KRS 517.030, defendants have caused damages to the Commonwealth, including the Kentucky Medicaid program, through the payment of grossly excessive prices for defendants’ prescription drugs.

PRAYER FOR RELIEF

WHEREFORE, the plaintiff, Commonwealth of Kentucky, by counsel, Attorney General Gregory D. Stumbo, prays for a judgment:

- A. Declaring that defendants committed repeated knowing and willful *per se* violations of KRS 367.170 by violating KRS 205.8463(4);
- B. Declaring that defendants committed repeated knowing and willful *per se* violations of KRS 367.170 by violating KRS 517.030;
- C. Declaring that defendants committed repeated willful violations of KRS 367.170;
- D. Declaring pursuant to KRS 446.070 that defendants committed repeated violations of KRS

205.8463(4);

- E. Declaring pursuant to KRS 446.070 that defendants committed repeated violations of KRS 517.030;
- F. Declaring that defendants have engaged in conduct, acts, or practices which resulted in fraudulent, erroneous, or illegal payments out of the Kentucky State Treasury.
- G. Permanently enjoining defendants and their employees, officers, directors, agents, successors, assigns, affiliates, merged or acquired predecessors, parent or controlling entities, subsidiaries, and any and all persons acting in concert or participation with defendants, from continuing their unlawful conduct, acts and practices.
- H. Awarding treble damages pursuant to KRS 205.8467 and KRS 446.070 and restitution pursuant to KRS 15.060 to the Kentucky Medicaid program on account of the damages caused to it as a result of defendants' unlawful conduct;
- I. Awarding civil penalties of \$2,000 for each willful violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990(2);
- J. Awarding civil penalties of \$10,000 for each violation of the Kentucky Consumer Protection Act pursuant to KRS 367.990 (2), where defendants' conduct was directed at a person aged sixty (60) or older;
- K. Awarding punitive damages against defendants pursuant to KRS 411.184;
- L. Awarding the Commonwealth of Kentucky its costs and attorneys' fees;
- M. Awarding the Commonwealth of Kentucky prejudgment interest as permitted by law;
- N. Awarding any other relief to which the Commonwealth is entitled or the Court deems appropriate and just.

Plaintiff demands trial by jury on all issues so triable.

Respectfully Submitted,

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Attorney General of Kentucky

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CERTIFICATE OF SERVICE

I hereby certify that a copy of the foregoing Second Amended Complaint was served on all counsel of record pursuant to Paragraph 7 of Case Management Order No. 1, by electronically transferring a conformed copy of same to LEXIS File & Serve Electronic Filing Service via the internet.

s/C. David Johnstone _____
C. David Johnstone
Assistant Attorney General