

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
FIFTH DIVISION

FILED

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PLAINTIFF
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STATE OF ARKANSAS

V.

CASE NO. CV04-634

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

DEFENDANTS

PLAINTIFF'S FIRST AMENDED COMPLAINT

Comes the Plaintiff, the State of Arkansas, by and through its Attorney General Mike Beebe, and for its Complaint against Defendants Dey, Inc., Warrick Pharmaceuticals Corporation, Schering-Plough Corporation, and Schering Corporation (hereinafter "Defendants"), states and alleges as follows:

I. INTRODUCTION

1. The Defendants have engaged in a scheme that siphons off money intended for the Arkansas Medicaid program, a governmental program designed to help poor and disabled Arkansans, and instead directs that money to enrich the Defendants and gain market share for their products. In the process, Defendants' illegal and unconscionable actions defraud not only elderly and disabled Arkansas Medicaid and Medicare beneficiaries, but also the State of Arkansas' Medicaid prescription drug program, and Arkansas consumers. The Defendants' fraudulent practices for pricing and marketing their prescription drugs have injured elderly, disabled and low-income Arkansas citizens covered by Medicare, as well as the State of Arkansas' Medicaid Program, by causing the Arkansas Medicaid Program to pay grossly excessive prices for

the Defendants' prescription drugs. This practice has also affected Arkansas residents covered by the Medicare, Part B program as well as all other non-Medicaid and non-Medicare Arkansas consumers who purchase these prescription drugs.

2. Fair, accurate and truthful pricing of prescription drugs is a vital concern to the State of Arkansas and its citizens. An equal concern to the state of Arkansas and its citizens is preventing drug companies from engaging in unconscionable business practices.

3. Plaintiff, State of Arkansas, by and through its Attorney General, Mike Beebe, seeks permanently to enjoin the Defendants from continuing to engage in fraudulent and deceptive drug pricing acts and practices, to recover damages and/or restitution on behalf of the State of Arkansas and its residents, and to impose civil penalties and punitive damages upon the Defendants for their fraudulent, illegal and unconscionable acts.

II. PARTIES

4. Mike Beebe is the duly elected Attorney General of the State of Arkansas and is authorized to bring this action on behalf of the State of Arkansas, its Medicaid Program, and its citizens. The Director of the Department of Human Services has expressly requested that the Attorney General implement the powers contained in the provisions of the Arkansas Deceptive Trade Practices to address the violations contained herein. (See Attached Exhibit "A"). The Attorney General has determined that this issue is of paramount importance to Arkansas citizens.

5. Defendant Warrick Pharmaceuticals Corporation ("Warrick") is a Delaware corporation with its principal places of business in Reno, Nevada and

Kenilworth, New Jersey. Warrick is a wholly owned subsidiary of Schering-Plough Corporation. At all relevant times, Warrick transacted business in the State of Arkansas by marketing, distributing and selling pharmaceutical drug products, directly or indirectly, to wholesalers, retailers, Medicaid providers, Medicaid beneficiaries, Medicare, Part B beneficiaries and consumers in the State of Arkansas.

6. Defendant Schering Corporation (“Schering”) is a New Jersey corporation with its principal offices located at 1 Giralda Farms, P.O. Box 1000, Madison, New Jersey 07940. At all relevant times, Schering transacted business in the State of Arkansas by marketing, distributing and selling pharmaceutical products, directly or indirectly, to wholesalers, retailers, Medicaid providers, Medicaid beneficiaries, Medicare, Part B beneficiaries and consumers in the State of Arkansas.

7. Defendant Schering-Plough Corporation (“Schering-Plough”) is a corporation organized under the laws of New Jersey with its principal offices in Madison, New Jersey. At all relevant times, Schering-Plough and its subsidiaries have transacted business in the State of Arkansas by marketing, distributing, and selling pharmaceutical drug products, directly or indirectly, to wholesalers, retailers, Medicaid providers, Medicaid beneficiaries, Medicare, Part B beneficiaries and consumers in the State of Arkansas. Schering-Plough is the parent company of both Schering and Warrick. Upon information and belief, Schering, along with Warrick and Schering-Plough, operate as one large company and not separate entities. Among these supposed “separate” companies there is unity of ownership and interest. Therefore, the acts of any one of those entities is properly imputed to each and all of them.

8. Defendant Dey, Inc. (“Dey”), formerly known as Dey Laboratories, Inc., is a Delaware corporation with its principal place of business in Napa, California. At all relevant times, Dey transacted business in the State of Arkansas by marketing, distributing and selling pharmaceutical drug products, directly or indirectly, to wholesalers, retailers, Medicaid providers, Medicaid beneficiaries, Medicare, Part B beneficiaries and consumers in the State of Arkansas.

III. JURISDICTION AND VENUE

9. This Court has jurisdiction over the State’s claims as they involve claims arising exclusively under Arkansas statutes and Arkansas common law.

10. Venue is proper in Pulaski County, Arkansas, pursuant to Ark. Code Ann. § 16-60-103 and Ark. Code Ann. § 4-88-112.

IV. FACTUAL BACKGROUND

A. Government Health Plans

1. The Arkansas Medicaid Program

11. The Arkansas Medicaid program is administered by the Arkansas Department of Human Services. The program pays for medical care, including prescription drug benefits, for Arkansas’ low-income citizens. In the year 2002, the Arkansas Medicaid program provided health benefits for 582,379 Arkansans, a figure that amounts to slightly more than 20% of the state’s population of 2.6 million. In 2002, Medicaid expenditures reached \$2,292,617,286.00. Of that amount, over \$266 million was allocated to cover the costs of prescription drugs. The substantial costs of the Medicaid Program have contributed heavily to the state’s budgetary problems.

12. Arkansas Medicaid reimburses medical providers, including pharmacies and physicians, for prescription drugs dispensed or administered to Medicaid recipients pursuant to a set methodology.

13. For each prescription drug, from the period beginning as early as 1995 until March 1, 2002, Medicaid reimbursements were based on whichever of the following formulas that when applied, resulted in the lowest cost:

A) the lowest of the pharmacy's usual and customary charge to the general public; or

(B) the Estimated Acquisition Cost ("EAC") of the drug dispensed, plus a dispensing fee (the EAC equaled Average Wholesale Price ("AWP") minus 10.5%); or

(C) the State or Federal Generic Upper Limit ("GUL") plus a dispensing fee.

14. For each generic prescription drug from the period beginning March 1, 2002 until the present, Medicaid reimbursements were based on the following formulas:

(A) For generic drugs having a State or Federal Upper Limit, the State/Federal Generic Upper Limit ("GUL") plus a dispensing fee of \$5.51.

(B) For generic drugs not having a State/Federal Generic Upper Limit, the Estimated Acquisition Cost ("EAC") of the generic drug dispensed, plus a dispensing fee of \$5.51 (the EAC equals Average Wholesale Price ("AWP") minus 20%), with an additional differential dispensing fee of \$2.00; or the lowest of the pharmacy's usual and customary charge to the

general public, whichever formula that, when applied, resulted in the lowest cost.

15. For each branded prescription drug from the period beginning March 1, 2002 until the present, Medicaid reimbursements were based on the following formulas:

(A) For branded drugs having a State/Federal Upper Limit, the State/Federal Upper Limit plus a dispensing fee of \$5.51.

(B) For branded drugs, not having a State/Federal Upper Limit, the Estimated Acquisition Cost (“EAC”) of the branded drug dispensed, plus a dispensing fee of \$5.51 (the EAC equals Average Wholesale Price (“AWP”) minus 14%); or the lowest of the pharmacy’s usual and customary charge to the general public, whichever formula that, when applied, resulted in the lowest cost.

16. Certain Medicaid recipients are also required to make a co-payment that ranges from \$.50 to \$3.00 per prescription. The co-payment is directly affected by the cost of the drug. As the price of the drug increases, the co-payment increases as well.

17. Pursuant to the methodology established by the State Plan as outlined in the State’s Pharmacy Manual, Medicaid prescription drug reimbursements are made according to federal regulations.

18. At all relevant times, the Defendants were aware of Arkansas’ Medicaid drug reimbursement formulas.

2. Medicare

19. Medicare is a health insurance program created by the federal government for the elderly, disabled, and other eligible persons. 42 U.S.C. §1395, et seq. Individuals

become eligible for Medicare health insurance benefits when they turn 65 years of age. There are two major components of the Medicare program, Part A and Part B. Medicare, Part B is administered by the U.S. Department of Human Services.

20. Medicare, Part B is an optional program that provides coverage for some healthcare services for Arkansas' participating elderly, disabled and other eligible citizens not covered by Part A. 42 U.S.C. § 1395j through 1395w-4. Medicare, Part B is supported by government funds and premiums paid by eligible individuals who choose to participate in the program.

21. Medicare, Part B pays for a portion of the cost of some prescription drugs.

22. In setting reimbursement rates, the Medicare program uses the AWP's that are reported by the pharmaceutical industry.

23. For prescription drugs covered by Part B, Medicare calculates the "allowable amount," the amount that Medicare will pay, based upon the formula set forth in 42 C.F.R. 405.517, which is the lower of the actual charge or 95% of the national AWP of the drug or biological. Medicare then pays 80% of the allowable amount. In addition, Medicare, Part B beneficiaries are required to pay an annual deductible amount before Part B benefits are payable.

24. At all relevant times, the Defendants were aware of the Medicare program's Part B drug reimbursement formula.

25. The false and inflated AWP amount caused Medicare Part B beneficiaries to pay increased and inflated co-payments for their drugs.

26. As a direct and proximate result of the Defendants' conduct, Medicare Part B beneficiaries have been damaged.

B. The Defendants' Reporting of Inflated AWP Information

27. Defendants have attempted to increase their profits and their market share by fraudulently inflating the reported Average Wholesale Price of drugs and thereby fraudulently increasing the amount providers are reimbursed for those drugs under Medicaid and Medicare reimbursement formulas. One of the primary methods the Defendants have utilized to increase market share is the manipulation of their reported AWP. By increasing the spread between the reported Average Wholesale Price and the actual price that they charge to health care providers to acquire those drugs, Defendants have created a fraudulent and illegal incentive for providers to prescribe Defendants' high-priced drugs rather than other drugs. As such, the Defendants have turned State Medicaid and Medicare reimbursement into a marketing tool used to increase the demand for their drugs.

28. At all relevant times, the Defendants knowingly, willfully and intentionally provided false and inflated AWP and other pricing information for their drugs, including, but not limited to, those listed on Exhibit "B" to this Complaint. Defendants provided such false pricing information to various nationally known pharmaceutical price reporting services, including First Data Bank, a/k/a Blue Book, which the State of Arkansas relies upon in setting its reimbursement rates.

29. First Data Bank does not independently determine the Defendants' drug AWP amount. The Defendants provide the AWP pricing information on their drug products to First Data Bank. First Data Bank then publishes the prices or provides the pricing information to entities such as wholesalers.

30. At all relevant times, the Arkansas Medicaid Program obtained the Defendants' published AWP pricing information from First Data Bank and other price reporting services.

31. At all relevant times, the Arkansas Medicaid Program relied upon the pricing information provided by the Defendants to nationally known price reporting services, including First Data Bank, in determining the amount the Arkansas Medicaid Program would reimburse providers.

32. At all relevant times, the Defendants were aware that the Arkansas Medicaid Program relied upon the Defendants' price representations that Defendants provided to the various price reporting services to determine the amounts Medicaid would reimburse providers for covered prescription drugs.

33. The Defendants had a duty to report pricing information that fairly and reasonably reflected actual prices paid rather than artificially inflated prices that fraudulently increased reimbursement payments.

34. The Defendants knowingly, willfully, and intentionally concealed the drugs' true and accurate pricing information from the Arkansas Medicaid Program.

35. The drug prices reported by Defendants that were used for Medicaid and Medicare reimbursements were false and greatly inflated. The reported prices greatly exceeded the actual average of the wholesale price. Such actual pricing information was readily available to the Defendants but was concealed or ignored by them. Thus the Average Wholesale Prices reported by Defendants for each of these drugs bears no relation to any actual purchase price paid by any health care provider; such prices were purely artificial numbers created and reported by Defendants for the purpose of obtaining

higher reimbursements for their drugs and increasing the market share of their pharmaceutical products.

36. At all relevant times, the Defendants reported the AWP for the drugs that bore no relation to any price, much less to an average wholesale price.

C. The Defendants' Marketing of the "Spread"

37. The Defendants commonly refer to the difference between the price they reported as the Average Wholesale Price for a drug (the price on which reimbursement would be calculated) and the actual price the Defendants charged health care providers to purchase that same drug as the "spread" for that drug.

38. The Defendants knowingly, willfully, and intentionally created a "spread" on their drugs, and marketed the "spread" on their drugs with the intent of inducing health care providers to purchase and prescribe Defendants' drugs rather than competitors' drugs. The results of this scheme were higher market share and profits for the Defendants and greater expenses for Medicaid, Medicare, beneficiaries of both Medicaid and Medicare, and consumers.

39. The Defendants controlled the size of the "spread" on their drugs by manipulating the difference between their reported AWP and the actual price that providers paid on those drugs.

40. In addition to manipulating the pricing information they reported, the Defendants used free goods, educational grants, and other incentives to induce providers to purchase their drugs. All of these incentives lowered the actual prices of Defendants' drugs, increased their market share and resulted in increased profits for providers, at the

expense of Medicaid, Medicare, beneficiaries of both Medicaid and Medicare, and consumers.

D. Damages to the Arkansas Medicaid Program

41. The fraudulent practices of the Defendants in creating and reporting false and inflated AWP or other pricing information for their drugs, or otherwise concealing actual pricing information, and “marketing the spread” on their drugs as an inducement to providers to utilize Defendants’ drugs, has resulted in the State of Arkansas paying millions of dollars in excessive Medicaid payments, while at the same time enriching the Defendants with excessive, unjust and illegal profits.

42. These practices have caused extensive damage to the Arkansas Medicaid program and resulted in millions of dollars in fraudulently inflated reimbursement claims being paid.

E. Damages to Arkansas Medicare, Part B beneficiaries

43. Medicare Part B Beneficiaries pay a 20% co-payment for their drugs that are covered under the Medicare Part B program.

44. The fraudulent practices of the Defendants in creating and reporting false and inflated AWP pricing information for their drugs, concealing actual pricing information and “marketing the spread” on their drugs as an inducement to providers to utilize or otherwise administer Defendants’ drugs, has resulted in Arkansas’ Medicare, Part B beneficiaries, many of whom are elderly and/or disabled, paying excessive co-payments for covered drugs.

45. As a direct and proximate result of the Defendants’ conduct, Arkansas Medicare, Part B beneficiaries have been injured.

F. Damages to Arkansas Medicaid beneficiaries

46. The Defendants' practice of creating and reporting false and inflated AWP pricing information for their drugs, concealing actual pricing information and marketing the "spread" on their drugs as an inducement to providers to utilize or otherwise administer Defendants' drugs, causes certain Arkansas Medicaid recipients to pay excessive co-payments for their prescription drugs.

47. Despite their knowledge of the Arkansas Medicaid Program and the increased costs to Medicaid recipients that would result from higher AWP amounts, the Defendants continue to report false and fraudulent AWP's. Such conduct exhibits utter and complete indifference to the financial plight of Arkansas' Medicaid recipients. The Defendants used funds from the Medicaid program to persuade providers to prescribe and dispense their drugs, while at the same time hurting the poor and disabled Arkansans whom the program was designed to protect. In an effort to build market share, the Defendants manipulated the provisions of the Medicaid program. Such conduct came at the expense of Medicaid beneficiaries, who depend on the Medicaid program for their health and well being.

48. The false and inaccurate AWP pricing information forced certain Medicaid recipients to pay increased co-payment amounts.

G. Damages to Arkansas Consumers

49. The cost of prescription drugs is often a significant expense for Arkansas residents. For many Arkansans, prescription drugs are necessary to maintain life and/or quality of life. Arkansans often have no choice but to pay the full amount, however expensive, necessary to obtain their prescription medications.

50. The high cost of prescription drugs has been exacerbated by the Defendants' submission of false and inflated pricing information to reporting services, which bears a direct relationship to the price all Arkansas consumers pay for their prescription drugs, including those consumers who are not covered by the Medicaid or Medicare programs.

51. Pharmacists, who participate in the Arkansas Medicaid Program, report a usual and customary charge to Medicaid, representing their usual and customary charge to the public for the prescription drugs they dispense. The usual and customary charge to the public is directly tied to the Defendant pharmaceutical companies' submission of false and inflated pricing information. As a result of Defendants' marketing program, including "marketing the spread," the prices reported by pharmacists as their usual and customary charge are also inflated and thus the amount paid for those drugs by ordinary consumers is arbitrarily raised.

52. Consequently, the artificially high prices being reported by the Defendants as the so-called Average Wholesale Price actually leads to higher prices being charged to consumers since it is illegal to charge consumers less than Medicaid.

53. The reporting of false and inflated AWP amounts by the Defendants to the drug reporting services causes consumers who are not Medicaid beneficiaries to pay grossly inflated amounts for their prescription drugs.

54. As a direct and proximate result of the Defendants' actions, Arkansas residents have suffered, and continue to suffer, injury.

V. CLAIMS
COUNT I
VIOLATION OF THE ARKANSAS
DECEPTIVE TRADE PRACTICES ACT

55. Plaintiff hereby incorporates by reference paragraphs 1 through 54.

56. Ark. Code Ann. § 4-88-104 provides that the State of Arkansas may seek civil enforcement of the Arkansas Deceptive Trade Practices Act against those parties alleged to be in violation thereof.

57. Ark. Code Ann. § 4-88-107(a)(10) provides that it shall be unlawful to engage in “unconscionable, false, or deceptive act(s) or practices in business, commerce, or trade.”

58. Pursuant to Ark. Code Ann. § 4-88-113(a)(1), the Attorney General may bring a civil action to prevent persons from engaging in the use or employment of any prohibited practices.

59. By reporting false and inflated prices to the reporting services, thereby causing the Arkansas Medicaid program, Medicaid recipients, Medicare, Part B recipients, and other Arkansas consumers to pay inflated prices for their prescription drugs, the Defendants have engaged in deceptive and unconscionable trade practices prohibited by the Arkansas Deceptive Trade Practices Act.

COUNT II
COMMON LAW FRAUD

60. Plaintiff hereby incorporates by reference paragraphs 1 through 59.

61. In Arkansas, an action for common law fraud may be had where the defendant makes (a) a false representation of a material fact, (b) having knowledge that

the representation is false, (c) with the intent to induce action or inaction in reliance upon the representation, (d) where the plaintiff acted in justifiable reliance thereon and, (f) which causes damage to the plaintiff.

62. The Defendants committed common law fraud by knowingly reporting false AWP or other pricing information concerning their drugs to national pharmaceutical reporting services, including First Data Bank, with the knowledge that Medicare and the Arkansas Medicaid Program would rely on the false AWP or other pricing information in reimbursing Arkansas Medicaid providers, thereby causing damages to the Arkansas Medicaid Program, Medicaid beneficiaries, Medicare, Part B beneficiaries and other consumers through the payment of grossly excessive prices for the Defendants' prescription drugs.

63. By engaging in the acts and practices described above, the Defendants have engaged and continue to engage in repeated fraudulent acts and practices in violation of the Arkansas common law.

PRAYER FOR RELIEF

WHEREFORE, the Plaintiff, State of Arkansas, by counsel, Attorney General Mike Beebe, prays for the following relief:

1. Judgment that the Defendants committed repeated willful and knowing violations of the Arkansas Deceptive Trade Practices Act by violating Ark. Code Ann. § 4-88-101, et seq.;

2. Judgment that the Defendants have engaged in a continuing course of common law fraud;

3. Judgment that the Defendants have engaged in acts or practices which resulted in fraudulent, erroneous, or illegal payments from the Arkansas Medicaid Program;

4. 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 their unlawful conduct, acts and practices;

5. Awarding damages and restitution for Arkansas Medicare, Part B beneficiaries and Medicaid recipients for the excessive prescription drug co-payments paid as a result of the Defendants' unlawful conduct;

6. Awarding damages and restitution for Medicaid beneficiaries, Medicare beneficiaries and other Arkansas consumers who overpaid for prescription drugs.

7. Awarding civil penalties of \$10,000 for each willful violation of the Arkansas Deceptive Trade Practices Act pursuant to Ark. Code Ann. § 4-88-113;

8. Imposing enhanced penalties for acts committed against Elder and Disabled persons pursuant to Ark. Code Ann. § 4-88-201, et seq.;

9. Awarding the State punitive damages against the Defendants;

10. Awarding the State a total recovery of damages in excess of the amount required for federal court jurisdiction in diversity of citizenship cases;

11. Awarding the State its costs and attorneys fees;

12. Awarding any other relief to which the State may be entitled.

WHEREFORE, Plaintiff prays for relief as set forth above and requests a trial by jury in this matter.

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
FIFTH DIVISION

STATE OF ARKANSAS

PLAINTIFF

V.

CASE NO. CV04-634

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PHARMACEUTICALS CORPORATION;
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AND SCHERING CORPORATION

DEFENDANTS

AFFIDAVIT OF JOHN SELIG

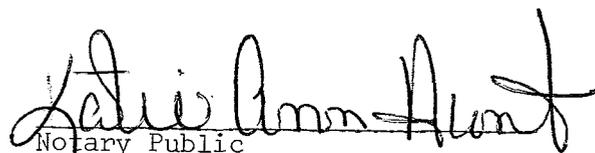
I, John Selig, being duly sworn and under oath state:

1. I am the Deputy Director of the Arkansas Department of Human Services.
2. One of the Divisions in the Arkansas Department of Human Services is the Division of Medical Services, which is the Single State Agency that administers the Medicaid Program for the State of Arkansas.
3. It has come to the attention of the Department that actions by certain drug manufacturers as described in the Complaint filed in this matter, have caused the aforementioned Division of Medical Services to pay excessive amounts in reimbursement for pharmaceutical drugs.
4. I have specifically requested the Attorney General of Arkansas to implement the powers provided for in the Arkansas Deceptive Trade Practices Act to redress any violations that may have occurred and recoup any damages or restitution that are owed to the Division of Medical Services for overpayments made, and seek any other appropriate relief due as a result of the Defendants' unlawful activities.


John Selig, Deputy Director
Arkansas Department of Human
Services

Subscribed and Sworn to before me this 25th day of May, 2004.

OFFICIAL SEAL
KATIE ANN HUNT
NOTARY PUBLIC - ARKANSAS
PERRY COUNTY
MY COMMISSION


Notary Public

**EXHIBIT B
TABLE I**

WARRICK, INC.

<u>DRUG</u>	<u>DOSAGE</u>	<u>NDC#</u>	<u>1999 AWP</u>	<u>2000 AWP</u>	<u>2001 AWP</u>	<u>2002 AWP</u>	<u>2003 AWP</u>
Albuterol Sulfate	.083%	59930 1500 08	\$30.24	\$30.24	\$30.24	\$30.24	\$30.24
Albuterol Sulfate	.083%	59930 1500 06	\$72.59	\$72.59	\$72.59	\$72.59	\$72.59
Albuterol Sulfate	.05%	59930 1515 04	\$14.99	\$14.99	\$14.99	\$14.99	\$14.99
Albuterol Aerosol Inhaler	90mcg	59930 1560 01	\$21.41	\$21.41	\$21.41	\$21.41	\$21.41
Isosorbide Mononitrate Tablet	60mg	59930 1549 01	\$117.40	\$117.40	\$117.40	\$117.40	\$117.40

TABLE II**DEY, INC.**

<u>DRUG</u>	<u>DOSAGE</u>	<u>NDC#</u>	<u>1999 AWP</u>	<u>2000 AWP</u>	<u>2001 AWP</u>	<u>2002 AWP</u>	<u>2003 AWP</u>
Albuterol Sulfate	.083%	49502 0697 03	\$30.25	\$30.25	\$30.25	\$30.25	\$30.25
Albuterol Sulfate	.083%	49502 0697 33	\$36.30	\$36.30	\$36.30	\$36.30	\$36.30
Albuterol Sulfate	.083%	49502 0697 60	\$72.59	\$72.59	\$72.59	\$72.59	\$72.59
Ipratropium Bromide	2.5ml 25's	49502 0685 03	\$44.10	\$44.10	\$44.10	\$44.10	\$44.10
Albuterol Aerosol Inhaler	90mcg	49502 0333 17	n/a	\$21.70	\$21.70	\$21.70	\$21.70
Albuterol Aerosol Inhaler	90mcg	49502 0303 17	\$21.70	\$21.70	\$21.70	\$21.70	\$21.70